FEDERAL REGISTER

Vol. 81 Friday,

No. 58 March 25, 2016

Book 1 of 3 Books

Pages 16053–16284

OFFICE OF THE FEDERAL REGISTER

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Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

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Presidential Documents

Title 3—

The President

Memorandum of March 21, 2016

Building National Capabilities for Long-Term Drought Resilience

Memorandum for the Heads of Executive Departments and Agencies

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

Section 1. *Purpose*. Our Nation must sustain and expand efforts to reduce the vulnerability of communities to the impacts of drought. Every year, drought affects millions of Americans and poses a serious and growing threat to the security and economies of communities nationwide. Drought presents challenges to the viability of agricultural production and to the quantity and quality of drinking water supplies that communities and industries depend upon. Drought jeopardizes the integrity of critical infrastructure, causes extensive economic and health impacts, harms ecosystems, and increases energy costs. In responding to and recovering from past droughts, we have learned that focused collaboration across all levels of government and the private sector is critical to enable productive and workable solutions to build regional resilience to drought.

Among other actions, this memorandum institutionalizes the National Drought Resilience Partnership (NDRP), which builds upon the National Integrated Drought Information System, an interagency program led by the Department of Commerce. The NDRP was outlined in the President's Climate Action Plan to better coordinate Federal support for drought-related efforts, help communities reduce the impact of current drought events, and prepare for future droughts. In sustaining this focused collaboration, the NDRP will provide the Federal Government with a lasting platform that enables locally and regionally driven priorities and needs to guide coordinated Federal activities.

Sec. 2. *Policy*. It is the policy of the Federal Government to coordinate and use applicable Federal investments, assets, and expertise to promote drought resilience and complement drought preparedness, planning, and implementation efforts of State, regional, tribal, and local institutions. In addition, where appropriate, the Federal Government shall seek partnerships with such institutions and the private sector in order to increase and diversify our Nation's water resources through the development and deployment of new technologies and improved access to alternative water supplies. Agencies shall also work with State, regional, tribal, and local institutions to support their efforts to maintain and enhance the long-term health and resilience of working lands and ecosystems. In carrying out this memorandum, executive departments and agencies (agencies) shall continue to recognize the primacy of States, regions, tribes, and local water users in building their resilience to drought.

Sec. 3. *Drought Resilience Goals*. (a) The heads of agencies shall, to the extent permitted by law and to the maximum extent possible, carry out the policy described in section 2 of this memorandum by implementing policies and taking actions to achieve the following drought resilience goals:

(i) *Data Collection and Integration*. Agencies shall share data and information related to drought, water use, and water availability, including data on snowpack, groundwater, stream flow, and soil moisture with State,

regional, tribal, and local officials to strengthen decisionmaking to support more adaptive responses to drought and drought risk.

(ii) *Communicating Drought Risk to Critical Infrastructure*. Agencies shall communicate with State, regional, tribal, local, and critical infrastructure officials, targeted information about drought risks, including specific risks to critical infrastructure.

(iii) *Drought Planning and Capacity Building*. Agencies shall assist State, regional, tribal, and local officials in building local planning capacity for drought preparedness and resilience.

(iv) *Coordination of Federal Drought Activity*. Agencies shall improve the coordination and integration of drought-related activities to enhance the collective benefits of Federal programs and investments.

(v) *Market-Based Approaches for Infrastructure and Efficiency*. Agencies shall support the advancement of innovative investment models and market-based approaches to increase resilience, flexibility, and efficiency of water use and water supply systems.

(vi) *Innovative Water Use, Efficiency, and Technology*. Agencies shall support efforts to conserve and make efficient use of water by carrying out relevant research, innovation, and international engagements.

(b) The NDRP, as described in section 5 of this memorandum, shall facilitate, coordinate, and monitor the implementation of the actions conducted to achieve these goals.

Sec. 4. *Drought Resilience Actions*. In furtherance of the policies and goals described in this memorandum, I hereby direct agencies to take, subject to the availability of appropriations, by December 31, 2016, the following actions:

(a) *Data Collection and Integration*.

(i) The heads of agencies participating in the NDRP shall:

(A) improve the integration of all relevant drought-related data and information, and facilitate the use of such data, in coordination with the National Integrated Drought Information System, by State, regional, tribal, and local officials in drought planning and decisionmaking; and

(B) identify and use data formats that will allow these datasets to be incorporated into existing geospatial data platforms.

(ii) The Secretaries of the Interior, Agriculture, Commerce, and the Director of the Office of Science and Technology Policy shall coordinate the implementation of the activities described in section 4(a)(i) of this memorandum.

(b) *Drought Planning and Capacity Building*.

(i) The heads of agencies participating in the NDRP shall:

(A) provide technical and scientific information to State, regional, tribal, and local officials concerning the integration of drought planning, hazard mitigation, and preparedness planning; and

(B) ensure that local and regional officials are aware of drought-related planning activities and similar initiatives occurring in their region, which will avoid duplication of effort and prompt peer-to-peer collaboration.

(ii) The Secretaries of the Interior, Agriculture, Commerce, and Homeland Security shall coordinate the implementation of the activities described in section 4(b)(i) of this memorandum.

(c) *Communicating Drought Risk to Critical Infrastructure*.

(i) The heads of agencies participating in the NDRP shall:

(A) support information gathering and analysis to assess the risk of drought to critical infrastructure; and

(B) use the assessment described in section 4(c)(ii) of this memorandum to inform agencies and to better communicate accurate, science-based information about drought, and the risks of drought to communities, critical

infrastructure owners and operators, and other drought resilience stakeholders.

(ii) The Secretaries of Commerce and Homeland Security shall coordinate the implementation of the activities described in section 4(c)(i) of this memorandum and jointly publish an assessment describing the risk that drought poses to U.S. critical infrastructure.

(d) *Coordination of Federal Drought Activity*.

(i) The heads of agencies participating in the NDRP shall:

(A) coordinate and use Federal programs and investments to better support drought resilience through improved information sharing and collaboration, building on existing place-based and program coordination efforts; and

(B) develop tools, guidance, and other relevant resources to ensure drought-related support to State, regional, tribal, and local officials occurs in an effective and efficient manner.

(ii) The Secretaries of the Interior, Agriculture, Commerce, and the Army shall coordinate the implementation of the activities described in section 4(d)(i) of this memorandum.

(e) *Market-Based Approaches for Infrastructure and Efficiency*.

(i) The heads of agencies participating in the NDRP shall:

(A) identify and share effective practices with State, regional, tribal, and local water users on the use of innovative financing opportunities to facilitate the construction, maintenance, rehabilitation, or restoration of drought-resilient infrastructure;

(B) test innovative financing opportunities, to the extent permitted by law, to attract private investment into underserved and drought-sensitive rural water infrastructure; and

(C) where appropriate, provide technical assistance to support State and local efforts to develop strategies for more flexible water management, including through market-based mechanisms.

(ii) The Secretaries of the Interior and Agriculture and the Administrator of the Environmental Protection Agency shall coordinate the implementation of the activities described in section 4(e)(i) of this memorandum.

(f) *Innovative Water Use, Efficiency, and Technology*.

(i) The heads of agencies participating in the NDRP shall:

(A) engage with foreign partners in order to establish mechanisms through which to implement relevant research, monitoring, and technical assistance to support transfer and adaptation of more water-efficient practices and technologies domestically;

(B) facilitate the development of new technologies and practices or the expansion of existing technologies and practices to mitigate the consequences of drought; and

(C) promote expanded use of technologies that allow the use of produced, reused, brackish, recycled, or other alternative water sources where possible and appropriate.

(ii) The Secretaries of State, Agriculture, Energy, the Interior, and the Environmental Protection Agency shall coordinate the implementation of the activities described in section 4(f)(i) of this memorandum.

Sec. 5. *National Drought Resilience Partnership*.

(a) *Establishment and Function*. There is established the National Drought Resilience Partnership (NDRP) as an interagency task force that is responsible for enhancing coordination of Federal drought resilience policies and monitoring the implementation of the activities and goals described in this memorandum.

(b) *Administration of the NDRP*. The NDRP administrative functions will be housed within the Department of Agriculture, which shall provide funding

and administrative support for the NDRP to the extent permitted by law and within existing appropriations.

(c) *Membership*. The NDRP shall consist of representatives, serving at the Assistant Secretary-level or higher, from the following:

(i) the Department of Defense, Office of the Secretary of Defense-Policy;

(ii) the Department of the Interior;

(iii) the Department of Agriculture;

(iv) the Department of Commerce;

(v) the Department of Energy;

(vi) the Department of Homeland Security;

(vii) the Environmental Protection Agency;

(viii) the Office of Management and Budget;

(ix) the Office of Science and Technology Policy;

(x) the National Economic Council;

(xi) the Council on Environmental Quality;

(xii) the National Security Council staff;

(xiii) the Army; and

(xiv) such other agencies or offices as the agencies set forth above, by consensus, deem appropriate.

(d) *NDRP Co-Chairs*. The NDRP shall have two Co-Chairs. The Secretary of Agriculture, or the Secretary's designated representative, shall continuously serve as the first Co-Chair of the NDRP. The Secretary of Commerce, or the Secretary's designated official, shall serve as the second Co-Chair for a period of 2 years. The NDRP members shall rotate the second Co-Chair responsibility every 2 years based on majority vote among the Departments of Defense, the Interior, Commerce, Energy, Homeland Security, and the Environmental Protection Agency. Members serving as the second Co-Chair shall not serve in that role over consecutive periods. The NDRP shall meet at minimum on a quarterly basis, with additional meetings as needed.

(e) *Charter*. Within 90 days of the date of this memorandum, the Co-Chairs of the NDRP shall, with consensus of the members, complete a charter, which shall include any administrative policies and processes necessary to ensure the NDRP can satisfy the functions and responsibilities described in this memorandum.

(f) *Reporting Requirements and Action Plan*. Within 150 days of the date of this memorandum, the Co-Chairs of the NDRP shall submit a report to the Co-Chairs of the Council on Climate Preparedness and Resilience established by Executive Order 13653 of November 1, 2013. The report shall describe the activities undertaken and progress made concerning the implementation of this memorandum and shall include, to the extent necessary and applicable, information from all NDRP participants. Thereafter, the Co-Chairs of the NDRP shall provide updates on the implementation of the goals described in section 3 of this memorandum to the Council on Climate Preparedness and Resilience following the NDRP's quarterly meetings, and annually in the National Preparedness Report, established in Presidential Policy Directive–8 or other appropriate annual reports submitted to the President.

(g) *Long-Term Drought Resilience Action Plan*. The NDRP Co-Chairs, with consensus of the NDRP agencies, shall maintain the Long-Term Drought Resilience Federal Action Plan (the ''Action Plan'') and update the Action Plan as necessary. The heads of agencies participating in the NDRP shall implement the Action Plan, or any successor plan or strategy promulgated by the NDRP to guide how agencies achieve the six drought resilience goals set forth in section 3 of this memorandum.

Sec. 6. *Regional Coordination and Implementation.*

(a) *Regional Capabilities.* The heads of agencies participating in the NDRP shall establish, and utilize through their regional and field offices, cross-agency methods to coordinate Federal assistance provided to States, regions, tribes, and localities facing drought challenges. These capabilities shall be integrated with existing regional planning and coordination initiatives, including with appropriate resiliency efforts conducted by State, regional, tribal, and local drought stakeholders.

(b) *Regional Engagement Coordination.* In regions where complementary drought resilience activities are implemented by multiple Federal agencies, those agencies shall coordinate regional outreach strategies. Further, these agencies shall collectively coordinate regional outreach and engagement efforts with the goal of reducing duplication of effort for State, regional, tribal, and local stakeholders.

Sec. 7. *Definitions.* (a) ''Agencies'' means any authority of the United States that is an ''agency'' under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies.

(b) ''Critical infrastructure'' has the meaning provided in section 1016(e) of the USA Patriot Act of 2001 (42 U.S.C. 5195c(e)), namely, systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters.

(c) ''Drought'' has the meaning provided in section 2(1) of the National Integrated Drought Information System Act of 2006 (15 U.S.C. 313d note), namely, a deficiency in precipitation that leads to a deficiency in surface or subsurface water supplies (including rivers, streams, wetlands, groundwater, soil moisture, reservoir supplies, lake levels, and snow pack); and that causes or may cause substantial economic or social impacts or substantial physical damage or injury to individuals, property, or the environment.

(d) ''Drought resilience'' means the ability to anticipate, prepare for, and adapt to the anticipated consequences of drought conditions, particularly long-term or extreme drought.

(e) ''Resilience'' means the ability to anticipate, prepare for, and adapt to changing conditions and withstand, respond to, and recover rapidly from disruptions.

Sec. 8. *General Provisions.* (a) This memorandum shall be implemented consistent with applicable laws, including international treaties, agreements, and obligations, and subject to the availability of appropriations.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to a department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary of Agriculture is hereby authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, March 21, 2016

[FR Doc. 2016–06901
Filed 3–24–16; 8:45 am]
Billing code 3410–10–P

Rules and Regulations

Federal Register
Vol. 81, No. 58
Friday, March 25, 2016

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 327

RIN 3064–AE40

Assessments

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule.

SUMMARY: Pursuant to the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) and the FDIC's authority under section 7 of the Federal Deposit Insurance Act (FDI Act), the FDIC is imposing a surcharge on the quarterly assessments of insured depository institutions with total consolidated assets of $10 billion or more. The surcharge will equal an annual rate of 4.5 basis points applied to the institution's assessment base (with certain adjustments). If the Deposit Insurance Fund (DIF or fund) reserve ratio reaches 1.15 percent before July 1, 2016, surcharges will begin July 1, 2016. If the reserve ratio has not reached 1.15 percent by that date, surcharges will begin the first day of the calendar quarter after the reserve ratio reaches 1.15 percent. (Lower regular quarterly deposit insurance assessment (regular assessment) rates will take effect the quarter after the reserve ratio reaches 1.15 percent.) Surcharges will continue through the quarter that the reserve ratio first reaches or exceeds 1.35 percent, but not later than December 31, 2018. The FDIC expects that surcharges will commence in the second half of 2016 and that they should be sufficient to raise the DIF reserve ratio to 1.35 percent in approximately eight quarters, *i.e.,* before the end of 2018. If the reserve ratio does not reach 1.35 percent by December 31, 2018 (provided it is at least 1.15 percent), the FDIC will impose a shortfall assessment on March 31, 2019, on insured depository institutions with total consolidated assets of $10 billion or more. The FDIC will provide assessment credits (credits) to insured depository institutions with total consolidated assets of less than $10 billion for the portion of their regular assessments that contribute to growth in the reserve ratio between 1.15 percent and 1.35 percent. The FDIC will apply the credits each quarter that the reserve ratio is at least 1.38 percent to offset the regular deposit insurance assessments of institutions with credits.

DATES: This rule will become effective on July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Munsell W. St. Clair, Chief, Banking and Regulatory Policy Section, Division of Insurance and Research, (202) 898–8967; Nefretete Smith, Senior Attorney, Legal Division, (202) 898–6851; and James Watts, Senior Attorney, Legal Division (202) 898–6678.

SUPPLEMENTARY INFORMATION:

I. Notice of Proposed Rulemaking and Comments

On October 22, 2015, the FDIC's Board of Directors (Board) authorized publication of a notice of proposed rulemaking (NPR) to impose a surcharge on the quarterly assessments of insured depository institutions with total consolidated assets of $10 billion or more.

The NPR was published in the **Federal Register** on November 6, 2015.[1] The FDIC sought comment on every aspect of the proposed rule and on alternatives. The FDIC received a total of eight letters. Of these letters, four were from trade groups and four were from banks. Comments are discussed in the relevant sections below.

II. Policy Objectives

The FDIC maintains a fund in order to assure the agency's capacity to meet its obligations as insurer of deposits and receiver of failed banks.[2] The FDIC considers the adequacy of the DIF in terms of the reserve ratio, which is equal to the DIF balance divided by estimated insured deposits. A higher minimum reserve ratio reduces the risk that losses from bank failures during a downturn will exhaust the DIF and reduces the risk of large, procyclical increases in deposit insurance assessments to maintain a positive DIF balance.

The Dodd-Frank Act, enacted on July 21, 2010, contained several provisions to strengthen the DIF.[3] Among other things, it: (1) Raised the minimum reserve ratio for the DIF to 1.35 percent (from the former minimum of 1.15 percent);[4] (2) required that the reserve ratio reach 1.35 percent by September 30, 2020;[5] and (3) required that, in setting assessments, the FDIC ''offset the effect of [the increase in the minimum reserve ratio] on insured depository institutions with total consolidated assets of less than $10,000,000,000.''[6]

Both the Dodd-Frank Act and the FDI Act grant the FDIC broad authority to implement the requirement to achieve the 1.35 percent minimum reserve ratio. In particular, under the Dodd-Frank Act, the FDIC is authorized to take such steps as may be necessary for the reserve ratio to reach 1.35 percent by September 30, 2020.[7] Furthermore, under the FDIC's special assessment authority in section 7(b)(5) of the FDI Act, the FDIC may impose special assessments in an amount determined to be necessary for any purpose that the FDIC may deem necessary.[8]

In the FDIC's view, the Dodd-Frank Act requirement to raise the reserve ratio to the minimum of 1.35 percent by September 30, 2020 reflects the importance of building the DIF in a timely manner to withstand future economic shocks. Increasing the reserve ratio faster reduces the likelihood of procyclical assessments, a key policy

[1] See 80 FR 68780 (Nov. 6, 2015).

[2] As used in this final rule, the term ''bank'' has the same meaning as ''insured depository institution'' as defined in section 3 of the FDI Act, 12 U.S.C. 1813(c)(2).

[3] Public Law 111–203, 334, 124 Stat. 1376, 1539 (12 U.S.C. 1817(note)).

[4] 12 U.S.C. 1817(b)(3)(B). The Dodd-Frank Act also removed the upper limit on the designated reserve ratio (which was formerly capped at 1.5 percent).

[5] 12 U.S.C. 1817(note).

[6] 12 U.S.C. 1817(note). The Dodd-Frank Act also: (1) eliminated the requirement that the FDIC provide dividends from the fund when the reserve ratio is between 1.35 percent and 1.5 percent; (2) eliminated the requirement that the amount in the DIF in excess of the amount required to maintain the reserve ratio at 1.5 percent of estimated insured deposits be paid as dividends; and (3) granted the FDIC's authority to declare dividends when the reserve ratio at the end of a calendar year is at least 1.5 percent, but granted the FDIC sole discretion in determining whether to suspend or limit the declaration of payment or dividends, 12 U.S.C. 1817(e)(2)(A)–(B).

[7] 12 U.S.C. 1817(note).

[8] 12 U.S.C. 1817(b)(5).

goal of the FDIC that is supported in the academic literature and acknowledged by banks.[9]

The purpose of the final rule is to meet the Dodd-Frank Act requirements in a manner that appropriately balances several considerations, including the goal of reaching the minimum reserve ratio reasonably promptly in order to strengthen the fund and reduce the risk of pro-cyclical assessments, the goal of maintaining stable and predictable assessments for banks over time, and the projected effects on bank capital and earnings. The primary mechanism described below for meeting the statutory requirements—surcharges on regular assessments—will ensure that the reserve ratio reaches 1.35 percent without inordinate delay (likely in 2018) and will ensure that assessments are allocated equitably among banks responsible for the cost of reaching the minimum reserve ratio.

III. Background

The Dodd-Frank Act gave the FDIC greater discretion to manage the DIF than it had previously, including greater discretion in setting the target reserve ratio, or designated reserve ratio (DRR), which the FDIC must set annually.[10] The Board has set a 2 percent DRR for each year starting with 2011.[11] The Board views the 2 percent DRR as a long-term goal.

By statute, the FDIC also operates under a Restoration Plan while the reserve ratio remains below 1.35 percent.[12] The Restoration Plan, originally adopted in 2008 and subsequently revised, is designed to ensure that the reserve ratio will reach 1.35 percent by September 30, 2020.[13]

In February 2011, the FDIC adopted a final rule that, among other things, contained a schedule of deposit insurance assessment rates that apply to regular assessments that banks pay. The FDIC noted when it adopted these rates that, because of the requirement making banks with $10 billion or more in assets responsible for increasing the reserve ratio from 1.15 percent to 1.35 percent, ''assessment rates applicable to all insured depository institutions need only be set high enough to reach 1.15 percent'' before the statutory deadline of September 30, 2020.[14] The February 2011 final rule left to a later date the method for assessing banks with $10 billion or more in assets for the amount needed to reach 1.35 percent.[15]

In the February 2011 final rule, the FDIC also adopted a schedule of lower regular assessment rates that will go into effect once the reserve ratio of the DIF reaches 1.15 percent.[16] These lower regular assessment rates will apply to all banks' regular assessments. Regular assessments paid under the schedule of lower rates are intended to raise the reserve ratio gradually to the long-term goal of 2 percent.

The FDIC expects that, under the current assessment rate schedule, the DIF reserve ratio will reach 1.15 percent in the first half of 2016.

IV. Description of the Final Rule

A. Surcharges

Surcharge Rate and Duration

As proposed in the NPR, to implement the requirements of the Dodd-Frank Act, and pursuant to the FDIC's authority in section 7 of the FDI Act,[17] the FDIC is adding a surcharge to the regular assessments of banks with $10 billion or more in assets. Also as proposed in the NPR, the surcharge will begin the quarter after the DIF reserve ratio first reaches or exceeds 1.15 percent and will continue until the reserve ratio first reaches or exceeds 1.35 percent, but no later than the fourth quarter of 2018.[18] For each quarter, the FDIC will notify banks that will be subject to the surcharge and inform those banks of the amount of the surcharge within the timeframe that applies to notification of regular assessment amounts.[19]

As proposed in the NPR, the annual surcharge rate will be 4.5 basis points, which the FDIC expects will be sufficient to raise the reserve ratio from 1.15 percent to 1.35 percent in 8 quarters, before the end of 2018.

Comments Received

The FDIC received several comments on the surcharge rate and estimated surcharge period. In a joint comment letter, three trade groups stated that a ''strong'' majority of large banks that they surveyed favored an alternative discussed in the NPR of charging lower surcharges over a longer period and imposing a shortfall assessment only if the reserve ratio has not reached 1.35 percent by a date nearer the statutory deadline. Specifically, the trade groups proposed an annual surcharge of no more than 2.25 basis points to reach 1.35 percent in 14 quarters, and a shortfall, if needed, to be assessed in the first quarter of 2020.[20] A few other commenters supported the three trade groups' proposal.

One commenter supported an alternative discussed in the NPR of foregoing surcharges entirely and, if the reserve ratio does not reach 1.35 percent by a deadline sometime near the statutory deadline, imposing a delayed

[9] In 2011, the FDIC Board of Directors adopted a comprehensive, long-range management plan for the DIF that is designed to reduce procyclicality in the deposit insurance assessment system. Input from bank executives and industry trade group representatives favored steady, predictable assessments and found high assessment rates during crises objectionable. In addition, economic literature points to the role of regulatory policy in minimizing procyclical effects. See, for example: 75 FR 66272 and George G. Pennacchi, 2004. ''Risk-Based Capital Standards, Deposit Insurance and Procyclicality,'' FDIC Center for Financial Research Working Paper No. 2004–05.

[10] 12 U.S.C. 1817(b)(3)(A)(i).

[11] A DRR of 2 percent was based on a historical analysis as well as on the statutory factors that the FDIC must consider when setting the DRR. In its historical analysis, the FDIC analyzed historical fund losses and used simulated income data from 1950 to 2010 to determine how high the reserve ratio would have to have been before the onset of the two banking crises that occurred during this period to maintain a positive fund balance and stable assessment rates.

[12] 12 U.S.C. 1817(b)(3)(E).

[13] 75 FR 66293 (Oct. 27, 2010).

[14] See 76 FR 10673, 10683 (Feb. 25, 2011).

[15] 76 FR at 10683. The Restoration Plan originally stated that the FDIC would pursue rulemaking on the offset in 2011, 75 FR 66293 (Oct. 27, 2010), but in 2011 the Board decided to postpone rulemaking until a later date.

[16] 76 FR at 10717; see also 12 CFR 327.10(b). The FDIC adopted this schedule of lower assessment rates following its historical analysis of the long-term assessment rates that would be needed to ensure that the DIF would remain positive without raising assessment rates even during a banking crisis of the magnitude of the two banking crises of the past 30 years. On June 16, 2015, the Board adopted a notice of proposed rulemaking that would revise the risk-based pricing methodology for established small institutions. See 80 FR 40838 (July 13, 2015). On January 21, 2016, the Board adopted a second notice of proposed rulemaking that would revise parts of the proposal adopted by the Board in 2015. The revised proposal would leave the overall range of initial assessment rates and the assessment revenue expected to be generated unchanged from the current assessment system for established small institutions. See 81 FR 6108 (Feb. 4, 2016).

[17] 12 U.S.C. 1817.

[18] As discussed below, this rule will become effective on July 1, 2016. If the reserve ratio reaches 1.15 percent before that date, surcharges will begin July 1, 2016. If the reserve ratio has not reached 1.15 percent by that date, surcharges will begin the first day of the calendar quarter after the reserve ratio reaches 1.15 percent.

[19] As with regular assessments, surcharges will be paid one quarter in arrears, based on the bank's previous quarter data and will be due on the 30th day of the last month of the quarter. (If the payment date is not a business day, the collection date will be the previous business day.) Thus, for example, if the surcharge is in effect for the first quarter of 2017, the FDIC will notify banks that are subject to the surcharge of the amount of each bank's surcharge obligation no later than June 15, 2017, 15 days before the first quarter 2017 surcharge payment due date of June 30, 2017 (which is also the payment due date for first quarter 2017 regular assessments). The notice may be included in the banks' invoices for their regular assessment.

[20] The trade groups noted that leaving the current assessment rate schedule in place when the reserve ratio reaches 1.15 percent would be roughly equivalent to an annual surcharge of no more than 2.25 basis points to reach 1.35 percent in 14 quarters.

shortfall assessment at the end of the following quarter.

On the other hand, the joint comment letter submitted by the three trade groups did note that a few large banks surveyed supported the proposed surcharge rate and timeline in the NPR, while a few others favored a one-time assessment once the reserve ratio first reaches 1.15 percent (an alternative also discussed in the NPR). One bank in its comment letter also preferred a one-time assessment just after the reserve ratio first reaches or exceeds 1.15 percent in order to raise the reserve ratio closer to 1.35 percent (but not all the way to 1.35 percent) sooner than would occur under the proposal. Another trade group preferred charging surcharges over a shorter timeframe—four quarters—but found that the proposal in the NPR and a one-time assessment just after the reserve ratio first reaches or exceeds 1.15 percent were also reasonable options.

In the FDIC's view, the final rule strikes an appropriate balance among these options after considering: (1) The statutory deadline for reaching the minimum reserve ratio; (2) the importance of strengthening the fund's ability to withstand a spike in losses; (3) the goal of reducing the risk of larger assessments for the entire industry in a future period of stress; and (4) the effects on the capital and earnings of surcharged banks.

The FDIC expects that surcharges will result in the reserve ratio reaching 1.35 percent in 2018. Reaching the statutory target reasonably promptly and in advance of the statutory deadline has benefits. First, it strengthens the fund so that it can better withstand an unanticipated spike in losses from bank failures or the failure of one or more large banks.

Second, it reduces the risk of the banking industry facing unexpected, large assessment rate increases in a future period of stress. Once the reserve ratio reaches 1.35 percent, the September 30, 2020 deadline in the Dodd-Frank Act will have been met and will no longer apply. If the reserve ratio later falls below 1.35 percent, even if that occurs before September 30, 2020, the FDIC will have a minimum of eight years to return the reserve ratio to 1.35 percent, reducing the likelihood of a large increase in assessment rates.[21] In contrast, if a spike in losses occurs before the reserve ratio reaches 1.35 percent, the Dodd-Frank Act deadline will remain in place, which could require that the entire banking industry—including banks with less than $10 billion in assets, if the reserve ratio falls below 1.15 percent—pay for the increase in the reserve ratio within a relatively short time. The final rule, therefore, reduces the risk of higher assessments being imposed at a time when the industry might not be as healthy and prosperous and could less afford to pay.

In addition, large banks will account for future surcharges in the quarterly report of condition and income (Call Report) and other banking regulatory reports based on generally accepted accounting principles (GAAP) as quarterly expenses, as they do for regular assessments, effectively spreading the cost of the requirement over approximately eight quarters in a simple, predictable manner.

In contrast, a longer surcharge period or a delayed one-time assessment without surcharges would reduce the fund's ability to withstand a spike in losses and increase the risk of larger assessments for the entire industry in a future period of stress.

Five comment letters also stated that, rather than imposing a separate surcharge at a uniform rate, the FDIC should implement surcharges in a risk-based manner.[22] One commenter argued that a risk-based surcharge would provide incentives to manage risk. Some commenters suggested foregoing a surcharge and instead leaving in place the current risk-based assessment rate schedule when the reserve ratio reaches 1.15 percent, rather than the lower one that is scheduled to go into effect. One commenter also recommended that surcharges be integrated into risk-based assessments in a way that maintains banks' incentives to hold long-term unsecured debt.[23]

The final rule uses a flat-rate surcharge. As one commenter acknowledged, while the FDI Act requires that regular assessments be risk-based, no such requirement exists for special assessments.[24] In fact, the most recent special assessment, imposed in 2009, was also a flat rate assessment, and, in 1996, Congress imposed a flat-rate special assessment on banks that held deposits insured by the Savings Association Insurance Fund.[25] In addition, nothing in the Dodd-Frank Act requires a risk-based assessment to raise the minimum reserve ratio from 1.15 percent to 1.35 percent.

Banks subject to the surcharge will continue to pay risk-based regular deposit insurance assessments. As a result, they will still have the incentives they now have to prudently manage risk and to issue long-term unsecured debt.

Moreover, because banks' risk profiles change over time, aggregate assessments using a risk-based surcharge would be more prone to vary than will a flat-rate surcharge. This variance would reduce the predictability of surcharge revenue and create additional uncertainty regarding the needed rates and the time required for the reserve ratio to reach 1.35 percent. Banks themselves would have less predictable surcharge assessments.

Banks Subject to the Surcharge

As proposed in the NPR, the banks subject to the surcharge (large banks) will be determined each quarter based on whether the bank was a ''large institution'' or ''highly complex institution'' for purposes of that quarter's regular assessments.[26] Generally, this includes institutions with total assets of $10 billion or more; however, an insured branch of a foreign bank whose assets as reported in its

[21] See generally 12 U.S.C. 1817(b)(3)(E)(ii).

[22] Suggested methods for implementing a risk-based surcharge included a surcharge based on a multiple of a bank's initial base assessment rate, a variable-rate surcharge, or imposing the surcharge only on the weakest or riskiest banks.

[23] A bank's total base assessment rate can vary from its initial base assessment rate as the result of three possible adjustments. One of these adjustments, the unsecured debt adjustment, lowers a bank's assessment rate based on the bank's ratio of long-term unsecured debt to the bank's assessment base. 12 CFR 327.9(d).

[24] Compare 12 U.S.C. 1817(b)(1), requiring a risk-based deposit insurance assessment system, with 12 U.S.C. 1817(b)(5), which allows the FDIC to impose special assessments and contains no requirement that they be risk-based.

[25] See 74 FR 25639 (May 29, 2009); 61 FR 53834 (Oct. 16, 1996).

[26] In general, a ''large institution'' is an insured depository institution with assets of $10 billion or more as of December 31, 2006 (other than an insured branch of a foreign bank or a highly complex institution) or a small institution that reports assets of $10 billion or more in its quarterly reports of condition for four consecutive quarters. 12 CFR 327.8(f). If an institution classified as large reports assets of less than $10 billion in its quarterly reports of condition for four consecutive quarters, the FDIC will reclassify the institution as small beginning the following quarter. 12 CFR 327.8(e). In general, a ''highly complex institution'' is: (1) An insured depository institution (excluding a credit card bank) that has had $50 billion or more in total assets for at least four consecutive quarters that is controlled by a U.S. parent holding company that has had $500 billion or more in total assets for four consecutive quarters, or controlled by one or more intermediate U.S. parent holding companies that are controlled by a U.S. holding company that has had $500 billion or more in assets for four consecutive quarters; or (2) a processing bank or trust company. If an institution classified as highly complex fails to meet the definition of a highly complex institution for four consecutive quarters (or reports assets of less than $10 billion in its quarterly reports of condition for four consecutive quarters), the FDIC will reclassify the institution beginning the following quarter. 12 CFR 327.8(g). In general, a ''small institution'' is an insured depository institution with assets of less than $10 billion as of December 31, 2006, or an insured branch of a foreign institution. 12 CFR 327.8(e).

most recent quarterly Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks equaled or exceeded $10 billion will also be considered a large bank and will be subject to the surcharge.[27] [28]

Comments Received

The FDIC received two comments from trade groups on which banks should be subject to the surcharge. One commenter suggested that the surcharge should not apply to mid-size banks and should only apply to highly complex banks, while another commenter proposed that the surcharge be restricted to only the largest banks, those considered ''too big to fail,'' or those controlling a large share of industry assets. As an alternative to their suggestions, both commenters proposed that the FDIC increase the $10 billion deduction from large banks' assessment bases for the surcharge (discussed below), for example, to $25 billion or $50 billion, which would effectively exempt banks with total assets under these threshold amounts from surcharges.

The FDIC has identified no compelling basis to distinguish between large banks based on any particular asset size or other profile. Further, the final rule is consistent with the statutory language. The Dodd-Frank Act requires the FDIC to ''offset the effect of [the increase in the minimum reserve ratio] on insured depository institutions with total consolidated assets of less than $10,000,000,000,'' and unlike other parts of the Act, there is no indication that section 334(e) should apply only to banks of a certain size or that engage in certain activities. The apparent purpose of the Act's requirement was to insulate banks with less than $10 billion in total assets from the cost of the increase in the minimum reserve ratio. The final rule appropriately meets this requirement.

The FDIC is cognizant of the concerns of large banks near the $10 billion threshold. As a practical matter, the $10 billion deduction from large banks' assessment bases for the surcharge has the effect of shifting the burden of the surcharges towards larger banks. While, as discussed later, the purpose of the $10 billion deduction is to avoid a ''cliff effect'' for banks near the $10 billion asset threshold, it has the concomitant effect of benefitting large banks closer in size to the $10 billion asset threshold relatively more than larger banks, since the relative effect of the $10 billion deduction decreases as asset size increases. As reflected in Table 1, based on data as of December 31, 2015, the simple average effective surcharge rate (the surcharge rate if applied to a bank's regular quarterly deposit insurance assessment base) for banks with assets between $10 billion and $50 billion will be approximately half the simple average effective rate for banks with assets greater than $100 billion. In fact, with lower regular assessment rates scheduled to take effect when the reserve ratio reaches 1.15 percent, more than half (36 out of 67) of large banks with total assets between $10 billion and $50 billion and roughly one-third of all large banks are expected to pay an effective assessment rate, even with the surcharge, that is lower than their current assessment rate.

TABLE 1—EFFECTIVE ANNUAL ASSESSMENT RATES BY SIZE GROUP

[Based on data as of December 31, 2015]

Assets (in $ billions)	Number of banks	Average effective surcharge rate *
$10 to $50	67	2.11
$50 to $100	15	3.73
Over $100	26	4.23
All Large	108	2.85

* The average is a simple average.

Banks' Assessment Bases for the Surcharge

Pursuant to the broad authorities under the Dodd-Frank Act and the FDI Act, including the authority to determine the assessment amount, which includes defining an appropriate assessment base for the surcharge (the surcharge base), each large bank's surcharge base for any given quarter will equal its regular quarterly deposit insurance assessment base (regular assessment base) for that quarter with certain adjustments.[29]

The first adjustment under the final rule differs from the NPR, but is similar to an alternative method of determining the surcharge base on which the NPR requested comment. The NPR would have added the entire regular assessment bases of affiliated small banks to the surcharge bases of large bank affiliates, but sought comment on an alternative that would add only the amount of any increase in the regular assessment bases of affiliated small banks. In response to a joint comment letter from three trade groups and after balancing all the considerations expressed in the NPR, the FDIC has decided to add to a large bank's surcharge base each quarter only the cumulative net increase in the aggregate regular assessment bases of affiliated small banks above the aggregate regular assessment bases as of December 31, 2015 of affiliated small banks as of that date that is in excess of an effective annual rate of 10 percent.[30] [31]

[27] Assets for foreign banks are reported in FFIEC 002 report (Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks), Schedule RAL, line 3, column A.

[28] For purposes of the final rule, a large bank also includes a small institution if, while surcharges were in effect, the small institution was the surviving institution or resulting institution in a merger or consolidation with a large bank or if the small institution acquired all or substantially all of the assets or assumed all or substantially all of the deposits of a large bank.

[29] Public Law 111–203, 334(e), 124 Stat. 1376, 1539 (12 U.S.C. 1817(note)); 12 U.S.C. 1817(b)(5). For purposes of regular assessments, the Dodd-Frank Act defines the assessment base with respect to an insured depository institution as an amount equal to the average consolidated total assets of the insured depository institution during the assessment period; minus the sum of the average tangible equity of the insured depository institution during the assessment period, and in the case of an insured depository institution that is a custodial bank (as defined by the FDIC, based on factors including the percentage of total revenues generated by custodial businesses and the level of assets under custody) or a banker's bank (as that term is used in . . . (12 U.S.C. 24)), an amount that the FDIC determines is necessary to establish assessments consistent with the definition under section 7(b)(1) of the [Federal Deposit Insurance] Act (12 U.S.C. 1817(b)(1)) for a custodial bank or a banker's bank. 12 U.S.C. 1817(note).

[30] As used in this final rule, the term ''affiliate'' has the same meaning as defined in section 3 of the FDI Act, 12 U.S.C. 3(w)(6), which references the Bank Holding Company Act (''any company that controls, is controlled by, or is under common control with another company''). 12 U.S.C. 1841(k).

The term ''small bank'' is synonymous with the term ''small institution'' as it is defined in 12 CFR 327.8(e) and used in existing portions of 12 CFR part 327 for purposes of regular assessments, except that it excludes: (1) An insured branch of a foreign bank whose assets as reported in its most recent most recent quarterly Call Report equal or exceed $10 billion; and (2) a small institution that, while surcharges are in effect, is the surviving or resulting institution in a merger or consolidation with a large bank or that acquired of all or substantially all of the assets or assumed all or substantially all of the deposits of a large bank.

[31] The final rule measures the net increase in affiliated small banks' assessment bases from December 31, 2015, which is the latest possible date that ensures that banks do not engage in avoidance behavior between issuance of the final rule and its effective date.

The cumulative net increase in excess of an effective annual rate of 10 percent in the aggregate regular assessment bases of affiliated small banks will be calculated by compounding a quarterly rate of approximately 2.41 percent from December 31, 2015. Thus, for example, at the end of September 2016 (3 quarters after December 31, 2015), assuming that surcharges are in effect, the final rule will add to a large bank's surcharge base for that quarter any cumulative net increase in the aggregate regular assessment bases of affiliated small banks in excess of approximately 7.41 percent (approximately 2.41 percent per quarter compounded for 3 quarters). Similarly, at the end of March 2017 (5 quarters after December 31, 2015), assuming that surcharges are in effect, the final rule will add to a large bank's surcharge base for that quarter any cumulative net increase in the aggregate regular assessment bases of affiliated small banks in excess of approximately

Adding cumulative growth in excess of an effective annual rate of 10 percent in the regular assessment bases of affiliated small banks to the assessment bases of their large bank affiliates limits the ability of large banks to reduce their surcharges (and potentially shift costs to other large banks) either by transferring assets and liabilities to existing or new affiliated small banks or by growing the businesses of affiliated small banks instead of the large bank without unduly constraining the normal growth of the affiliated small banks.[32]

Including only the amount of any cumulative net increase that is in excess of an effective annual rate of 10 percent in the aggregate regular assessment bases of affiliated small banks, rather than their entire assessment bases as proposed in the NPR, will have only a very small effect on total surcharge revenue and is unlikely to increase the number of quarters that surcharges are in effect.

The second adjustment is as proposed in the NPR. It deducts $10 billion from a large bank's regular assessment base (as increased by the first adjustment) to produce the surcharge base. Deducting $10 billion from each large bank's assessment base for the surcharge avoids a ''cliff effect'' for banks near the $10 billion asset threshold, thereby ensuring equitable treatment. Otherwise, a bank with just over $10 billion in assets would pay significant surcharges, while a bank with $9.9 billion in assets would pay none. The $10 billion reduction reduces incentives for banks to limit their growth to stay below $10 billion in assets, or to reduce their size to below $10 billion in assets, solely to avoid surcharges.

In a banking organization that includes more than one large bank, both (1) the $10 billion deduction, and (2) the cumulative net increase in affiliated small banks' regular assessment bases exceeding a 10 percent effective annual rate will be apportioned among all large banks in the banking organization in proportion to each large bank's regular assessment base for that quarter.[33] Appendix 1 gives examples of the calculation of the surcharge base for a banking organization that has more than one large bank and for a banking organization that has both large and small banks.

Comments Received

The FDIC received one joint comment letter from three trade groups related to the first adjustment. As proposed in the NPR, the first adjustment would have added the entire regular assessment bases of affiliated small banks to the surcharge bases of large bank affiliates. The joint comment letter opposed adding any portion of the assessment bases of small bank affiliates to large banks, but argued that, if any addition were to occur, it should be limited to no more than any increase in the assessment bases of small bank affiliates above ''normal growth'' after surcharges begin.[34] As described above, the final rule uses the net increase in excess of a 10 percent effective annual rate in the aggregate regular assessment bases of affiliated small banks above their aggregate regular assessment bases as of December 31, 2015.

The FDIC received three comments related to the second adjustment, the deduction of $10 billion from a large bank's assessment base and apportioning the deduction among all large banks in the banking organization. Two commenters proposed a larger deduction (discussed above). A joint comment letter submitted by three trade groups proposed that bank holding companies with multiple large banks be allowed to deduct $10 billion for each large bank, arguing that limiting large banks in a bank holding company to a single $10 billion deduction ''discriminates against banking organizations with multiple affiliated large banks.''

The provisions in the final rule regarding the second deduction are unchanged from those proposed in the NPR. Allocation of the $10 billion deduction among affiliated large banks ensures that banking organizations of a similar size (in terms of large bank assessment bases) pay a similar surcharge. Thus, a banking organization with multiple large banks will not have an advantage over other similarly sized banking organizations that have only one large bank because, instead of deducting $10 billion from each large bank in the organization, the deduction will be apportioned among the multiple affiliated large banks.

Moreover, allowing each large bank in a banking organization to take a $10 billion deduction could, in effect, penalize the large majority of banking organizations that do not have more than one large bank by increasing the risk that surcharges would last longer than envisioned under the proposal.

B. Shortfall Assessment

The FDIC expects that surcharges combined with regular assessments will raise the reserve ratio to 1.35 percent before December 31, 2018. It is possible, however, that unforeseen events could result in higher DIF losses or faster insured deposit growth than expected, or that banks may take steps to reduce or avoid quarterly surcharges. While not expected, these events or actions could prevent the reserve ratio from reaching 1.35 percent by the end of 2018. In this case, provided the reserve ratio is at least 1.15 percent, the FDIC will impose a shortfall assessment on large banks.[35]

12.65 percent (approximately 2.41 percent per quarter compounded for 5 quarters).

A net increase in affiliated small banks' assessment bases includes any increase resulting from a merger or consolidation with an unaffiliated insured depository institution. A net decrease in the aggregate regular assessment bases of affiliated small banks below their aggregate regular assessment bases as of December 31, 2015 will not reduce the surcharge bases of affiliated large banks.

To prevent assessment avoidance, if a banking organization with at least one large bank but no small banks acquires or establishes a small bank after December 31, 2015, the entire assessment base of the small bank will be apportioned among the surcharge bases of large banks in the holding company in the manner discussed below. Also, if a large bank in a banking organization with multiple large bank affiliates becomes a small bank during the surcharge period, its entire assessment base will be apportioned among the surcharge bases of its large bank affiliates in the manner discussed below.

As of December 31, 2015, 19 banking organizations had both large and small banks.

[32] As noted in the NPR, however, some large banks may be able to shift the burden of the surcharge by transferring assets and liabilities to a nonbank affiliate, or by shrinking or limiting growth.

[33] As of December 31, 2015, 9 banking organizations had multiple affiliated large banks.

[34] The joint comment letter argued that the proposed addition of the entire regular assessment bases of affiliated small banks to the surcharge bases of large bank affiliates ''would abrogate the intent of [Sec.] 334 [of the Dodd-Frank Act] by imposing de facto assessment surcharges on small banks affiliated with large banks, albeit indirectly by assessing their larger affiliates,'' and, therefore, these small banks would not receive a full offset for their contribution towards raising the reserve ratio from 1.15 percent to 1.35 percent. In fact, however, small bank affiliates of large banks will not pay any surcharge assessment and will be entitled to credits on the same basis as all other small banks.

The joint comment letter also argued that Sec. 334 of the Dodd-Frank Act does not authorize the FDIC to augment large banks' assessment bases with those of their small bank affiliates. In fact, however, the Dodd-Frank Act and the FDI Act give the FDIC broad authority to determine the amount of any special assessments, including the surcharges, and thus an appropriate assessment base for the surcharge. See Public Law 111–203, 334(e), 124 Stat. 1376, 1539 (12 U.S.C. 1817(note)); 12 U.S.C. 1817(b)(5). The FDI Act contains no provisions mandating any particular assessment base for a special assessment.

[35] In the unlikely event that the reserve ratio is below 1.15 percent on December 31, 2018, the FDIC will impose a shortfall assessment at the end of the calendar quarter immediately following the first calendar quarter after December, 31, 2018, in which the reserve ratio first reaches or exceeds 1.15 percent. The aggregate amount of such a shortfall assessment will equal 0.2 percent of estimated insured deposits at the end of the calendar quarter in which the reserve ratio first reaches or exceeds 1.15 percent. If surcharges have been in effect (that

Continued

The provisions in the final rule regarding the shortfall assessment are as proposed in the NPR. If the reserve ratio has not reached 1.35 percent by the end of 2018, the FDIC will impose a shortfall assessment on large banks on March 31, 2019 and collect it on June 30, 2019.[36] The aggregate amount of the shortfall assessment will equal 1.35 percent of estimated insured deposits on December 31, 2018 minus the actual fund balance on that date.

If a shortfall assessment is needed, it will be imposed on any bank that was a large bank in any quarter during the period that surcharges are in effect (the surcharge period). Each large bank's share of any shortfall assessment will be proportional to the average of its surcharge bases (the average surcharge base) during the surcharge period. If a bank was not a large bank during a quarter of the surcharge period, its surcharge base will be deemed to equal zero for that quarter.[37]

If a bank of any size acquires—through merger or consolidation—a large bank that had paid surcharges for one or more quarters, the acquiring bank will be subject to a shortfall assessment and its average surcharge base will be increased by the average surcharge base of the acquired bank.[38]

A large bank's share of the total shortfall assessment will equal its average surcharge base divided by the sum of the average surcharge bases of all large banks subject to the shortfall assessment. Using an average of surcharge bases ensures that anomalous growth or shrinkage in a large bank's assessment base will not subject it to a disproportionately large or small share of any shortfall assessment.

Comments Received

In addition to the comments discussed above regarding the duration of the surcharge and timing of any required corresponding shortfall assessment, the FDIC received two other comments on the shortfall assessment. One commenter suggested that the shortfall assessment, in addition to the surcharges, should only be applied to ''highly complex'' banks. Another commenter stated that the shortfall assessment and surcharges should be risk-based.

For the reasons discussed previously in connection with the surcharge assessment, the shortfall assessment in the final rule is as proposed in the NPR. If a shortfall assessment is necessary, the expected revenue based on the calculation method adopted will be much more predictable than the expected revenue from a risk-based method. In previous special assessments, the FDIC used a uniform rate, rather than a risk-based rate, and large banks will continue to pay risk-based regular assessments. Moreover, as also noted above, neither the statute nor its legislative history suggest that only highly complex banks should be responsible for raising the reserve ratio from 1.15 percent to 1.35 percent. The statute requires that the FDIC offset the effect of the increase in the minimum reserve ratio on banks with less than $10 billion in consolidated assets.

C. Payment Mechanism for the Surcharge and Any Shortfall Assessment

Each large bank is required to take any actions necessary to allow the FDIC to debit its share of the surcharge from the bank's designated deposit account used for payment of its regular assessment. Similarly, each large bank subject to any shortfall assessment is required to take any actions necessary to allow the FDIC to debit its share of the shortfall assessment from the bank's designated deposit account used for payment of its regular assessment. Before the dates that payments are due, each bank must ensure that sufficient funds to pay its obligations are available in the designated account for direct debit by the FDIC. Failure to take any such action or to fund the account will constitute nonpayment of the assessment. Penalties for nonpayment will be as provided for nonpayment of a bank's regular assessment.[39]

Comments Received

The FDIC received no comments on this part of the proposal. The final rule adopts this part of the proposal without change.

D. Additional Provisions Regarding Mergers, Consolidations and Terminations of Deposit Insurance

Under existing regulations, a bank that is not the resulting or surviving bank in a merger or consolidation must file a Call Report for every assessment period prior to the assessment period in which the merger or consolidation occurs. The surviving or resulting bank is responsible for ensuring that these Call Reports are filed. The surviving or resulting bank is also responsible and liable for any unpaid assessments on behalf of the bank that is not the resulting or surviving bank.[40] Unpaid assessments also include any unpaid surcharges and shares of a shortfall assessment under the final rule.

Thus, for example, a large bank's first quarter 2017 surcharge (assuming that the surcharge is in effect then), which will be collected on June 30, 2017, will include the large bank's own first quarter 2017 surcharge plus any unpaid first quarter 2017 or earlier surcharges owed by any large bank it acquired between April 1, 2017 and June 30, 2017 by merger or through the acquisition of all or substantially all of the acquired bank's assets. The acquired bank will be required to file Call Reports through the first quarter of 2017 and the acquiring bank will be responsible for ensuring that these Call Reports were filed.

Existing regulations also provide that, for an assessment period in which a merger or consolidation occurs, total consolidated assets for the surviving or resulting bank include the total consolidated assets of all banks that are parties to the merger or consolidation as if the merger or consolidation occurred on the first day of the assessment period. Tier 1 capital (which is deducted from total consolidated assets to determine a bank's regular assessment base) is to be reported in the

is, if the reserve ratio reaches but then falls below 1.15 percent before December 31, 2018), the shortfall assessment will be imposed on the banks described in the text using average surcharge bases as described in the text. If surcharges have never been in effect: (1) The banks subject to the shortfall assessment will be the banks that were large banks as of the calendar quarter in which the reserve ratio first reached or exceeded 1.15 percent; and (2) an individual large bank's share of the shortfall assessment will be proportional to the average of what its surcharge bases would have been over the four calendar quarters ending with the calendar quarter in which the reserve ratio first reaches or exceeds 1.15 percent. The shortfall assessment will be collected on the 30th day of the last month of the quarter after the assessment was imposed. If that date is not a business day, the collection date will be the previous business day.

If the reserve ratio remains or is projected to remain below 1.15 percent for a prolonged period after 2018 (and never reaches 1.35 percent), the FDIC Board may have to consider increases to regular assessment rates on all banks (in addition to the shortfall assessment on banks with $10 billion or more in assets) in order to achieve the minimum reserve ratio of 1.35 percent by the September 30, 2020 statutory deadline.

[36] The FDIC will notify each bank subject to a shortfall assessment of its share of the shortfall assessment no later than 15 days before payment is due.

[37] Thus, for example, if a large bank were subject to a shortfall assessment because it had been subject to a surcharge for only one quarter of the surcharge period, the bank's surcharge base for seven quarters would be deemed to be zero and its average surcharge base would be its single positive surcharge base divided by eight (assuming that the surcharge period had lasted eight quarters).

[38] With respect to surcharges and shares of any shortfall assessment, a surviving or resulting bank in a merger or consolidation includes any bank that acquires all or substantially all of another bank's assets or assumes all or substantially all of another bank's deposits.

[39] See 12 CFR 308.132(c)(3)(v).

[40] 12 CFR 327.6(a).

same manner.[41] These provisions will also apply to surcharges and shares of any shortfall assessment under the final rule.

Existing regulations also provide that, when the insured status of a bank is terminated and the deposit liabilities of the bank are not assumed by another bank, the bank whose insured status is terminating must, among other things, continue to pay assessments for the assessment periods that its deposits are insured, but not thereafter.[42] These provisions will also apply to surcharges and shares of any shortfall assessment under the final rule.

Finally, in the case of one or more transactions in which one bank voluntarily terminates its deposit insurance under the FDI Act and sells certain assets and liabilities to one or more other banks, each bank must report the increase or decrease in assets and liabilities on the Call Report that is due after the transaction date and the banks will be assessed accordingly under existing FDIC assessment regulations. The bank whose insured status is terminating must, among other things, continue to pay assessments for the assessment periods that its deposits are insured. The same process will also apply to surcharges and shares of any shortfall assessment under the final rule.

Comments Received

The FDIC received no comments on this part of the proposal. The final rule adopts this part of the proposal without change.

E. Credits for Small Banks [43]

While the reserve ratio remains between 1.15 percent and 1.35 percent, some portion of the deposit insurance assessments paid by small banks will contribute to increasing the reserve ratio. To meet the Dodd-Frank Act requirement to offset the effect on small banks of raising the reserve ratio from 1.15 percent to 1.35 percent, the FDIC will provide assessment credits to these banks for the portion of their assessments that contribute to the increase from 1.15 percent to 1.35 percent.[44] The provisions in the final rule governing how credits are calculated and awarded are as proposed in the NPR. The FDIC will apply credits to reduce future regular deposit insurance assessments.

Aggregate Amount of Credits

As proposed in the NPR, to determine the aggregate amount of credits awarded small banks, the FDIC will first calculate 0.2 percent of estimated insured deposits (the difference between 1.35 percent and 1.15 percent) on the date that the reserve ratio first reaches or exceeds 1.35 percent.[45] The amount that small banks contributed to this increase in the DIF through regular assessments—and the resulting aggregate amount of credits to be awarded small banks—will equal the small banks' portion of all large and small bank regular assessments during the ''credit calculation period'' times an amount equal to the increase in the DIF calculated above less surcharges. (The ''credit calculation period'' covers the period beginning the quarter after the reserve ratio first reaches or exceeds 1.15 percent through the quarter that the reserve ratio first reaches or exceeds 1.35 percent (or December 31, 2018, if the reserve ratio has not reached 1.35 percent by then).) Surcharges will be subtracted from the increase in the DIF calculated above before determining the amount by which small banks contributed to that increase because surcharges are intended to increase the reserve ratio above 1.15 percent, not to maintain it at 1.15 percent.[46]

This method of determining the aggregate small bank credit implicitly assumes that all non-assessment revenue (for example, investment income) during the credit calculation period will be used to maintain the fund at a 1.15 percent reserve ratio and that regular assessment revenue will be used to maintain the fund at that reserve ratio only to the extent that other revenue is insufficient. Essentially, the method attributes reserve ratio growth to assessment revenue as much as possible and, with one exception, maximizes the amount of the aggregate small bank assessment credit. The exception is the assumption that all surcharge payments contribute to growth of the reserve ratio (to the extent of that growth), which is consistent with the purpose of the surcharge payments.

The FDIC projects that the aggregate amount of credits will total approximately $1 billion, but the actual amount of credits may differ.

Comments Received

The FDIC received only one comment on the proposed method of determining the aggregate amount of small bank credits. That comment, from a trade group, supported the proposal.

Individual Small Banks' Credits

As proposed in the NPR, credits will be awarded to any bank, including a small bank affiliate of a large bank, that was a small bank at some time during the credit calculation period. An individual small bank's share of the aggregate credit (a small bank's credit share) will be proportional to its credit base, defined as the average of its regular assessment bases during the credit calculation period.[47] [48] If, before the DIF reserve ratio reaches 1.35 percent, a small bank acquires another small bank through merger or consolidation, the acquiring small bank's regular assessment bases for purposes of determining its credit base will include the acquired bank's regular assessment bases for those quarters during the credit calculation period that were before the merger or consolidation. No small bank can receive more in credits than it (and any small bank acquired through merger or consolidation) paid during the credit calculation period in regular assessments while it is a small bank not subject to the surcharge.

By making a small bank's credit share proportional to its credit base rather than, for example, its actual assessments paid, the final rule reduces the chances that a riskier bank assessed at higher than average rates will receive credits for these higher rates. The final rule thus reduces the incentive for banks to take on higher risk.

[41] 12 CFR 327.6(b).

[42] 12 CFR 327.6(c).

[43] Large banks will not receive a refund or credit if surcharges bring the reserve ratio above 1.35 percent. Thus, for example, if the reserve ratio is 1.34 percent at the end of September 2018 and is 1.37 percent at the end of December 2018, large banks will not receive a refund or credit for the two basis points in the reserve ratio above 1.35 percent. Similarly, large banks will not receive a refund or credit if a shortfall assessment brings the reserve ratio above 1.35 percent.

[44] Small banks will not be entitled to any credits for the quarter in which a shortfall is assessed because large banks will be responsible for the entire remaining amount needed to raise the reserve ratio to 1.35 percent.

[45] If the reserve ratio does not reach 1.35 percent by December 31, 2018, the amount calculated will be the increase in the DIF needed to raise the DIF reserve ratio from 1.15 percent to the actual reserve ratio on December 31, 2018; that amount equals the DIF balance on December 31, 2018 minus 1.15 percent of estimated insured deposits on that date.

[46] If total assessments, including surcharges, during the credit calculation period are less than or equal to the increase in the DIF calculated above, the aggregate amount of credits to be awarded small banks will equal the aggregate amount of regular assessments paid by small banks during the credit calculation period.

[47] When determining the credit base, a small bank's assessment base is deemed to equal zero for any quarter in which it is a large bank.

[48] Call Report amendments after the payment date for the final quarter of the surcharge period do not affect a bank's credit share.

Comments Received

The FDIC received no comments on this part of the proposal.

Successors

If any bank acquires a bank with credits through merger or consolidation after the DIF reserve ratio reaches 1.35 percent, the acquiring bank will acquire the credits of the acquired small bank. Other than through merger or consolidation, credits are not transferable.[49] Also, credits held by a bank that fails or ceases being an insured depository institution will expire. These provisions are as proposed in the NPR.

Use of Credits

After the reserve ratio reaches 1.38 percent (and provided that it remains at or above 1.38 percent), the FDIC will automatically apply a small bank's credits to reduce its regular deposit insurance assessment up to the full amount of the bank's credits or assessment, whichever is less.[50] [51] [52] In response to comments, this portion of the final rule differs from the proposal in two ways. First, the final rule allows credit use as long as the reserve ratio is at or above 1.38 percent, rather than when it is at or above 1.40 percent as proposed in the NPR. Under the FDI Act, the Board is required to adopt a restoration plan if the reserve ratio falls below 1.35 percent. Allowing credit use only when the reserve ratio is at or above 1.38 percent should provide sufficient cushion for the DIF to remain above 1.35 percent in the event of rapid growth in insured deposits and ensure that credit use alone will not result in the reserve ratio falling below 1.35 percent. Allowing credit use before the reserve ratio reaches this level, however, would create a greater risk of the reserve ratio falling below 1.35 percent, triggering the need for a restoration plan.[53]

Second, the final rule provides that credits available to an institution may be used to offset the institution's entire quarterly insurance assessment, rather than limiting credit use to an annual rate of 2 basis points as proposed in the NPR.

Notices of Credits

As soon as practicable after the DIF reserve ratio reaches 1.35 percent, the FDIC will notify each small bank of the FDIC's preliminary estimate of the small bank's credit and the manner in which the credit was calculated (the notice). The estimate will be based on information derived from the FDIC's official system of records. The FDIC will provide the notice through FDICconnect or other means in accordance with existing practices for assessment invoices.[54]

After the initial notice, periodic updated notices will be provided to reflect adjustments that may be made as the result of credit use, requests for review of credit amounts, or any subsequent merger or consolidation.

Requests for Review and Appeals

The final rule includes provisions that allow a small bank that disagrees with the FDIC's computation of, or basis for, its credits to request review or appeal. These provisions are unchanged from those proposed in the NPR.

The FDIC received no comments on this part of the proposal.

V. Economic Effects

The FDIC estimates that it will collect approximately $10 billion in surcharges and award approximately $1 billion in credits to small banks, although actual amounts may vary from these estimates. The FDIC projects that a shortfall assessment will be unnecessary.

As discussed above, the benefits of the final rule will be to quickly strengthen the fund's ability to withstand an unanticipated spike in losses and reduce the risk of larger assessments for the entire industry. Under the final rule, the cost of raising the minimum reserve ratio will be spread over approximately eight quarters and calculated in a simple, predictable manner.

A. Accounting Treatment

Based on FDIC analysis, banks subject to the surcharge will not account for future surcharges or a possible shortfall assessment as a present liability or a recognized loss contingency in the Call Report and other banking regulatory reports based on GAAP because the surcharges do not relate to a current condition or event giving rise to a liability under Financial Accounting Standards Board Accounting Standards Codification Topic 450, *Contingencies.* Surcharges will become recognized loss contingencies in a then current quarter if (i) the bank is in existence during that quarter; and (ii) the bank is a large bank as of that quarter and, therefore, subject to the surcharge. Surcharges are based on the bank's regular assessment bases in future periods, and recognized in regulatory reports for those periods, just as regular assessments are now (where each assessment is accounted for as a

[49] A joint comment letter from three trade groups recommended that the FDIC allow a small bank to sell or transfer its credits. The final rule does not adopt this recommendation because of the small amount of expected credits, the short period they are expected to last, and the low number of banks that used transfer provisions in the past. The credits to be awarded pursuant to this final rule are expected to be relatively small (approximately $1 billion in credits compared to approximately $4.7 billion in credits awarded pursuant to the Federal Deposit Insurance Reform Act of 2005 (Reform Act). See 71 FR 61374 (Oct. 18, 2006) implementing one-time assessment credits awarded pursuant to the Reform Act. Credits awarded under the Reform Act also lasted considerably longer than the credits to be awarded under the final rule are expected to last. Over 50 percent of banks still had credits remaining under the Reform Act after five quarters and over 20 percent had credits remaining after eight quarters, while virtually all banks are expected to use up credits awarded under the final rule in five quarters or less. In addition, although the credits awarded under the Reform Act were transferrable, 71 FR at 61377, only one-half percent of banks (36 banks) actually transferred them (other than through merger). Similarly, although the FDIC allowed banks to transfer unused portions of approximately $45.7 billion in assessments that were prepaid at the end of 2009, 74 FR, 59056, 59060 (Nov. 17, 2009), only 20 banks actually transferred any of their prepaid assessment amounts (again, other than through merger). While credits are not transferrable under the final rule, the final rule provides that all banks may use credits to fully offset their assessments, and the final rule provides that credits may be used earlier than proposed in the NPR—when the reserve ratio reaches 1.38 percent, rather than 1.40 percent.

[50] The amount of credits applied each quarter will not be recalculated as the result of subsequent amendments to the quarterly Call Reports or the quarterly Reports of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks. Credit amounts may not be used to pay Financing Corporation (FICO) assessments. See section 21(f) of the Federal Home Loan Bank Act, 12 U.S.C. 1441(f).

[51] A joint comment from three trade groups expressed concern that credits could be viewed as assets on a bank's balance sheet and, therefore, included in the bank's assessment base. The commenters recommended that the FDIC revise ''the assessments pricing formula'' for small institutions so that credits are not assessed. Assessment credits awarded pursuant to the Reform Act were not recognized as assets for accounting purposes. See 71 FR 61374 (Oct. 18, 2006). Even if the credits to be awarded pursuant to this final rule are recognized as assets under GAAP, the FDIC would not adopt the commenters' recommendation. Revising assessments in this manner so that credits are not assessed is equivalent to excluding credits from small institutions' assessment bases. Except as specifically authorized by statute, the FDIC does not exclude assets, even securities issued or guaranteed by the U.S. government or its agencies, from banks' assessment bases. Moreover, as discussed in a previous footnote, the credits to be awarded under the final rule are expected to be relatively small, are expected to last only two to five quarters for most small banks, and would have only a minimal effect on small institutions' assessments even if treated as assets.

[52] Any credits in excess of a bank's assessment will be used to fully offset a bank's entire deposit insurance assessments in future quarters until credits are exhausted, as long as the reserve ratio exceeds 1.38 percent.

[53] Also, allowing credit use before the reserve ratio reaches 1.35 percent, as one trade group suggested, would delay the reserve ratio's reaching 1.35 percent and would add complexity because credits would have to be estimated and later adjusted, since the actual amount of credits will not be known until the reserve ratio reaches 1.35 percent.

[54] See generally 12 CFR 327.2(b).

liability and expensed for the quarter it is assessed). A shortfall assessment will be a recognized loss contingency if (i) the reserve ratio has not reached 1.35 percent by the end of 2018; and (ii) the bank has been subject to a surcharge.

B. Capital and Earnings Analysis

Consistent with section 7(b)(2)(B) of the FDI Act, the analysis that follows estimates the effects of a 4.5 basis point surcharge on the equity capital and earnings of large banks.[55] Because small banks will not pay surcharges, surcharges will affect neither their capital nor their earnings; however, the analysis also estimates the effect of credits on small bank earnings.

The FDIC has estimated the effect of a 4.5 basis-point surcharge on large banks' earnings in two ways. First, as a percentage of *adjusted earnings,* to take into account the savings projected to result from lower assessment rates implemented in the future when the reserve ratio reaches 1.15 percent. Second, as a percentage of *current earnings.* Current earnings are assumed to equal pre-tax income before extraordinary and other items from January 1, 2015 through December 31, 2015. Adjusted earnings are current earnings plus the savings to be gained by large banks from lower future assessments that will result from the lower assessment rate schedule that will apply to regular assessments once the reserve ratio reaches 1.15 percent.

Assumptions and Data

The analysis is based on large banks as of December 31, 2015. As of that date, there were 108 large banks. Banks are merger-adjusted, except for failed bank acquisitions, for purposes of determining income.

Although the surcharge is expected to continue for 8 quarters, the analysis examines the effect of the surcharge over one year. Each large bank's surcharge base is calculated as of December 31, 2015. Data from January 1, 2015 through December 31, 2015 are used to calculate each large bank's current earnings and adjusted earnings. Capital for each large bank is the amount reported as of December 31, 2015. The analysis assumes that current earnings equal pre-tax income before extraordinary and other items from January 1, 2015 through December 31, 2015. Using this measure eliminates the potentially transitory effects of extraordinary items and taxes on profitability. In calculating the effect on capital and banks' ability to maintain a leverage ratio of at least 4 percent (the minimum capital requirement [56]), however, the analysis considers the effective after-tax cost of assessments.[57] The analysis assumes that the large banks do not transfer the surcharge to customers in the form of changes in borrowing rates, deposit rates, or service fees.

Projected Effects

For all or almost all large banks, the effective surcharge annual rate measured against large banks' regular assessment base will be less than the nominal surcharge rate of 4.5 basis points because of the $10 billion deduction. The FDIC projects that the net effect of lower assessment rates that go into effect when the reserve ratio reaches 1.15 percent and the imposition of the surcharge will result in lower assessments for approximately one-third of all large banks. Specifically, the analysis estimates that 37 of the 108 large banks will pay lower assessments in the future than they pay currently.

The analysis reveals no significant capital effects from the surcharge. All large institutions continue to maintain a 4 percent leverage ratio, at a minimum, both before and after the imposition of the surcharge.[58]

The annual surcharge also represents only a small percentage of bank earnings for most large banks. In the aggregate, the annual surcharge absorbs 2.33 percent of total large bank adjusted earnings and 2.36 percent of total large bank current earnings.

Table 2.A shows that as of December 31, 2015, for 83 percent of all large banks (86 large banks) the surcharge represents 3 percent or less of adjusted annual earnings. For 92 percent (96 large banks), the surcharge represents 5 percent or less of adjusted annual earnings. Only 8 large banks' adjusted annual earnings are affected by more than 5 percent, with the maximum effect on any single bank being 9.6 percent.

TABLE 2.A—THE EFFECT OF THE FINAL RULE ON ADJUSTED EARNINGS OF INDIVIDUAL LARGE BANKS

Large banks				
Surcharge relative to adjusted earnings	Population		Assets	
	Number	Percentage of total large banks	Total ($ in billions)	Percentage of total large banks
Equal to 0%	2	2	21	0
Between 0% and 1%	23	22	604	5
Between 1% and 2%	32	31	1,925	15
Between 2% and 3%	29	28	6,608	51
Between 3% and 4%	6	6	2,473	19
Between 4% and 5%	4	4	444	3
Over 5%	8	8	828	6
All Large Banks	104	100	12,904	100

Notes:

(1) Effect of Surcharge on Current Earnings: Mean = 2.17%; Median = 1.88%; Max = 9.61%; Min = 0.00%.

(2) Four large banks were excluded from the original population of 108. One large bank is an insured branch of a foreign bank and does not report income in its quarterly financial filings and the other three large banks reported negative income. Figures may not add to totals due to rounding.

[55] Equity capital is defined as tier 1 capital for this purpose.

[56] See 12 CFR 324.10(a).

[57] Since deposit insurance assessments are a tax-deductible operating expense, increases in assessment expenses can lower taxable income and decreases in the assessment rate can raise taxable income.

[58] Of the 108 large banks, 107 continue to maintain a leverage ratio of at least 4 percent. The other large bank is an insured branch of a foreign bank and does not report income in its quarterly financial filings, so its regulatory capital ratios cannot be calculated.

When evaluating the effect of the surcharge on current earnings (that is, excluding the gains projected from lower future regular assessments), the effect of surcharges is slightly greater, as expected, but the results are not materially different. Table 2.B shows that, for 82 percent of large banks as of December 31, 2015, (85 large banks), the surcharge represents 3 percent or less of current earnings. For 91 percent (95 large banks), the surcharge represents 5 percent or less of current earnings. Only 9 large banks' current earnings are affected by more than 5 percent, with the maximum effect on any single bank being 10.11 percent.

TABLE 2.B—THE EFFECT OF THE FINAL RULE ON CURRENT EARNINGS OF INDIVIDUAL LARGE BANKS

Large banks				
Surcharge relative to current earnings	Population		Assets	
	Number	Percentage of total large banks	Total ($ in billions)	Percentage of total large banks
Equal to 0	2	2	21	0
Between 0% and 1%	23	22	604	5
Between 1% and 2%	31	30	1,906	15
Between 2% and 3%	29	28	6,568	51
Between 3% and 4%	7	7	2,532	20
Between 4% and 5%	3	3	171	1
Over 5%	9	9	1,101	9
All Large Banks	104	100	12,904	100

Notes:
(1) Effect of Surcharge on Current Earnings: Mean = 2.23%; Median = 1.90%; Max = 10.11%; Min = 0.00%.
(2) Four large banks were excluded from the original population of 108. One large bank is an insured branch of a foreign bank and does not report income in its quarterly financial filings and the other three large banks reported negative income. Figures may not add to totals due to rounding.

Finally, credits will result in a small increase in the income of small banks. Small bank annual earnings are estimated to increase between 2.5 and 2.7 percent due to these credits.

The FDIC received five comments noting the effects of the surcharge on banks' capital and earnings, including the effects of banks' ability to pay dividends or to grow. As discussed above, however, FDIC analysis reveals no significant capital effects on large banks from the surcharge. On average, the annual surcharge would absorb about 2.4 percent of large bank annual income.

VI. Alternatives Considered

In the NPR, the FDIC solicited comments on several alternatives.

Under the first alternative presented, the FDIC would forego surcharges and instead impose a one-time assessment, similar to a shortfall assessment, at the end of the quarter after the DIF reserve ratio first reaches or exceeds 1.15 percent. As previously discussed, the FDIC received two comments supporting this alternative. These comments are discussed earlier.

The second alternative would also forego surcharges and, if the reserve ratio does not reach 1.35 percent by a date sometime near the statutory deadline, impose a shortfall assessment at the end of the following quarter, to be collected at the end of the next quarter. The FDIC received one comment supporting this alternative, and a few banks surveyed by three trade groups submitting a joint comment letter also supported this alternative. These comments are also previously discussed.

The FDIC solicited comment on additional alternatives that are essentially variations of certain aspects of the surcharge proposal, including the method of determining the surcharge base, the method of allocating credits, and the length of the surcharge period. Comments in response to these alternatives are discussed in the relevant sections.

VII. Effective Date

This rule will become effective on July 1, 2016. If the reserve ratio reaches 1.15 percent before that date, surcharges will begin July 1, 2016. If the reserve ratio has not reached 1.15 percent by that date, surcharges will begin the first day of the calendar quarter after the reserve ratio reaches 1.15 percent.

VIII. Regulatory Analysis and Procedure

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that an agency, in connection with a notice of final rulemaking, prepare a final regulatory flexibility analysis describing the impact of the rule on small entities or certify that the final rule will not have a significant economic impact on a substantial number of small entities.[59] Certain types of rules, such as rules of particular applicability relating to rates or corporate or financial structures, or practices relating to such rates or structures, are expressly excluded from the definition of the term ''rule'' for purposes of the RFA.[60] This final rule relates directly to the rates imposed on insured depository institutions for deposit insurance. For this reason, the requirements of the RFA do not apply. Nonetheless, the FDIC is voluntarily undertaking a regulatory flexibility analysis.

As of December 31, 2015, of 6,191 FDIC-insured institutions,[61] there were 4,921 small insured depository institutions as that term is defined for purposes of the RFA (*i.e.,* those with $550 million or less in assets).[62] As described in the **SUPPLEMENTARY INFORMATION** section of the preamble, the purpose of this final rule is to meet the Dodd-Frank Act requirements to increase the DIF reserve ratio from 1.15 to 1.35 by September 30, 2020, and offset the effect of that increase on banks

[59] See 5 U.S.C. 604, 605(b).

[60] 5 U.S.C. 601.

[61] The total at December 31, 2015, includes 6,182 insured commercial banks and savings institutions and 9 insured U.S. branches of foreign banks.

[62] Throughout this RFA analysis, a ''small institution'' or ''small insured depository institution'' refers to an institution with assets of $550 million or less. As of December 31, 2015, one insured branch of a foreign bank had less than $550 million in assets and is included in the small insured depository institution total.

with less than $10 billion in total consolidated assets. The final rule meets those requirements in a manner that appropriately balances several considerations, including the goal of reaching the statutory minimum reserve ratio reasonably promptly in order to strengthen the fund and reduce the risk of pro-cyclical assessments, the goal of maintaining stable and predictable assessments for banks over time, and the projected effects on bank capital and earnings. Both the Dodd-Frank Act and the FDI Act grant the FDIC broad authority to implement the requirement to offset the effect of the increase in the minimum reserve ratio on banks with less than $10 billion in total assets.

The final rule affects small entities to the extent that they are eligible for credits in exchange for their contributions toward raising the DIF reserve ratio from 1.15 percent to 1.35 percent. The FDIC will apply these credits to future regular assessments, resulting in estimated average savings of 2.4 to 2.6 percent of annual earnings for small insured depository institutions.

The final rule does not directly impose any ''reporting'' or ''recordkeeping'' requirements, and the compliance requirements for the final rule would not exceed (and, in fact, would be the same as) existing compliance requirements for the current risk-based deposit insurance assessment system for small banks.[63] The FDIC is unaware of any duplicative, overlapping or conflicting federal rules.[64] The final rule will not have a significant economic impact on a substantial number of small entities within the meaning of those terms as used in the RFA and the FDIC so certifies.[65]

B. Small Business Regulatory Enforcement Fairness Act

The final rule has been determined to be a ''major rule'' within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Title II, Pub. L. 104–121) by the Office of Management and Budget.

C. Riegle Community Development and Regulatory Improvement Act

The Riegle Community Development and Regulatory Improvement Act requires that the FDIC, in determining the effective date and administrative compliance requirements of new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations.[66] Subject to certain exceptions, new regulations and amendments to regulations prescribed by a Federal banking agency which impose additional reporting, disclosures, or other new requirements on insured depository institutions shall take effect on the first day of a calendar quarter which begins on or after the date on which the regulations are published in final form.[67] In accordance with these provisions and as discussed above, the FDIC considered any administrative burdens, as well as benefits, that the final rule would place on depository institutions and their customers in determining the effective date and administrative compliance requirements of the final rule. Thus, the final rule will be effective no earlier than the first day of a calendar quarter that begins after publication of the rule.

D. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (''PRA'') of 1995, 44 U.S.C. 3501–3521, the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (''OMB'') control number.

This final rule does not revise FDIC's Assessments Information Collection 3064–0057, Quarterly Certified Statement Invoice for Deposit Insurance Assessment. The FDIC will continue to obtain the information necessary to calculate the surcharge assessment and assessment credits from the Call Report. Therefore, no submission to OMB need be made.

E. The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The FDIC has determined that the final rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681).

F. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, 113 Stat. 1338, 1471 (Nov. 12, 1999), requires the Federal banking agencies to use plain language in all proposed and final rulemakings published in the **Federal Register** after January 1, 2000. The FDIC invited comments on how to make this proposal easier to understand. No comments addressing this issue were received.

List of Subjects in 12 CFR Part 327

Bank deposit insurance, Banks, Banking, Savings associations.

For the reasons set forth above, the FDIC amends part 327 as follows:

PART 327—ASSESSMENTS

■ 1. The authority citation for 12 CFR part 327 continues to read as follows:

Authority: 12 U.S.C. 1441, 1813, 1815, 1817–19, 1821.

■ 2. Revise § 327.11 to read as follows:

§ 327.11 Surcharges and assessments required to raise the reserve ratio of the DIF to 1.35 percent.

(a) *Surcharge*—(1) *Institutions subject to surcharge.* The following insured depository institutions are subject to the surcharge described in this paragraph:

(i) Large institutions, as defined in § 327.8(f);

(ii) Highly complex institutions, as defined in § 327.8(g); and

(iii) Insured branches of foreign banks whose assets are equal to or exceed $10 billion, as reported in Schedule RAL of the branch's most recent quarterly Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks.

(2) *Surcharge period.* The surcharge period shall begin the later of the first day of the assessment period following the assessment period in which the reserve ratio of the DIF first reaches or exceeds 1.15 percent, or the assessment period beginning on July 1, 2016. The surcharge period shall continue through the earlier of the assessment period ending December 31, 2018, or the end of the assessment period in which the reserve ratio of the DIF first reaches or exceeds 1.35 percent.

(3) *Notification of surcharge.* The FDIC shall notify each insured depository institution subject to the surcharge of the amount of such surcharge no later than 15 days before such surcharge is due, as described in paragraph (a)(4) of this section.

(4) *Payment of any surcharge.* Each insured depository institution subject to

[63] 5 U.S.C. 604.

[64] 5 U.S.C. 605.

[65] 5 U.S.C. 605.

[66] 12 U.S.C. 4802(a).

[67] 12 U.S.C. 4802(b).

the surcharge shall pay to the Corporation any surcharge imposed under paragraph (a) of this section in compliance with and subject to the provisions of §§ 327.3, 327.6 and 327.7. The payment date for any surcharge shall be the date provided in § 327.3(b)(2) for the institution's quarterly certified statement invoice for the assessment period in which the surcharge was imposed.

(5) *Calculation of surcharge.* An insured depository institution's surcharge for each assessment period during the surcharge period shall be determined by multiplying 1.125 basis points times the institution's surcharge base for the assessment period.

(i) *Surcharge base—Insured depository institution that has no affiliated insured depository institution subject to the surcharge.* The surcharge base for an assessment period for an insured depository institution subject to the surcharge that has no affiliated insured depository institution subject to the surcharge shall equal:

(A) The institution's deposit insurance assessment base for the assessment period, determined according to § 327.5; plus

(B) The greater of the increase amount determined according to paragraph (a)(5)(iii) of this section or zero; minus

(C) $10 billion; provided, however, that an institution's surcharge base for an assessment period cannot be negative.

(ii) *Surcharge base—insured depository institution that has one or more affiliated insured depository institutions subject to the surcharge.* The surcharge base for an assessment period for an insured depository institution subject to the surcharge that has one or more affiliated insured depository institutions subject to the surcharge shall equal:

(A) The institution's deposit insurance assessment base for the assessment period, determined according to § 327.5; plus

(B) The greater of the institution's portion, determined according to paragraph (a)(5)(v) of this section, of the increase amount determined according to paragraph (a)(5)(iii) of this section or zero; minus

(C) The institution's portion, determined according to paragraph (a)(5)(v) of this section, of $10 billion; provided, however, that an institution's surcharge base for an assessment period cannot be negative.

(iii) *Surcharge base—determination of increase amount.* The increase amount for an assessment period shall equal:

(A) The amount of the aggregate deposit insurance assessment bases for the assessment period, determined according to § 327.5, of all of the institution's affiliated insured depository institutions that are not subject to the surcharge, minus

(B) The product of the increase multiplier set out in paragraph (a)(5)(iv) of this section and the aggregate deposit insurance assessment bases, determined according to § 327.5, as of December 31, 2015, of all of the small institutions, as defined in § 327.8(e), that were the institution's affiliated insured depository institutions for the assessment period ending December 31, 2015.

(iv) *Increase multiplier for the assessment periods during the surcharge period.* During the surcharge period, the increase multiplier shall be the amount prescribed in the following schedule:

INCREASE MULTIPLIERS FOR THE ASSESSMENT PERIODS DURING THE SURCHARGE PERIOD

For the assessment period ending—	
September 30, 2016	1.0740995
December 31, 2016	1.1000000
March 31, 2017	1.1265251
June 30, 2017	1.1536897
September 30, 2017	1.1815094
December 31, 2017	1.2100000
March 31, 2018	1.2391776
June 30, 2018	1.2690587
September 30, 2018	1.2996604
December 31, 2018	1.3310000

(A) For the assessment period ending September 30, 2016, the increase multiplier shall be 1.0740995.

(B) For the assessment period ending December 31, 2016, the increase multiplier shall be 1.1000000.

(C) For the assessment period ending March 31, 2017, the increase multiplier shall be 1.1265251.

(D) For the assessment period ending June 30, 2017, the increase multiplier shall be 1.1536897.

(E) For the assessment period ending September 30, 2017, the increase multiplier shall be 1.1815094.

(F) For the assessment period ending December 31, 2017, the increase multiplier shall be 1.2100000.

(G) For the assessment period ending March 31, 2018, the increase multiplier shall be 1.2391776.

(H) For the assessment period ending June 30, 2018, the increase multiplier shall be 1.2690587.

(I) For the assessment period ending September 30, 2018, the increase multiplier shall be 1.2996604.

(J) For the assessment period ending December 31, 2018, the increase multiplier shall be 1.33100000.

(v) *Surcharge base—institution's portion.* For purposes of paragraphs (a)(5)(ii)(B) and (C) of this section, an institution's portion shall equal the ratio of the institution's deposit insurance assessment base for the assessment period, determined according to § 327.5, to the sum of the institution's deposit insurance assessment base for the assessment period, determined according to § 327.5, and the deposit insurance assessment bases for the assessment period, determined according to § 327.5, of all of the institution's affiliated insured depository institutions subject to the surcharge.

(vi) For the purposes of this section, an affiliated insured depository institution is an insured depository institution that meets the definition of ''affiliate'' in section 3 of the FDI Act, 12 U.S.C. 1813(w)(6).

(6) *Effect of mergers and consolidations on surcharge base.* (i) If an insured depository institution acquires another insured depository institution through merger or consolidation during the surcharge period, the acquirer's surcharge base will be calculated consistent with § 327.6 and § 327.11(a)(5). For the purposes of the surcharge, a merger or consolidation means any transaction in which an insured depository institution merges or consolidates with any other insured depository institution, and includes transactions in which an insured depository institution either directly or indirectly acquires all or substantially all of the assets, or assumes all or substantially all of the deposit liabilities of any other insured depository institution where there is not a legal merger or consolidation of the two insured depository institutions.

(ii) If an insured depository institution not subject to the surcharge is the surviving or resulting institution in a merger or consolidation with an insured depository institution that is subject to the surcharge or acquires all or substantially all of the assets, or assumes all or substantially all of the deposit liabilities, of an insured depository institution subject to the surcharge, then the surviving or resulting insured deposit institution or the insured depository institution that acquires such assets or assumes such deposit liabilities is subject to the surcharge.

(b) *Shortfall assessment.*—(1) *Institutions subject to shortfall assessment.* Any insured depository institution that was subject to a surcharge under paragraph (a)(1) of this section, in any assessment period during the surcharge period described

in paragraph (a)(2) of this section, shall be subject to the shortfall assessment described in this paragraph (b). If surcharges under paragraph (a) of this section have not been in effect, the insured depository institutions subject to the shortfall assessment described in this paragraph (b) will be the insured depository institutions described in paragraph (a)(1) of this section as of the assessment period in which the reserve ratio of the DIF reaches or exceeds 1.15 percent.

(2) *Notification of shortfall.* The FDIC shall notify each insured depository institution subject to the shortfall assessment of the amount of such institution's share of the shortfall assessment described in paragraph (b)(5) of this section no later than 15 days before such shortfall assessment is due, as described in paragraph (b)(3) of this section.

(3) *Payment of any shortfall assessment.* Each insured depository institution subject to the shortfall assessment shall pay to the Corporation such institution's share of any shortfall assessment as described in paragraph (b)(5) of this section in compliance with and subject to the provisions of §§ 327.3, 327.6 and 327.7. The payment date for any shortfall assessment shall be the date provided in § 327.3(b)(2) for the institution's quarterly certified statement invoice for the assessment period in which the shortfall assessment is imposed.

(4) *Amount of aggregate shortfall assessment.* (i) If the reserve ratio of the DIF is at least 1.15 percent but has not reached or exceeded 1.35 percent as of December 31, 2018, the shortfall assessment shall be imposed on March 31, 2019, and shall equal 1.35 percent of estimated insured deposits as of December 31, 2018, minus the actual DIF balance as of that date.

(ii) If the reserve ratio of the DIF is less than 1.15 percent and has not reached or exceeded 1.35 percent by December 31, 2018, the shortfall assessment shall be imposed at the end of the assessment period immediately following the assessment period that occurs after December 31, 2018, during which the reserve ratio first reaches or exceeds 1.15 percent and shall equal 0.2 percent of estimated insured deposits as of the end of the calendar quarter in which the reserve ratio first reaches or exceeds 1.15 percent.

(5) *Institutions' shares of aggregate shortfall assessment.* Each insured depository institution's share of the aggregate shortfall assessment shall be determined by apportioning the aggregate amount of the shortfall assessment among all institutions subject to the shortfall assessment in proportion to each institution's shortfall assessment base as described in this paragraph.

(i) *Shortfall assessment base if surcharges have been in effect.* If surcharges have been in effect, an institution's shortfall assessment base shall equal the average of the institution's surcharge bases during the surcharge period. For purposes of determining the average surcharge base, if an institution was not subject to the surcharge during any assessment period of the surcharge period, its surcharge base shall equal zero for that assessment period.

(ii) *Shortfall assessment base if surcharges have not been in effect.* If surcharges have not been in effect, an institution's shortfall assessment base shall equal the average of what its surcharge bases would have been over the four assessment periods ending with the assessment period in which the reserve ratio first reaches or exceeds 1.15 percent. If an institution would not have been subject to a surcharge during one of those assessment periods, its surcharge base shall equal zero for that assessment period.

(6) *Effect of mergers and consolidations on shortfall assessment.* (i) If an insured depository institution, through merger or consolidation, acquires another insured depository institution that paid surcharges for one or more assessment periods, the acquirer will be subject to a shortfall assessment and its average surcharge base will be increased by the average surcharge base of the acquired institution, consistent with paragraph (b)(5) of this section.

(ii) For the purposes of the shortfall assessment, a merger or consolidation means any transaction in which an insured depository institution merges or consolidates with any other insured depository institution, and includes transactions in which an insured depository institution either directly or indirectly acquires all or substantially all of the assets, or assumes all or substantially all of the deposit liabilities of any other insured depository institution where there is not a legal merger or consolidation of the two insured depository institutions.

(c) *Assessment credits.* (1)(i) *Eligible Institutions.* For the purposes of this paragraph (c) an insured depository institution will be considered an eligible institution, if, for at least one assessment period during the credit calculation period, the institution was a credit accruing institution.

(ii) *Credit accruing institutions.* A credit accruing institution is an institution that, for a particular assessment period, is not:

(A) A large institution, as defined in § 327.8(f);

(B) A highly complex institution, as defined in § 327.8(g); or

(C) An insured branch of a foreign bank whose assets are equal to or exceed $10 billion, as reported in Schedule RAL of the branch's most recent quarterly Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks.

(2) *Credit calculation period.* The credit calculation period shall begin the first day of the assessment period after the reserve ratio of the DIF reaches or exceeds 1.15 percent, and shall continue through the earlier of the assessment period that the reserve ratio of the DIF reaches or exceeds 1.35 percent or the assessment period that ends December 31, 2018.

(3) *Determination of aggregate assessment credit awards to all eligible institutions.* The FDIC shall award an aggregate amount of assessment credits equal to the product of the *fraction of quarterly regular deposit insurance assessments paid by credit accruing institutions* during the credit calculation period and the amount by which the *DIF increase,* as determined under paragraph (c)(3)(ii) or (iii) of this section, exceeds total surcharges imposed under paragraph (b) of this section; provided, however, that the aggregate amount of assessment credits cannot exceed the aggregate amount of quarterly deposit insurance assessments paid by credit accruing institutions during the credit calculation period.

(i) *Fraction of quarterly regular deposit insurance assessments paid by credit accruing institutions.* The fraction of assessments paid by credit accruing institutions shall equal quarterly deposit insurance assessments, as determined under § 327.9, paid by such institutions for each assessment period during the credit calculation period, divided by the total amount of quarterly deposit insurance assessments paid by all insured depository institutions during the credit calculation period, excluding the aggregate amount of surcharges imposed under paragraph (b) of this section.

(ii) *DIF increase if the DIF reserve ratio has reached 1.35 percent by December 31, 2018.* If the DIF reserve ratio has reached 1.35 percent by December 31, 2018, the DIF increase shall equal 0.2 percent of estimated insured deposits as of the date that the DIF reserve ratio first reaches or exceeds 1.35 percent.

(iii) *DIF Increase if the DIF reserve ratio has not reached 1.35 percent by*

December 31, 2018. If the DIF reserve ratio has not reached 1.35 percent by December 31, 2018, the DIF increase shall equal the DIF balance on December 31, 2018, minus 1.15 percent of estimated insured deposits on that date.

(4) *Determination of individual eligible institutions' shares of aggregate assessment Credit.*—

(i) *Assessment credit share.* To determine an eligible institution's assessment credit share, the aggregate assessment credits awarded by the FDIC shall be apportioned among all eligible institutions in proportion to their respective assessment credit bases, as described in paragraph (c)(4)(ii) of this section.

(ii) *Assessment credit base.* An eligible institution's assessment credit base shall equal the average of its quarterly deposit insurance assessment bases, as determined under § 327.5, during the credit calculation period, as defined in paragraph (c)(2) of this section. An eligible institution's credit base shall be deemed to equal zero for any assessment period during which the institution was not a credit accruing institution.

(iii) *Limitation.* The assessment credits awarded to an eligible institution shall not exceed the total amount of quarterly deposit insurance assessments paid by that institution for assessment periods during the credit calculation period in which it was a credit accruing institution.

(5) *Effect of merger or consolidation on assessment credit base.* If an eligible institution acquires another eligible institution through merger or consolidation before the reserve ratio of the DIF reaches 1.35 percent, the acquirer's quarterly deposit insurance assessment base (for purposes of calculating the acquirer's assessment credit base) shall be deemed to include the acquired institution's deposit insurance assessment base for the assessment periods during the credit calculation period that were prior to the merger or consolidation and in which the acquired institution was a credit accruing institution.

(6) *Effect of call report amendments.* Amendments to the quarterly Reports of Condition and Income or the quarterly Reports of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks that occur subsequent to the payment date for the final assessment period of the credit calculation period shall not affect an eligible institution's credit share.

(7) *Award and notice of assessment credits*—(i) *Award of assessment credits.* As soon as practicable after the earlier of either December 31, 2018, or the date on which the reserve ratio of the DIF reaches 1.35 percent, the FDIC shall notify an eligible institution of the FDIC's preliminary estimate of such institution's assessment credits and the manner in which the FDIC calculated such credits.

(ii) *Notice of assessment credits.* The FDIC shall provide eligible institutions with periodic updated notices reflecting adjustments to the institution's assessment credits resulting from requests for review or appeals, mergers or consolidations, or the FDIC's application of credits to an institution's quarterly deposit insurance assessments.

(8) *Requests for review and appeal of assessment credits.* Any institution that disagrees with the FDIC's computation of or basis for its assessment credits, as determined under this paragraph (c), may request review of the FDIC's determination or appeal that determination. Such requests for review or appeal shall be filed pursuant to the procedures set forth in paragraph (d) of this section.

(9) *Successors.* If an insured depository institution acquires an eligible institution through merger or consolidation after the reserve ratio of the DIF reaches 1.35 percent, the acquirer is successor to any assessment credits of the acquired institution.

(10) *Mergers and consolidation include only legal mergers and consolidation.* For the purposes of this paragraph (c), a merger or consolidation does not include transactions in which an insured depository institution either directly or indirectly acquires the assets of, or assumes liability to pay any deposits made in, any other insured depository institution, but there is not a legal merger or consolidation of the two insured depository institutions.

(11) *Use of credits.* (i) The FDIC shall apply assessment credits awarded under paragraph (c) of this section to an institution's deposit insurance assessments, as calculated under § 327.9, only for assessment periods in which the reserve ratio of the DIF exceeds 1.38 percent.

(ii) The FDIC shall apply assessment credits to reduce an institution's quarterly deposit insurance assessments by each institution's remaining credits. The assessment credit applied to each institution's deposit insurance assessment for any assessment period shall not exceed the institution's total deposit insurance assessment for that assessment period.

(iii) The amount of credits applied each quarter will not be recalculated as a result of amendments to the quarterly Reports of Condition and Income or the quarterly Reports of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks pertaining to any quarter in which credits have been applied.

(12) *Transfer or sale of credits.* Other than through merger or consolidation, credits may not be sold or transferred.

(d) *Request for review and appeals of assessment credits.* (1) An institution that disagrees with the basis for its assessment credits, or the Corporation's computation of its assessments credits under paragraph (c) of this section and seeks to change it must submit a written request for review and any supporting documentation to the FDIC's Director of the Division of Finance.

(2) *Timing.* (i) Any request for review under this paragraph must be submitted within 30 days from

(A) The initial notice provided by the FDIC to the insured depository institution under paragraph (c)(7) of this section stating the FDIC's preliminary estimate of an eligible institution's assessment credit and the manner in which the assessment credit was calculated; or

(B) Any updated notice provided by the FDIC to the insured depository institution under paragraph (c)(7) of this section.

(ii) Any requests submitted after the deadline in paragraph (d)(2)(i) of this section will be considered untimely filed and the institution will be subsequently barred from submitting a request for review of its assessment credit.

(3) *Process of review.* (i) Upon receipt of a request for review, the FDIC shall temporarily freeze the amount of the assessment credit being reviewed until a final determination is made by the Corporation.

(ii) The FDIC may request, as part of its review, additional information from the insured depository institution involved in the request and any such information must be submitted to the FDIC within 21 days of the FDIC's request;

(iii) The FDIC's Director of the Division of Finance, or his or her designee, will notify the requesting institution of his or her determination of whether a change is warranted within 60 days of receipt by the FDIC of the request for review, or if additional information had been requested from the FDIC, within 60 days of receipt of any such additional information.

(4) *Appeal.* If the requesting institution disagrees with the final determination from the Director of the Division of Finance, that institution may appeal its assessment credit

determination to the FDIC's Assessment Appeals Committee within 30 days from the date of the Director's written determination. Notice of the procedures applicable to an appeal before the Assessment Appeals Committee will be included in the Director's written determination.

(5) *Adjustments to assessment credits.* Once the Director of the Division of Finance, or the Assessment Appeals Committee, as appropriate, has notified the requesting bank of its final determination, the FDIC will make appropriate adjustments to assessment credit amounts consistent with that determination. Adjustments to an insured depository institution's assessment credit amounts will not be applied retroactively to reduce or increase the quarterly deposit insurance assessment for a prior assessment period.

■ 3. In § 327.35, revise paragraph (a) to read as follows:

§ 327.35 Application of credits.

(a) Subject to the limitations in paragraph (b) of this section, the amount of an eligible insured depository institution's one-time credit shall be applied to the maximum extent allowable by law against that institution's quarterly assessment payment under subpart A of this part, after applying assessment credits awarded under § 327.11(c), until the institution's credit is exhausted.

* * * * *

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix 1

Example Calculations of Surcharge Bases in Banking Organizations With Multiple Large Banks and Affiliated Small Banks

Table 1.1 gives an example of the calculation of the surcharge base for a banking organization that comprises three large banks but no affiliated small banks.

TABLE 1.1—EXAMPLE APPLICATION OF $10 BILLION DEDUCTION WITHIN A BANKING ORGANIZATION

[$ in billions]

Affiliated large banks	Assessment base	Share of $10 billion deduction		Surcharge base
		%	$	
	A	B (A/$116)	C (B * $10)	A − C
#1	$25.00	21.6	$2.16	$22.84
#2	55.00	47.4	4.74	50.26
#3	36.00	31.0	3.10	32.90
Total	116.00	100	10.00	106.00

* Some figures are rounded for simplicity of presentation.

The next tables give an example of the calculation of the surcharge base for a banking organization that comprises three large banks and two affiliated small banks. Table 1.2 shows the applicable amounts by which affiliated small banks' December 31, 2015 regular assessment bases will be multiplied to determine growth at a 10 percent effective annual rate. (The amounts in the table are calculated by compounding a quarterly rate of approximately 2.41 percent from December 31, 2015, to achieve a 10 percent effective annual rate.) Table 1.3 shows the calculation of the gross amount of the first adjustment (the net increase in affiliated small banks' assessment bases after December 31, 2015). Table 1.4 shows the apportionment of the first adjustment and the second adjustment (the $10 billion deduction) among the large banks in the banking organization.

The first adjustment calculates the cumulative net increase from December 31, 2015, in affiliated small banks' aggregate assessment bases in excess of an effective annual rate of 10 percent. In the example shown in Table 1.3, affiliated small bank X had an assessment base of $2.00 billion as of December 31, 2015, and affiliated small bank Y had an assessment base of $6.00 billion, or $8.00 billion in aggregate. On March 31, 2017, affiliated small bank X has increased its assessment base to $6.01 billion, and affiliated small bank Y has decreased its assessment base to $5.00 billion, so the affiliated small banks' aggregate assessment base is $11.01 billion. The amount of growth in excess of an effective annual rate of 10 percent is calculated by first multiplying the amount corresponding with March 31, 2017 in Table 1.2 (1.1265251) by the affiliated small banks aggregate assessment base of $8.00 billion as of December 31, 2015, and then subtracting the product from the affiliated small banks' aggregate assessment base of $11.01 billion as of March 31, 2017. The resulting amount, $2.00 billion, is the gross amount of the first adjustment.

The second adjustment deducts $10 billion from large banks' assessment bases. Both adjustments are apportioned among all large bank affiliates in a holding company in proportion to each large bank's regular assessment base. As shown in Table 1.4, each affiliated large bank's share of the banking organization's assessment base (the large bank share) is calculated by dividing the affiliated large bank's assessment base by the sum of all affiliated large bank assessment bases. Next, each large bank's share is multiplied by the gross amount ($2.0 billion) of the first adjustment, as calculated in Table 1.3, and the product is added to each large bank's surcharge base. Finally, each large bank's share is multiplied by the $10 billion deduction, and the product is subtracted from each large bank's surcharge base as increased by the first adjustment. The remaining amount constitutes each large bank's surcharge base for the quarter.

TABLE 1.2—MULTIPLIER AMOUNTS

For the assessment period ending—	
September 30, 2016	1.0740995
December 31, 2016	1.1000000
March 31, 2017	1.1265251
June 30, 2017	1.1536897
September 30, 2017	1.1815094
December 31, 2017	1.2100000
March 31, 2018	1.2391776
June 30, 2018	1.2690587
September 30, 2018	1.2996604
December 31, 2018	1.3310000

TABLE 1.3—EXAMPLE CALCULATION OF THE GROSS AMOUNT OF THE FIRST ADJUSTMENT

[Net increase in affiliated small banks' assessment bases after December 31, 2015]

[$ in billions] *

Affiliated small banks	Assessment base		Growth under a 10% effective annual rate, compounded quarterly	Growth in excess of 10% effective annual rate
	Year-end 2015	First quarter 2017		
	A	B	C = A * 1.1265	D = B − C
X	$2.00	$6.01		
Y	6.00	5.00		
Total	8.00	11.01	$9.01	$2.00

* Some figures are rounded for simplicity of presentation.

TABLE 1.4—EXAMPLE APPORTIONMENT OF THE FIRST ADJUSTMENT AND THE SECOND ADJUSTMENT (THE $10 BILLION DEDUCTION) AMONG THE LARGE BANKS IN A BANKING ORGANIZATION

[$ in billions] *

Affiliated large banks	Assessment base	Share of affiliated large banks' assessment bases (%)	Share of affiliated small banks' assessment bases	Share of $10 billion deduction	Surcharge base
	E	F (E/$113)	G (F * D)	H (F * $10)	E + G − H
#1	$35.0	31.0	$0.62	$3.10	$32.52
#2	22.0	19.5	0.39	1.95	20.44
#3	56.0	49.6	0.99	4.96	52.04
Total	113.0	100.0	2.00	10.00	105.00

* Some figures are rounded for simplicity of presentation.

By order of the Board of Directors.

Dated at Washington, DC, this 15th day of March, 2016.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2016–06770 Filed 3–24–16; 8:45 am]

BILLING CODE 6714–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

[Docket No. CFPB–2016–0013]

RIN 3170–AA59

Operations in Rural Areas Under the Truth in Lending Act (Regulation Z); Interim Final Rule

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Interim final rule with request for public comment.

SUMMARY: This interim final rule amends certain provisions of Regulation Z in light of title LXXXIX of the Fixing America's Surface Transportation Act, entitled the Helping Expand Lending Practices in Rural Communities Act, Public Law 114–94. The amendments to Regulation Z concern two matters: The eligibility of certain small creditors that operate in rural or underserved areas for special provisions that permit the origination of balloon-payment qualified mortgages and balloon-payment high cost mortgages and for an exemption from the requirement to establish an escrow account for higher-priced mortgage loans and the determination of whether an area is rural for the purposes of Regulation Z.

DATES: This final rule is effective on March 31, 2016. Comments may be submitted on or before April 25, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CFPB–2016–0013 or RIN 3170–AA59, by any of the following methods:

- *Email: FederalRegisterComments@cfpb.gov.* Include Docket No. CFPB–2016–0013 or RIN 3170–AA59 in the subject line of the email.
- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier:* Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1275 First Street NE., Washington, DC 20002.

Instructions: All submissions should include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. Because paper mail in the Washington, DC area and at the Consumer Financial Protection Bureau (Bureau) is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to *http://www.regulations.gov.* In addition, comments will be available for public inspection and copying at 1275 First Street NE., Washington, DC 20002, on official business days between the hours of 10 a.m. and 5 p.m. eastern time. You can make an appointment to inspect the documents by telephoning (202) 435–7275.

All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive

personal information, such as account numbers or Social Security numbers, should not be included. Comments will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Carl Owens, Terry J. Randall, or James Wylie, Counsels, Office of Regulations, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Summary of Interim Final Rule

The Bureau is issuing this interim final rule to amend Regulation Z to address the Helping Expand Lending Practices in Rural Communities Act of 2015 (HELP Rural Communities Act or the Act), which was enacted on December 4, 2015.[1] The Act has two substantive sections. First, the Act broadened the class of creditors that may be eligible under the Truth in Lending Act (TILA) for provisions that relieve burden for small, rural mortgage creditors.[2] Second, it requires the Bureau to establish a process under which a person may apply to have an area designated by the Bureau as a rural area for purposes of a Federal consumer financial law.[3] On March 3, 2016, the Bureau published a rule establishing the application process mandated by the Act.[4] This interim final rule addresses the Act's amendments to TILA and defines the term ''area'' for purposes of the application process.

This interim final rule is implementing Congress's intention to expand the cohort of small creditors that are eligible for a special provision of Regulation Z that permits origination of balloon-payment qualified mortgages under § 1026.43(f) and for an exemption from the requirement to establish an escrow account for higher-priced mortgages (escrow exemption) under § 1026.35(b)(2)(iii). The Act's amendments to TILA authorize the Bureau to extend the special provision and exemption to certain small creditors that operate in rural or underserved areas, and remove TILA's prior limitation that eligible creditors must operate predominantly in such areas.[5] In addition to the special provision and escrow exemption addressed in the Act, to promote consistent regulatory requirements and reduce unwarranted burdens on small creditors, the interim final rule also expands eligibility for a special provision which allows rural, small creditors to originate high cost mortgages with balloon-payment terms (balloon-payment high cost mortgages) under § 1026.32(d)(1)(ii)(C).

To expand eligibility for the special provisions and exemption, the interim final rule revises § 1026.35(b)(2)(iii)(A), which specifies the level of operations in rural or underserved areas at which a creditor is eligible for the special provisions and exemption. Under the interim final rule, a creditor satisfies the rural-or-underserved component of the eligibility criteria if the creditor originated a covered transaction secured by a property located in a rural or underserved area in the preceding calendar year or, if the application for the transaction was received before April 1 of the current calendar year, during either of the two preceding calendar years. The interim final rule also amends the current eligibility criteria for the escrow exemption to ensure that creditors that established escrow accounts solely to comply with the current rule will be eligible for the exemption if they otherwise meet its criteria under this interim final rule.

In addition to addressing the Act's amendments to TILA, this rule also amends § 1026.35(b)(2)(iv)(A), which sets forth the rule for determining whether an area is rural for the purposes of Regulation Z, by inserting a reference to any areas designated as rural through the application process mandated by the Act. This amendment also establishes that, consistent with the current definition of rural area in Regulation Z, only counties or census blocks are eligible areas for the purpose of the application process established by the Bureau pursuant to the Act. The Bureau is soliciting comments on the interim final rule's amendments to Regulation Z.

II. Background

In response to an unprecedented cycle of expansion and contraction in the mortgage market that sparked the most severe U.S. recession since the Great Depression, Congress passed the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), signed into law on July 21, 2010.[6] In the Dodd-Frank Act, Congress significantly amended the statutory requirements governing mortgage practices.[7]

As part of these changes, Congress vested the Bureau with specific authority to modify certain requirements with respect to small creditors operating predominantly in rural or underserved areas. TILA sections 129C(b)(2)(E)(iv)(I) and 129D(c)(1) granted the Bureau the discretion to create a special provision allowing origination of balloon-payment qualified mortgages, even though balloon-payment mortgages are otherwise precluded from being considered qualified mortgages, and an exemption from the requirement to establish an escrow account for higher-priced mortgage loans.[8] TILA limited the cohort of creditors to which the Bureau may grant the special provision and exemption to include only small creditors that operate predominantly in rural or underserved areas.

The Bureau issued several rules in early 2013 to implement these new statutory requirements.[9] As directed by Congress, the Bureau considered the issues facing rural, small creditors and determined that it was appropriate to exercise its discretion under TILA to reduce burden on certain small creditors that operate predominantly in rural or underserved areas. Accordingly, the Bureau established a special provision allowing origination of balloon-payment qualified mortgages, even though balloon-payment mortgages are otherwise precluded from being considered qualified mortgages, and an exemption from the pre-existing requirement to establish an escrow account for higher-priced mortgage loans.[10] To synchronize the treatment of balloon-payment loans for purposes of qualified mortgages and high cost mortgages, the Bureau exercised discretionary authority under TILA section 129(p)(1) to establish a special provision allowing creditors that satisfy

[1] Public Law 114–94 (2015).

[2] Public Law 114–94, section 89003 (2015).

[3] Public Law 114–94, section 89002 (2015).

[4] Application Process for Designation of Rural Area under Federal Consumer Financial Law, 81 FR 11099 (Mar. 3, 2016).

[5] Public Law 114–94, section 89003 (2015).

[6] Public Law 111–203, 124 Stat. 1376 (2010).

[7] *See* title XIV of the Dodd-Frank Act, Public Law 111–203, 124 Stat. 1376 (2010) (codified in scattered sections of titles 12, 15, and 42 of the United States Code).

[8] *See* Escrow Requirements Under the Truth in Lending Act (Regulation Z), 78 FR 4726, 4736 (Jan. 22, 2013) (January 2013 Escrows Final Rule); Ability-to-Repay and Qualified Mortgage Standards Under the Truth in Lending Act (Regulation Z) January 2013 ATR Final Rule, 78 FR 6408, 6538 (Jan. 30, 2013) (January 2013 ATR Final Rule).

[9] *See, e.g.,* January 2013 Escrows Final Rule, 78 FR 4726 (Jan. 22, 2013); January 2013 ATR Final Rule, 78 FR 6408 (Jan. 30, 2013); High Cost Mortgage and Homeownership Counseling Amendments to the Truth in Lending Act (Regulation Z) and Homeownership Counseling Amendments to the Real Estate Settlement Procedures Act (Regulation X), 78 FR 6856 (Jan. 31, 2013) (2013 HOEPA Final Rule); Ability-to-Repay and Qualified Mortgage Standards Under the Truth in Lending Act (Regulation Z), 78 FR 35430 (June 12, 2013) (May 2013 ATR Final Rule); Amendments to the 2013 Mortgage Rules Under the Equal Credit Opportunity Act (Regulation B), Real Estate Settlement Procedures Act (Regulation X), and the Truth in Lending Act (Regulation Z), 78 FR 60382, 60416 (Oct. 1, 2013) (September 2013 Final Rule).

[10] *See* January 2013 Escrows Final Rule, 78 FR 4726, 4736 (Jan. 22, 2013); January 2013 ATR Final Rule, 78 FR 6408, 6538 (Jan. 30, 2013).

the same eligibility criteria as the special provision and exemption to originate high cost mortgages with balloon-payment features.[11]

The Bureau adopted a single test to determine whether a small creditor operated predominantly in rural or underserved areas for the purposes of eligibility for the special provisions and exemption.[12] In adopting this test, the Bureau stated that it interpreted the use of ''predominantly'' in the statute to ''[indicate] a portion greater than half'' [13] and therefore conditioned eligibility on whether the small creditor extended more than 50 percent of its total first-lien covered transactions [14] on properties that are located in areas designated as either rural or underserved.[15]

In the spring of 2013, the Bureau adopted provisions establishing a two-year transition period during which small creditors that did not operate predominantly in rural or underserved areas could originate balloon-payment qualified mortgages. The Bureau explained that the transition period provided time for small creditors to make changes to their business practices, and noted the particular challenges posed by existing balloon-payment loans that would be due for renewal in the near term. The Bureau also stated that the transition period would give it time to study whether the definitions of rural or underserved should be adjusted.[16] In the fall of 2013, the Bureau extended the same two-year transition period to balloon-payment high cost mortgages for the same reasons that it established the transition period for balloon-payment qualified mortgages.[17] The Bureau did not make any changes to the escrow exemption in these rules.

In the fall of 2015, the Bureau adopted revisions that affected the special provisions and the escrow exemption.[18] As part of these revisions, the Bureau expanded eligibility for the exemption and special provisions by raising the loan origination limit for determining eligibility for small creditor status from no more than 500 applicable loans to no more than 2,000 applicable loans. In addition, the Bureau broadened the definition of ''rural'' by adding census blocks that are not in urban areas as defined by the U.S. Census Bureau to the existing county-based definition. The Bureau noted that the special provisions and exemption facilitate the ability of rural, small creditors to provide access to mortgage credit for consumers they serve. At that time, the Bureau also extended the temporary provisions that allow certain small creditors to make balloon-payment qualified mortgages and balloon-payment high cost mortgages regardless of whether they operated predominantly in rural or underserved areas for an additional three and a half months.[19] The Bureau explained that it extended the temporary provisions to provide time for small creditors to understand how the changes that the Bureau was making to the definition of rural would affect their status and to make any necessary adjustments to their business practices. The transition period expires on April 1, 2016.

Just over two months after the Bureau adopted these revisions, on December 4, 2015, the HELP Rural Communities Act was enacted into law.[20] The Act broadened the class of creditors that may be eligible under TILA for the special provision allowing origination of balloon-payment qualified mortgages and for the escrow exemption.[21] Prior to the HELP Rural Communities Act amendments, both TILA sections 129C(b)(2)(E)(iv)(I) and 129D(c)(1), the sections under which the Bureau exercised its authority to create the special provision and exemption, limited eligibility to small creditors that ''operate predominantly in rural or underserved areas.'' The Act struck the term ''predominantly'' from both sections.[22] In addition, the Act requires the Bureau to establish a temporary application process to have an area designated by the Bureau as a rural area for purposes of a Federal consumer financial law.[23]

On March 3, 2016, the Bureau published a procedural rule in the **Federal Register** to establish the application process mandated by the Act.[24] Pursuant to that process, the Bureau will begin accepting applications for areas to be designated as rural areas on March 31, 2016, and the application process will terminate on December 4, 2017.[25] The Bureau is issuing this interim final rule to amend Regulation Z to exercise the authority granted to the Bureau by the Act's amendments to TILA and to insert a reference to rural areas designated through the application process mandated by the Act.

III. Legal Authority

The Bureau is issuing this final rule pursuant to its authority under TILA and the Dodd-Frank Act. TILA, as amended by the Dodd-Frank Act and the HELP Rural Communities Act, provides specific statutory bases for the Bureau's interim final rule. TILA section 129D(c) authorizes the Bureau to exempt, by regulation, a creditor from the requirement (in section 129D(a)) that escrow accounts be established for higher-priced mortgage loans if the creditor operates in rural or underserved areas, retains its mortgage loans in portfolio, does not exceed (together with all affiliates) a total annual mortgage loan origination limit set by the Bureau, and meets any asset-size threshold, and any other criteria, the Bureau may establish. TILA section 129C(b)(2)(E) authorizes the Bureau to provide, by regulation, that certain balloon-payment mortgages originated by small creditors receive qualified mortgage status, even though qualified mortgages are otherwise prohibited from having balloon-payment features.

With respect to the high cost mortgage provisions of TILA section 129, TILA section 129(p), as amended by the Dodd-Frank Act, grants the Bureau the

[11] Section 1026.32(d)(1)(ii)(C); 2013 HOEPA Final Rule, 78 FR 6856, 6921–22 (Jan. 31, 2013) (adopting same criteria for eligibility as the 2013 ATR Final Rule to promote consistency and facilitate compliance).

[12] *See* §§ 1026.35(b)(2)(iii)(A) (establishing test to determine whether the creditor operates predominantly in a rural or underserved area for purposes of escrow exemption); 1026.43(f)(1)(vi) (referring to criterion set forth in § 1026.35(b)(2)(iii)(A) for purposes of eligibility to originate balloon-payment qualified mortgages); § 1026.32(d)(1) (referring to the criteria set forth in § 1026.43(f)(1)(i) through (vi) and 1026.43(f)(2)).

[13] 2013 Escrows Final Rule, 78 FR 4726, 4736 (Jan. 22, 2013).

[14] ''Covered transaction'' is defined in § 1026.43(b)(1) to mean a consumer credit transaction that is secured by a dwelling, as defined in § 1026.2(a)(19), including any real property attached to a dwelling, other than a transaction exempt from coverage under § 1026.43(a).

[15] 2013 Escrows Final Rule, 78 FR 4726, 4736 (Jan. 22, 2013).

[16] May 2013 ATR Final Rule, 78 FR 35430, 35488–89 (June 12, 2013) (adopting § 1026.43(e)(6)).

[17] September 2013 Final Rule, 78 FR 60382, 60413 (Oct. 1, 2013) (amending § 1026.32(d)(1)(ii)(C)).

[18] Amendments Relating to Small Creditors and Rural or Underserved Areas Under the Truth in Lending Act (Regulation Z), 80 FR 59944 (Oct. 2, 2015) (October 2015 Small Creditor Final Rule).

[19] *Id.*

[20] Public Law 114–94 (2015).

[21] Public Law 114–94, section 89003 (2015); *see also* Joint Explanatory Statement of the Committee of the Conference, H.R. 22, *Title LXXXIX—Helping Expand Lending Practices in Rural Communities* at 55–56, *http://transportation.house.gov/uploadedfiles/joint_explanatory_statement.pdf.*

[22] Public Law 114–94, section 89003 (2015).

[23] Public Law 114–94, section 89002 (2015).

[24] Application Process for Designation of Rural Area under Federal Consumer Financial Law, 81 FR 11099 (Mar. 3, 2016).

[25] The Bureau will consider any application received before April 8, 2017. The Bureau may not consider an application received on or after April 8, 2017, if it determines that it is not possible to complete the statutorily designed potential 240-day application process for that application by the sunset date, based on the time remaining, the complexity of the application, and any other relevant factors. *Id.*

authority to create exemptions to the restrictions on high cost mortgages and to expand the protections that apply to high cost mortgages. Under TILA section 129(p)(1), the Bureau may exempt specific mortgage products or categories from any or all of the prohibitions specified in TILA section 129(c) through (i), if the Bureau finds that the exemption is in the interest of the borrowing public and will apply only to products that maintain and strengthen homeownership and equity protections. Among these referenced provisions of TILA is section 129(e), the prohibition on balloon payments for high cost mortgages.

In addition, as amended by the Dodd-Frank Act, TILA section 105(a) authorizes the Bureau to prescribe regulations to carry out the purposes of TILA. Under section 105(a), such regulations may contain such additional requirements, classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for all or any class of transactions, as in the judgment of the Bureau are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. Dodd-Frank Act section 1100A clarified the Bureau's TILA section 105(a) authority by amending that section to provide express authority to prescribe regulations that contain ''additional requirements'' that the Bureau finds are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

In addition, section 1061 of the Dodd-Frank Act transferred to the Bureau the ''consumer financial protection functions'' previously vested in certain other Federal agencies, including the Board of Governors of the Federal Reserve System (Board). The term ''consumer financial protection function'' is defined to include ''all authority to prescribe rules or issue orders or guidelines pursuant to any Federal consumer financial law, including performing appropriate functions to promulgate and review such rules, orders, and guidelines.'' [26] Title X of the Dodd-Frank Act, including section 1061 of the Dodd-Frank Act, along with TILA and certain subtitles and provisions of title XIV of the Dodd-Frank Act, are Federal consumer financial laws.[27] In addition, section 1022(b)(1) of the Dodd-Frank Act authorizes the Bureau to prescribe rules ''as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.'' TILA is a Federal consumer financial law. Accordingly, the Bureau is exercising its authority under Dodd-Frank Act section 1022(b) to issue rules that carry out the purposes and objectives of TILA.

IV. Administrative Procedure Act

To the extent that notice and comment would otherwise be required, the Bureau finds that there is good cause due to the exigencies created by the HELP Rural Communities Act to publish this interim final rule without notice and comment and for the rule to be effective less than 30 days after publication.[28] It is necessary to finalize the interim final rule before April 1, 2016, for the reasons discussed below. As a result, the Bureau finds that it is impracticable both to provide notice and accept comment on the amendments to Regulation Z before finalizing the rule and to provide a 30-day period between publication and when the rule is effective.[29]

A. Revisions to Effectuate the Amendments to TILA

This interim final rule revises certain provisions in Regulation Z to effectuate the HELP Rural Communities Act's amendments to TILA, which broadened the cohort of creditors that may be eligible under TILA for the special provision permitting origination of balloon-payment qualified mortgages and for the escrow exemption.[30] Prior to these amendments to TILA, eligibility was limited to creditors that operate predominantly in rural or underserved areas. Congress struck the word ''predominantly'' from the TILA sections.[31]

These amendments to TILA, which were effective upon enactment on December 4, 2015, create uncertainty and confusion for creditors that are not currently eligible for the special provisions and exemption. For example, these creditors may question how the Act changes their eligibility for the special provisions and exemption. This uncertainty may lead these creditors to change their business practices, potentially imposing burden and costs on creditors to update their policies and procedures, make changes to their technology, and train staff. This uncertainty also creates legal risks for these creditors. They may mistakenly believe that the amendments to TILA automatically broadened the regulatory exemption and may take steps that might lead them out of compliance with the requirements in Regulation Z.

With respect to the special provisions pertaining to balloon-payment features, the consequences of this confusion can be avoided if the interim final rule is effective before April 1, 2016. Currently, the rural-or-underserved aspect of the eligibility criteria for the special provisions has no practical effect because, under temporary provisions that expire on April 1, 2016, creditors that meet all of the other eligibility criteria for the special provisions may originate balloon-payment qualified mortgages and balloon-payment high cost mortgages even if they do not satisfy the rural-or-underserved component of the test.[32] If the temporary provisions expire before the Bureau resolves the uncertainty created by the amendments to TILA by revising the rural-or-underserved component of the eligibility criteria in § 1026.35(b)(2)(iii)(A), creditors face significant confusion about the status of the exemptions, which may cause the potential legal risks described above and may impose unnecessary burden and costs on newly eligible creditors. The amendment to TILA, striking ''predominantly,'' suggests that Congress intended to expand eligibility for the special provision to additional creditors that operate in rural or underserved areas, but that do not operate ''predominantly'' in rural or underserved areas, and thereby reduce burden on this expanded cohort of small creditors. To exercise the Bureau's authority consistent with that intent while avoiding imposing unnecessary burden and costs on newly eligible small creditors, the revisions to the rural-or-underserved test in § 1026.35(b)(2)(iii)(A) must take effect prior to the April 1, 2016, expiration of the temporary provisions. If new § 1026.35(b)(2)(iii)(A) is not effective

[26] Dodd-Frank Act section 1061(a)(1)(A), 12 U.S.C. 5581(a)(1)(A).

[27] Dodd-Frank Act section 1002(14), 12 U.S.C. 5481(14) (defining ''Federal consumer financial law'' to include the ''enumerated consumer laws,'' the provisions of title X of the Dodd-Frank Act, and the laws for which authorities are transferred under title X subtitles F and H of the Dodd-Frank Act); Dodd-Frank Act section 1002(12), 12 U.S.C. 5481(12) (defining ''enumerated consumer laws'' to include TILA); Dodd-Frank section 1400(b), 12 U.S.C. 5481(12) note (defining ''enumerated consumer laws'' to include certain subtitles and provisions of Dodd-Frank Act title XIV).

[28] 5 U.S.C. 553(b)(3)(B); 5 U.S.C. 553(d)(3).

[29] This finding also satisfies the requirements of 5 U.S.C. 808(2), allowing the interim final rule to become effective notwithstanding the requirements of 5 U.S.C. 801 for the same reasons discussed in this section.

[30] Public Law 114–94, section 89003 (2015).

[31] *Id.*

[32] 12 CFR 1026.43(e)(6); 1026.32(d)(1)(ii)(C).

before the temporary provisions expire, newly eligible small creditors would have to change their business practices temporarily to comply with the requirements imposed by the current rule and then, later, when the revisions to the rule were effective, would have to change their business practices again to reverse course. To avoid imposing these unnecessary burdens and costs, the amendment to the rural-or-underserved test under § 1026.35(b)(2)(iii)(A) and conforming changes to the commentary must take effect before April 1, 2016.

The need to clarify the amendment to TILA's effect on the escrow exemption is also urgent because the requirement that creditors operate predominantly in rural or underserved areas to be eligible for the escrow exemption currently applies and will continue to apply as long as the current version of § 1026.35(b)(2)(iii)(A) is still in effect. In light of the Act, creditors now face uncertainty surrounding the status of their eligibility for the exemption. As noted above, some creditors that are not eligible for the current exemption may be under the mistaken impression that the amendments to TILA automatically broadened the regulatory exemption and that they are no longer required to establish escrow accounts for higher-priced mortgage loans. This confusion creates legal risks for these creditors. In addition, some creditors may be uncertain about whether establishing an escrow account to comply with current law will disqualify them from the escrow exemption in the future, because creditors generally are not eligible for the escrow exemption if they maintain escrow accounts for any extension of consumer credit secured by real property or a dwelling that it or its affiliate currently services that were established after January 1, 2016.[33] Some creditors may be adjusting their business practices as a result of this uncertainty. To resolve this uncertainty, the interim final rule's revisions to both the rural-or-underserved test under § 1026.35(b)(2)(iii)(A), discussed above, and the ''no harm'' provision under § 1026.35(b)(2)(iii)(D)(*1*) must be effective. The ''no harm'' provision ensures that any creditors that are currently ineligible for the escrow exemption, but that would qualify under the interim final rule, do not lose eligibility for the escrow exemption because of escrow accounts they established pursuant to requirements in the current rule. The amendments to both sections must take effect urgently to resolve the uncertainty surrounding the exemption and eliminate the legal risks described above.

B. Amendments Related to the Application Process

The amendment to the definition of rural area under § 1026.35(b)(2)(iv)(A) must take effect by March 31, 2016. New § 1026.35(b)(2)(iv)(A)(*3*) amends Regulation Z to refer to the application process mandated by the Act, which requires the Bureau to establish the application process by March 3, 2016.[34] The statute's inclusion of a deadline for establishing the application process suggests that Congress intended the Bureau to begin accepting applications as promptly after March 3, 2016, as possible. Accordingly, the Bureau's procedural rule established March 31, 2016, as the date when it would begin accepting applications. To provide potential applicants with notice of the types of areas for which they may submit applications before the Bureau begins accepting applications, it is necessary for new § 1026.35(b)(2)(iv)(A)(*3*) to be effective by March 31, 2016.

V. Section-by-Section Analysis

Section 1026.35 Requirements for Higher-Priced Mortgage Loans

35(b) Escrow Accounts

35(b)(2)(iii)

35(b)(2)(iii)(A)

Section 1026.35(b)(2)(iii) currently provides that an escrow account need not be established for a higher-priced mortgage loan by small creditors if four conditions identified in § 1026.35(b)(2)(iii)(A) through (D) are satisfied at the time of consummation. Under current § 1026.35(b)(2)(iii)(A), a creditor satisfies the rural-or-underserved component of the eligibility criteria if, during the preceding calendar year or, if the application for the transaction was received before April 1 of the current calendar year, during either of the two preceding calendar years, a creditor extended more than 50 percent of its total covered transactions secured by first liens on properties that are located in rural or underserved areas. This provision is consistent with the statutory provision as adopted by the Dodd-Frank Act requiring that, in order for the Bureau to have the authority to grant the exemption, the creditor must operate predominantly in rural or underserved areas. The Bureau is revising § 1026.35(b)(2)(iii)(A) to remove the ''more than 50 percent'' aspect of the test and condition eligibility on a creditor extending one covered transaction secured by a first lien on a property located in a rural or underserved area.

The Bureau is revising § 1026.35(b)(2)(iii)(A) to reflect Congress's intent to expand the cohort of small creditors eligible for the special provision and exemptions by amending TILA sections 129C(b)(2)(E)(iv)(I) and 129D(c)(1) by removing ''predominantly'' from the statute. These sections of TILA relate to special provisions and an exemption that applies to certain small creditors operating in rural or underserved areas. Previously, TILA section 129C(b)(2)(E)(iv)(I) permitted the Bureau, by regulation, to define qualified mortgage as including a balloon loan for certain small creditors that operate predominantly in rural or underserved areas. Similarly, TILA section 129D(c)(1) permitted the Bureau, by regulation, to exempt certain small creditors that operate predominantly in rural or underserved areas from the requirement to establish an escrow account under TILA section 129D(a) in certain circumstances. The Act amended both provisions of TILA by striking the word ''predominantly'' and thereby extending the class of eligible creditors under TILA for the special provisions that permit balloon-payment qualified mortgages and for the escrow exemption.[35]

The Bureau previously issued regulations exercising its authority under TILA sections 129C(b)(2)(E)(iv)(I) and 129D(c)(1).[36] In addition, the Bureau also issued regulations using discretionary authority under TILA section 129(p)(1) to allow certain small creditors that operate predominantly in rural or underserved areas to originate balloon-payment high cost mortgages.[37] In October 2015, the Bureau finalized amendments to Regulation Z that broadened the definition of small creditor and rural area and thereby expanded the number of eligible creditors.[38]

Regulation Z uses a single test to determine whether a small creditor

[33] 12 CFR 1026.35(b)(2)(iii)(D)(*1*).

[34] Public Law 114–94, section 89002 (2015).

[35] Public Law 114–94, section 89003 (2015).

[36] *See* January 2013 Escrows Final Rule, 78 FR 4726 (Jan. 22, 2013); January 2013 ATR Final Rule, 78 FR 6408 (Jan. 30, 2013); May 2013 ATR Final Rule, 78 FR 35430 (June 12, 2013); October 2015 Small Creditor Final Rule, 80 FR 59944 (Oct. 2, 2015).

[37] Section 1026.32(d)(1)(ii)(C); 2013 HOEPA Final Rule, 78 FR 6856, 6921–22 (Jan. 31, 2013) (adopting same criteria for eligibility as the 2013 ATR Final Rule to promote consistency and ''facilitate compliance'').

[38] October 2015 Small Creditor Final Rule, 80 FR 59944 (Oct. 2, 2015).

operates predominantly in rural or underserved areas for the purposes of eligibility for the two balloon-payment special provisions and the escrow exemption.[39] In adopting this test, the Bureau stated that it interpreted the use of ''predominantly'' in the statute to ''[indicate] a portion greater than half'' and therefore conditioned eligibility on whether the small creditor extended more than 50 percent of its total first-lien covered transactions on properties that are located in areas designated as either rural or underserved.[40] The Bureau is revising § 1026.35(b)(2)(iii)(A) to remove the ''more than 50 percent'' aspect of the current test for purposes of the eligibility for the escrow exemption, the eligibility to originate balloon-payment qualified mortgages, and the eligibility to originate balloon-payment high cost mortgages.[41] Under these revisions, a creditor operates in a rural or underserved area if the creditor extended at least one first-lien covered transaction on a property that is located in a rural or underserved area in the previous calendar year, or if the application for the transaction was received before April 1 of the current calendar year, during either of the two preceding calendar years. The Bureau is also making conforming revisions to comment 35(b)(2)(iii)–1.

When the Bureau adopted the ''more than 50 percent'' aspect of the test, it stated that it was implementing the use of ''predominantly'' in the statute.[42] The amendments in section 89003 of the Act, striking ''predominantly,'' suggest that Congress intended to expand eligibility for the exemption to additional creditors that operate in rural or underserved areas, but that do not operate ''predominantly'' in those areas by currently making ''more than 50 percent'' of their covered transactions in such areas, and to thereby reduce burden on this expanded cohort of small creditors.

The Bureau believes that TILA sections 129C(b)(2)(E)(iv)(I) and 129D(c)(1), as revised by the Act, are ambiguous with respect to what it means to ''operate in a rural area,'' and are subject to various possible reasonable interpretations. The Bureau believes that the one-loan test adopted by revised § 1026.35(b)(2)(iii)(A) is a reasonable interpretation of these provisions of TILA and is appropriate at this time in light of the recent regulatory context, including Congress's decision to remove the term that the Bureau had relied on to establish the ''more than 50 percent'' aspect of the test from the statute and the limited data currently available upon which to base consideration of other potentially reasonable interpretations. Furthermore, as discussed above in part IV, the Bureau believes that the amendments must take effect before April 1, 2016, to provide timely guidance for creditors who may have uncertainty about the effect of the Act on § 1026.35(b)(2)(iii)(A) and need to make prompt decisions for the near term about their business operations in light of the Act's amendments, including whether to apply for an area to be designated as rural.[43] This certainty is critical to such creditors now, for purposes of making near-term business decisions, notwithstanding the Bureau's intent to monitor and potentially to revisit this interpretation in the future, as discussed below. The Bureau requests comment concerning any information or data relevant to the revisions to § 1026.35(b)(2)(iii)(A) in addition to the information or data discussed in part VII below.

The nearer term practical effect of the revisions to § 1026.35(b)(2)(iii)(A) is that they will likely preserve, for the most part, the current status of many small creditors eligible for the special provisions. As discussed above, under temporary provisions that expire on April 1, 2016, creditors that meet all of the other eligibility criteria for the special provisions may originate balloon-payment qualified mortgages and balloon-payment high cost mortgages even if they do not satisfy the rural-or-underserved component of the test.[44] Consequently, this final rule effectively adds to the special provisions' eligibility criteria a new prerequisite that the entity issue at least one loan in a rural or underserved area.

The Bureau intends to monitor the market closely and thoroughly for negative effects on consumers or unintended effects on the mortgage market as a result of these revisions to § 1026.35(b)(2)(iii)(A). The Bureau expects to have better information available for analyzing these effects and considering other potentially reasonable interpretations of ''operates in rural or underserved areas'' in the future, including more data available from the National Survey of Mortgage Borrowers (NSMB), as well as the National Mortgage Database (NMDB).[45]

At least one year after the effective date of this rule, and further dependent on when the Bureau believes newly available information may support considering additional rulemaking related to § 1026.35(b)(2)(iii)(A), the Bureau intends to invite public comment on the effect of these revisions to § 1026.35(b)(2)(iii)(A). If better information available to the Bureau, including further information provided by the public, shows that the revisions to § 1026.35(b)(2)(iii)(A) have had unintended effects on the mortgage market or negative effects on consumers, the Bureau intends to publish a notice of proposed rulemaking to exercise its authority to implement a revised test under § 1026.35(b)(2)(iii)(A). The Bureau requests comment on the optimal scope of the exemption for these creditors that the Bureau should consider as new data becomes available, and in what timeframe the Bureau should consider undertaking additional rulemaking related to the exemption. The Bureau also requests comment, including relevant data, on whether the

[39] 12 CFR 1026.35(b)(2)(iii).

[40] January 2013 Escrows Final Rule, 78 FR 4726, 4736 (Jan. 22, 2013); January 2013 ATR Final Rule, 78 FR 6408, 6543 (Jan. 30, 2013).

[41] Allowing § 1026.35(b)(2)(iii)(A), as revised by this rule, to continue to apply for purposes of eligibility to originate balloon-payment high cost mortgages promotes consistency between the Bureau's ability-to-repay requirements and the high cost mortgage requirements and facilitates compliance for creditors who operate in these areas. *See* 2013 HOEPA Final Rule, 78 FR 6856, 6921–22 (Jan. 31, 2013). The special provisions and exemptions facilitate the ability of small creditors that operate in rural or underserved areas to provide access to mortgage credit for consumers they serve.

[42] January 2013 Escrows Final Rule, 78 FR 4726, 4736 (Jan. 22, 2013); January 2013 ATR Final Rule, 78 FR 6408, 6543 (Jan. 30, 2013).

[43] Application Process for Designation of Rural Area under Federal Consumer Financial Law, 81 FR 11099 (Mar. 3, 2016).

[44] 12 CFR 1026.43(e)(6); § 1026.32(d)(1)(ii)(C).

[45] *See http://www.fhfa.gov/Homeownersbuyer/Pages/National-Survey-of-Mortgage-Borrowers.aspx. See also http://www.consumerfinance.gov/reports/technical-reports-national-survey-of-mortgage-borrowers-and-national-mortgage-database/.* The NSMB is one component of the NMDB project, a multi-year project being jointly undertaken by the Federal Housing Finance Agency and the Bureau. For the Bureau, the NMDB project will support policymaking and research efforts and help identify and understand emerging mortgage and housing market trends. The Bureau expects to use the NMDB, among other purposes, in support of the market monitoring called for by the Dodd-Frank Act, including understanding how mortgage debt affects consumers and for retrospective rule review required by the statute. The Bureau can use the NSMB to gather additional information about balloon-payment loans, escrow accounts, and creditors operating rural or underserved areas and the NMDB to provide additional data relevant to a future rulemaking involving creditors that operate in rural areas. For example, the Bureau may be able to use NSMB data to monitor the self-reported number of consumers that have a mortgage with a balloon feature. The Bureau can monitor the self-reported number of consumers that had an escrow account at origination. The Bureau can track the areas where either mortgages with balloon features or loans without escrow accounts are prevalent. The Bureau may also be able to extrapolate the number of loans that the creditor providing the loan originated, allowing the Bureau to focus on creditors operating predominantly in rural or underserved areas if necessary.

revisions will result in expanded access to credit.

35(b)(2)(iii)(D)

35(b)(2)(iii)(D)(1)

Section 1026.35(b)(1) generally requires a creditor to establish an escrow account for a higher-priced mortgage loan secured by a first lien on a consumer's principal dwelling. Section 1026.35(b)(2)(iii) provides an exemption from that requirement for certain small creditors. Section 1026.35(b)(2)(iii)(D) makes creditors that maintain existing escrow accounts ineligible for that exemption, with certain exceptions. One such exception, § 1026.35(b)(2)(iii)(D)(*1*), currently excludes escrow accounts established on or after April 1, 2010, and before January 1, 2016, from counting for purposes of the limitation in § 1026.35(b)(2)(iii)(D). The Bureau is revising § 1026.35(b)(2)(iii)(D)(*1*) to extend the excluded period to May 1, 2016. The Bureau believes that the period should be extended to accommodate creditors who established escrow accounts after January 1, 2016, to comply with the previous requirement. Some of these creditors who did not previously satisfy the rural-or-underserved test under § 1026.35(b)(2)(iii)(A) may now qualify under the newly revised rural-or-underserved test. Creditors should not be precluded from qualifying under the newly revised test based solely on their having established escrow accounts to comply with requirements that the Bureau is now revising.

35(b)(2)(iv)(A)

35(b)(2)(iv)(A)(3)

Section 1026.35(b)(2)(iv)(A) currently considers an area as rural during a calendar year if it is: A county that is neither in a metropolitan statistical area nor in a micropolitan statistical area that is adjacent to a metropolitan statistical area; or a census block that is not in an urban area, as defined by the U.S. Census Bureau using the latest decennial census of the United States. The Bureau is adding new § 1026.35(b)(2)(iv)(A)(*3*) to add to this definition an area that has been designated as rural pursuant to the application process established under section 89002 of the Act.[46]

As discussed above, on March 3, 2016, the Bureau published a procedural rule in the **Federal Register** establishing an application process through which a person may apply to have an area designated by the Bureau as a rural area for purposes of a Federal consumer financial law.[47] New § 1026.35(b)(2)(iv)(A)(*3*) defines rural area to include a county or a census block that has been designated as rural by the Bureau pursuant to the application process established under section 89002 of the Act. This amendment is necessary to incorporate areas designated as rural through that application process into the definition of rural area set forth in Regulation Z. Per the statute, designations through this process are time-limited and expire on December 4, 2017.

The Bureau interprets the term ''rural area,'' as that term is used in section 89002 of the Act, to be an area comprising counties or census blocks. For reasons set forth in the section-by-section analysis of the October 2015 amendments to § 1026.35(b)(2)(iv)(A), the Bureau adopted counties or census blocks as the appropriate units of analysis for its rural classification scheme and rejected alternative proposals.[48] Because the Act did not define the term ''rural area'' and did not revise this interpretation, the Bureau believes that Congress intended for the new designation process to be consistent with the current rural designation scheme and thus intended for the continued use of counties and census blocks as the units of analysis for defining rural areas for purposes of § 1026.35(b)(2)(iv)(A). Accordingly, only counties or census blocks are eligible for designation as rural under the application process, consistent with the interpretation of rural area already set forth in Regulation Z.

The Bureau is also making conforming changes to comments 35(b)(2)(iv)–1.i and –2.i.

Section 1026.43 Minimum Standards for Transactions Secured by a Dwelling

43(f) Balloon-Payment Qualified Mortgages Made by Certain Creditors

43(f)(1) Exemption

43(f)(1)(vi)

The Bureau is revising comment 43(f)(1)(vi)–1 to remove references to the ''more than 50 percent'' test and replace them with references to the test under revised § 1026.35(b)(2)(iii)(A) for the reasons discussed above in the section-by-section analysis of that section and to add references to new § 1026.35(b)(2)(iv)(A)(*3*) for the reasons discussed above in the section-by-section analysis of that section. The Bureau is revising the examples provided in the comment to reflect the revised test.

43(f)(2)(ii)

The Bureau is revising comment 43(f)(2)(ii)–1 to remove references to the ''more than 50 percent'' test and replace them with references to the revised test under § 1026.35(b)(2)(iii)(A) for the reasons discussed above in the section-by-section analysis of that section.

VI. Effective Date

This interim final rule is effective on March 31, 2016.

VII. Dodd-Frank Act Section 1022(b) Analysis

A. Overview

In developing the final rule, the Bureau has considered potential benefits, costs, and impacts.[49] The Bureau has consulted, or offered to consult with, the prudential regulators, the Federal Housing Finance Agency, the Federal Trade Commission, the U.S. Department of Agriculture, the U.S. Department of Housing and Urban Development, the U.S. Department of the Treasury, the U.S. Department of Veterans Affairs, and the U.S. Securities and Exchange Commission, including regarding consistency with any prudential, market, or systemic objectives administered by such agencies.

The discussion below considers the benefits, costs, and impacts of expanding eligibility of certain small creditors that operate in rural or underserved areas for special provisions that permit originations of balloon-payment qualified mortgages and for the escrow exemption for higher-priced mortgage loans (HPMLs).[50] The Bureau

[46] Public Law 114–94, title LXXXIX (2015).

[47] Application Process for Designation of Rural Area under Federal Consumer Financial Law, 81 FR 11099 (Mar. 3, 2016).

[48] October 2015 Small Creditor Final Rule, 80 FR 59943, 59955 (Oct. 2, 2015).

[49] Specifically, § 1022(b)(2)(A) of the Dodd-Frank Act calls for the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act; and the impact on consumers in rural areas.

[50] As explained in the section-by-section analysis above, the exception to the general prohibition on balloon-payment features for high cost mortgages in the 2013 HOEPA Final Rule is also affected by the final provisions. The Bureau estimates that there were about 1,000 high cost mortgage loans across all creditors in the U.S. in 2014. The Bureau believes that the number of high cost loans that also had a balloon feature and were originated by a small creditor that was not already qualified for this provision is negligible. The Bureau does not expect this to change in the future. Therefore, the Bureau believes that the effect of the final rule on the rural balloon-payment provision in the 2013 HOEPA Final Rule is relatively small, in terms of both the

does not possess the data to evaluate the number of creditors that would benefit from the amendment to the extension of the ''no harm provision'' [51] for the escrow exemption. This rule also applies the current definition of eligible ''areas'' (*i.e.,* counties or census blocks) used for existing rural designations to the new application process to have an area designated as rural by the Bureau. The impacts of that definition were previously considered and discussed in the October 2015 Small Creditor Final Rule. This 1022(b) analysis assumes this existing definition of area for purposes of analyzing the costs, benefits, and impacts of this rule.

The Bureau has chosen to evaluate the benefits, costs, and impacts of this rule relative to the current regulatory structure, including the October 2015 Small Creditor Final Rule.[52] The baseline considers economic attributes of the relevant market.

The Bureau has relied on a variety of data sources to consider the potential benefits, costs and impacts of this rule.[53] However, in some instances, the requisite data are not available or are quite limited. Data with which to quantify the benefits of this rule are particularly limited. As a result, portions of this analysis rely in part on general economic principles to provide a qualitative discussion of the benefits, costs, and impacts of the final rule.

The primary source of data used in this analysis is 2013 data collected under the Home Mortgage Disclosure Act (HMDA). The empirical analysis also uses data from the 4th quarter 2013 bank and thrift Call Reports [54] and the 4th quarter 2013 credit union Call Reports from the National Credit Union Administration (NCUA) to identify financial institutions and their characteristics. Appropriate projections have been made to account for gaps in the data, including, for example, institutions that do not report under HMDA. The Bureau also used data from the National Survey of Mortgage Borrowers.[55]

This rule expands the number of institutions that, under special provisions, are eligible to originate certain types of qualified mortgages and to take advantage of an exemption from the requirement to establish an escrow account for HPMLs under the January 2013 ATR Final Rule, the May 2013 ATR Final Rule, the January 2013 Escrows Final Rule, and the 2015 October Small Creditor Final Rule.[56]

These special provisions and exemption are only available to small creditors that operate in rural or underserved areas (rural small creditors). Rural small creditors can originate qualified mortgages with balloon-payment features, as long as these loans are kept in portfolio and other requirements are met. These qualified mortgages with balloon-payment features are deemed to comply with the ability-to-repay requirement as long as these loans have an APR of less than 3.5 percentage points over APOR for a comparable transaction.[57] Also, rural small creditors are generally allowed to originate higher-priced mortgage loans without setting up an escrow account for property taxes and insurance.

The Bureau discussed the benefits and costs of expanding the number of creditors eligible for the special provisions and exemption in detail in its 2015 October Small Creditor Final Rule Section 1022(b)(2) discussion.[58] Thus, the Bureau refers to that discussion for detailed explanations of effects and only provides here the numerical estimates of creditors and consumers affected.

B. Potential Benefits and Costs to Consumers and Covered Persons

Covered Persons Benefits and Costs

Based on the 2013 data, the Bureau estimated in its 2015 October Small Creditor Final Rule that about 4,100 out of the 10,400 small creditors would qualify as rural based on the revised definitions and ''predominantly'' test as it had been defined by the Bureau. Based on the same data, roughly an additional 6,000 small creditors will qualify as rural under the new provisions. Approximately 300 small creditors did not make any loans in rural or underserved areas in 2013, but may do so going forward.

The roughly 6,000 small creditors that will qualify as rural under this rule originated approximately 1.1 million loans, including 360,000 portfolio loans and 70,000 HPMLs in 2013. The Bureau is unaware of how many of these loans were balloon loans. However, estimates from the National Survey of Mortgage Borrowers indicate that about 4 percent of the loans in rural areas had a balloon feature and about 2 percent of the loans in non-rural areas had a balloon feature. The Bureau does not know and lacks a method for estimating how many creditors who are newly eligible for the escrow exemption will choose to stop providing escrow accounts when originating HPMLs.

All methods of compliance under current law remain available to covered persons when this rule becomes effective.[59] Thus, a covered person that is in compliance with current law will not need to take any additional action under the final rule; however, it might choose to do so to benefit from the special provisions and exemption.

Consumer Benefits and Costs

As the Bureau noted in its 2015 October Small Creditor Final Rule that similarly expanded the set of creditors eligible for the special provisions, consumer benefit from the final provisions of this rule is a potential expansion or avoidance of contraction in access to credit. The Bureau outlined its analysis of the available data on access to credit in its 2015 October Small Creditor Final Rule, and that analysis still applies. Prior to its 2015 October Small Creditor Final Rule, the

consumers and covered persons affected, and thus does not merit further discussion in this 1022(b) analysis.

[51] 12 CFR 1026.35(b)(2)(iii)(D)(*1*).

[52] The Bureau has discretion in future rulemakings to choose the relevant provisions to discuss and to choose the most appropriate baseline for that particular rulemaking.

[53] The quantitative estimates in this analysis are based upon data and statistical analyses performed by the Bureau. To estimate counts and properties of mortgages for entities that do not report under HMDA, the Bureau has matched HMDA data to Call Report data and National Mortgage Licensing System data and has statistically projected estimated loan counts for those depository institutions that do not report these data either under HMDA or on the NCUA Call Report. The Bureau has projected originations of higher-priced mortgage loans in a similar fashion for depositories that do not report under HMDA. These projections use Poisson regressions that estimate loan volumes as a function of an institution's total assets, employment, mortgage holdings, and geographic presence.

[54] Every national bank, State member bank, and insured nonmember bank is required by its primary Federal regulator to file consolidated Reports of Condition and Income, also known as Call Reports, for each quarter as of the close of business on the last day of each calendar quarter (the report date). The specific reporting requirements depend upon the size of the bank and whether it has any foreign offices. For more information, see *http://www2.fdic.gov/call_tfr_rpts/.*

[55] *See http://files.consumerfinance.gov/f/201508_cfpb_national-survey-of-mortgage-borrowers-technical-report-15-02.pdf.*

[56] *See,* January 2013 ATR Final Rule, 78 FR 6408 (Jan. 30, 2013); May 2013 ATR Final Rule, 78 FR 35430 (June 12, 2013); January 2013 Escrows Final Rule, 78 FR 4726 (Jan. 22, 2013); October 2015 Small Creditor Final Rule, 80 FR 59944 (Oct. 2, 2015).

[57] Note that currently, due to a temporary exemption in the May 2013 Qualified Mortgage Final Rule, all small creditors are allowed to originate qualified mortgages with balloon-payment features.

[58] October 2015 Small Creditor Final Rule, 80 FR 59944, 59961–67 (Oct. 2, 2015).

[59] This discussion takes into account the temporary provisions that expire on April 1, 2016, that allow small creditors to originate balloon-payment qualified mortgages and balloon-payment high cost mortgages regardless of their operations in rural or underserved areas.

Bureau received numerous comments suggesting that more creditors should be eligible for the special provisions and exemption above in order to expand access to credit.

As noted in the 2015 October Small Creditor Final Rule, the potential cost to consumers is the reduction of certain consumer protections as compared to the baseline established by the January 2013 ATR Final Rule, the May 2013 ATR Final Rule, and the January 2013 Escrows Final Rule. This rule would further reduce consumer protections from the 2015 October Small Creditor Final Rule. These consumer protections include a consumer's private cause of action against a creditor for violating the general ability-to-repay requirements for balloon loans and the requirement that every higher-priced mortgage loan have an associated escrow account for the payment of property taxes and insurance for five years.

The number of consumers affected is the same as the number of loans discussed above.

C. Impact on Covered Persons With No More Than $10 Billion in Assets

The only covered persons affected by this rule are those with no more than $10 billion in assets. The effect on these covered persons is described above.

D. Impact on Access to Credit

The Bureau does not believe that there will be an adverse impact on access to credit resulting from the final provisions. Moreover, it is possible that there will be an expansion of access to credit.

E. Impact on Rural Areas

Despite the Bureau's estimate that balloon loans are about twice as frequent in rural areas, this rule is not likely to disproportionately impact non-rural areas. The approximately 4,100 small creditors that operate predominantly in rural areas are already eligible for the special provisions and for the exemption due to the 2015 October Small Creditor Final Rule, and are thus unaffected by this rule.

VIII. Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[60]

IX. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies are generally required to obtain Office of Management and Budget (OMB) approval for information collection requirements before implementation. The collections of information related to Regulation Z have been previously reviewed and approved by OMB in accordance with the PRA and assigned OMB Control Number 3170–0015 (Regulation Z). Under the PRA, the Bureau may not conduct or sponsor, and, notwithstanding any other provision of law, a person is not required to respond to an information collection unless the information collection displays a valid control number assigned by OMB.

Consistent with the discussion in Section 1022(b)(2), the Bureau has determined that this rule does not impose any new or revised information collection requirements (recordkeeping, reporting, or disclosure requirements) on covered entities or members of the public that would constitute collections of information requiring OMB approval under the PRA.

[60] 5 U.S.C. 603(a), 604(a).

List of Subjects in 12 CFR Part 1026

Advertising, Appraisal, Appraiser, Banking, Banks, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

Authority and Issuance

For the reasons set forth in the preamble, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

Subpart E—Special Rules for Certain Home Mortgage Transactions

■ 2. Section 1026.35 is amended by revising paragraphs (b)(2)(iii)(A), (b)(2)(iii)(D)(*1*), and (b)(2)(iv)(A) to read as follows:

§ 1026.35 Requirements for higher-priced mortgage loans.

* * * * *

(b) * * *

(2) * * *

(iii) * * *

(A) During the preceding calendar year, or, if the application for the transaction was received before April 1 of the current calendar year, during either of the two preceding calendar years, the creditor extended a covered transaction, as defined by § 1026.43(b)(1), secured by a first lien on a property that is located in an area that is either ''rural'' or ''underserved,'' as set forth in paragraph (b)(2)(iv) of this section;

* * * * *

(D) * * *

(*1*) Escrow accounts established for first-lien higher-priced mortgage loans for which applications were received on or after April 1, 2010, and before May 1, 2016; or

* * * * *

(iv) * * *

(A) An area is ''rural'' during a calendar year if it is:

(*1*) A county that is neither in a metropolitan statistical area nor in a micropolitan statistical area that is adjacent to a metropolitan statistical area, as those terms are defined by the U.S. Office of Management and Budget and as they are applied under currently applicable Urban Influence Codes (UICs), established by the United States Department of Agriculture's Economic Research Service (USDA–ERS);

(*2*) A census block that is not in an urban area, as defined by the U.S. Census Bureau using the latest decennial census of the United States; or

(*3*) A county or a census block that has been designated as rural by the Bureau pursuant to the application process established under section 89002 of the Helping Expand Lending Practices in Rural Communities Act, Public Law 114–94, title LXXXIX (2015). The provisions of this paragraph (b)(2)(iv)(A)(*3*) shall cease to have any force or effect on December 4, 2017.

* * * * *

■ 3. In Supplement I to Part 1026—Official Interpretations:

■ A. Under *Section 1026.35—Requirements for Higher-Priced Mortgage Loans:*

■ i. Under *Paragraph 35(b)(2)(iii),* paragraph 1.i is revised.

■ ii. Under *Paragraph 35(b)(2)(iii)(D)*(1*),* paragraph 1 is revised.

■ iii. Under *Paragraph 35(b)(2)(iv),* paragraphs 1.i and 2.i are revised.

■ B. Under *Section 1026.43—Minimum Standards for Transactions Secured by a Dwelling:*

■ i. Under *Paragraph 43(f)(1)(vi),* paragraph 1.i is revised.

■ ii. Under *Paragraph 43(f)(2)(ii),* paragraph 1 is revised.

The revisions read as follows:

Supplement I to Part 1026—Official Interpretations

Subpart E—Special Rules for Certain Home Mortgage Transactions

* * * * *

Section 1026.35—Requirements for Higher-Priced Mortgage Loans

* * * * *

35(b) Escrow Accounts

* * * * *

35(b)(2) Exemptions

* * * * *

Paragraph 35(b)(2)(iii)

1. * * *

i. During the preceding calendar year, or during either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year, a creditor extended a first-lien covered transaction, as defined in § 1026.43(b)(1), secured by a property located in an area that is either ''rural'' or ''underserved,'' as set forth in § 1026.35(b)(2)(iv).

A. In general, whether the rural-or-underserved test is satisfied depends on the creditor's activity during the preceding calendar year. However, if the application for the loan in question was received before April 1 of the current calendar year, the creditor may instead meet the rural-or-underserved test based on its activity during the next-to-last calendar year. This provides creditors with a grace period if their activity meets the rural-or-underserved test (in § 1026.35(b)(2)(iii)(A)) in one calendar year but fails to meet it in the next calendar year.

B. A creditor meets the rural-or-underserved test for any higher-priced mortgage loan consummated during a calendar year if it extended a first-lien covered transaction in the preceding calendar year secured by a property located in a rural-or-underserved area. If the creditor does not meet the rural-or-underserved test in the preceding calendar year, the creditor meets this condition for a higher-priced mortgage loan consummated during the current calendar year only if the application for the loan was received before April 1 of the current calendar year and the creditor extended a first-lien covered transaction during the next-to-last calendar year that is secured by a property located in a rural or underserved area. The following examples are illustrative:

1. Assume that a creditor extended during 2016 a first-lien covered transaction that is secured by a property located in a rural or underserved area. Because the creditor extended a first-lien covered transaction during 2016 that is secured by a property located in a rural or underserved area, the creditor can meet this condition for exemption for any higher-priced mortgage loan consummated during 2017.

2. Assume that a creditor did not extend during 2016 a first-lien covered transaction secured by a property that is located in a rural or underserved area. Assume further that the same creditor extended during 2015 a first-lien covered transaction that is located in a rural or underserved area. Assume further that the creditor consummates a higher-priced mortgage loan in 2017 for which the application was received in November 2017. Because the creditor did not extend during 2016 a first-lien covered transaction secured by a property that is located in a rural or underserved area, and the application was received on or after April 1, 2017, the creditor does not meet this condition for exemption. However, assume instead that the creditor consummates a higher-priced mortgage loan in 2017 based on an application received in February 2017. The creditor meets this condition for exemption for this loan because the application was received before April 1, 2017, and the creditor extended during 2015 a first-lien covered transaction that is located in a rural or underserved area.

* * * * *

Paragraph 35(b)(2)(iii)(D)(*1*)

1. *Exception for certain accounts.* Escrow accounts established for first-lien higher-priced mortgage loans for which applications were received on or after April 1, 2010, and before May 1, 2016, are not counted for purposes of § 1026.35(b)(2)(iii)(D). For applications received on and after May 1, 2016, creditors, together with their affiliates, that establish new escrow accounts, other than those described in § 1026.35(b)(2)(iii)(D)(*2*), do not qualify for the exemption provided under § 1026.35(b)(2)(iii). Creditors, together with their affiliates, that continue to maintain escrow accounts established for first-lien higher-priced mortgage loans for which applications were received on or after April 1, 2010, and before May 1, 2016, still qualify for the exemption provided under § 1026.35(b)(2)(iii) so long as they do not establish new escrow accounts for transactions for which they received applications on or after May 1, 2016, other than those described in § 1026.35(b)(2)(iii)(D)(*2*), and they otherwise qualify under § 1026.35(b)(2)(iii).

* * * * *

Paragraph 35(b)(2)(iv)

1. * * *

i. Under § 1026.35(b)(2)(iv)(A), an area is rural during a calendar year if it is: A county that is neither in a metropolitan statistical area nor in a micropolitan statistical area that is adjacent to a metropolitan statistical area; a census block that is not in an urban area, as defined by the U.S. Census Bureau using the latest decennial census of the United States; or a county or a census block that has been designated as ''rural'' by the Bureau pursuant to the application process established in 2016. *See* Application Process for Designation of Rural Area under Federal Consumer Financial Law; Procedural Rule, 81 FR 11099 (Mar. 3, 2016). Metropolitan statistical areas and micropolitan statistical areas are defined by the Office of Management and Budget and applied under currently applicable Urban Influence Codes (UICs), established by the United States Department of Agriculture's Economic Research Service (USDA–ERS). For purposes of § 1026.35(b)(2)(iv)(A)(*1*), ''adjacent'' has the meaning applied by the USDA–ERS in determining a county's UIC; as so applied, ''adjacent'' entails a county not only being physically contiguous with a metropolitan statistical area but also meeting certain minimum population commuting patterns. A county is a ''rural'' area under § 1026.35(b)(2)(iv)(A)(*1*) if the USDA–ERS categorizes the county under UIC 4, 6, 7, 8, 9, 10, 11, or 12. Descriptions of UICs are available on the USDA–ERS Web site at *http://www.ers.usda.gov/data-products/urban-influence-codes/documentation.aspx.* A county for which there is no currently applicable UIC (because the county has been created since the USDA–ERS last categorized counties) is a rural area only if all counties from which the new county's land was taken are themselves rural under currently applicable UICs.

* * * * *

2. *Examples.* i. An area is considered ''rural'' for a given calendar year based on the most recent available UIC designations by the USDA–ERS and the most recent available delineations of urban areas by the U.S. Census Bureau that are available at the beginning of the calendar year. These designations and delineations are updated by the USDA–ERS and the U.S. Census Bureau respectively once every ten years. As an example, assume a creditor makes first-

lien covered transactions in Census Block X that is located in County Y during calendar year 2017. As of January 1, 2017, the most recent UIC designations were published in the second quarter of 2013, and the most recent delineation of urban areas was announced in the **Federal Register** in 2012, *see* U.S. Census Bureau, *Qualifying Urban Areas for the 2010 Census,* 77 FR 18652 (Mar. 27, 2012). To determine whether County Y is rural under the Bureau's definition during calendar year 2017, the creditor can use USDA–ERS's 2013 UIC designations. If County Y is not rural, the creditor can use the U.S. Census Bureau's 2012 delineation of urban areas to determine whether Census Block X is rural and is therefore a ''rural'' area for purposes of § 1026.35(b)(2)(iv)(A). In addition, an area is considered ''rural'' if it is a county or a census block that has been designated as rural by the Bureau using the application process established in 2016. *See* Application Process for Designation of Rural Area under Federal Consumer Financial Law; Procedural Rule, 81 FR 11099 (Mar. 3, 2016). Designations under this process are time-limited and expire on December 4, 2017.

* * * * *

Section 1026.43—Minimum Standards for Transactions Secured by a Dwelling

* * * * *

43(f) Balloon-Payment Qualified Mortgages Made By Certain Creditors

43(f)(1) Exemption.

* * * * *

Paragraph 43(f)(1)(vi)

1. * * *

i. During the preceding calendar year or during either of the two preceding calendar years if the application for the transaction was received before April 1 of the current calendar year, the creditor extended a first-lien covered transaction, as defined in § 1026.43(b)(1), on a property that is located in an area that is designated either ''rural'' or ''underserved,'' as defined in § 1026.35(b)(2)(iv), to satisfy the requirement of § 1026.35(b)(2)(iii)(A) (the rural-or-underserved test). Pursuant to § 1026.35(b)(2)(iv), an area is considered to be rural if it is: A county that is neither in a metropolitan statistical area, nor a micropolitan statistical area adjacent to a metropolitan statistical area, as those terms are defined by the U.S. Office of Management and Budget; a census block that is not in an urban area, as defined by the U.S. Census Bureau using the latest decennial census of the United States; or a county or a census block that has been designated as ''rural'' by the Bureau pursuant to the application process established in 2016. *See* Application Process for Designation of Rural Area under Federal Consumer Financial Law; Procedural Rule, 81 FR 11099 (Mar. 3, 2016). An area is considered to be underserved during a calendar year if, according to HMDA data for the preceding calendar year, it is a county in which no more than two creditors extended covered transactions secured by first liens on properties in the county five or more times.

A. The Bureau determines annually which counties in the United States are rural or underserved as defined by § 1026.35(b)(2)(iv)(A)(*1*) or § 1026.35(b)(2)(iv)(B) and publishes on its public Web site lists of those counties to assist creditors in determining whether they meet the criterion at § 1026.35(b)(2)(iii)(A). Creditors may also use an automated tool provided on the Bureau's public Web site to determine whether specific properties are located in areas that qualify as ''rural'' or ''underserved'' according to the definitions in § 1026.35(b)(2)(iv) for a particular calendar year. In addition, the U.S. Census Bureau may also provide on its public Web site an automated address search tool that specifically indicates if a property address is located in an urban area for purposes of the Census Bureau's most recent delineation of urban areas. For any calendar year that begins after the date on which the Census Bureau announced its most recent delineation of urban areas, a property is located in an area that qualifies as ''rural'' according to the definitions in § 1026.35(b)(2)(iv) if the search results provided for the property by any such automated address search tool available on the Census Bureau's public Web site do not identify the property as being in an urban area. A property is also located in an area that qualifies as ''rural,'' if the Bureau has designated that area as rural under § 1026.35(b)(2)(iv)(A)(*3*) and published that determination in the **Federal Register**. *See* Application Process for Designation of Rural Area under Federal Consumer Financial Law; Procedural Rule, 81 FR 11099 (Mar. 3, 2016).

B. For example, if a creditor extended during 2017 a first-lien covered transaction that is secured by a property that is located in an area that meets the definition of rural or underserved under § 1026.35(b)(2)(iv), the creditor meets this element of the exception for any transaction consummated during 2018.

C. Alternatively, if the creditor did not extend in 2017 a transaction that meets the definition of rural or underserved test under § 1026.35(b)(2)(iv), the creditor satisfies this criterion for any transaction consummated during 2018 for which it received the application before April 1, 2018, if it extended during 2016 a first-lien covered transaction that is secured by a property that is located in an area that meets the definition of rural or underserved under § 1026.35(b)(2)(iv).

* * * * *

Paragraph 43(f)(2)(ii)

1. *Transfer to another qualifying creditor.* Under § 1026.43(f)(2)(ii), a balloon-payment qualified mortgage under § 1026.43(f)(1) may be sold, assigned, or otherwise transferred at any time to another creditor that meets the requirements of § 1026.43(f)(1)(vi). That section requires that a creditor: (1) Extended a first-lien covered transaction, as defined in § 1026.43(b)(1), on a property located in a rural or underserved area; (2) together with all affiliates, extended no more than 2,000 first-lien covered transactions that were sold, assigned, or otherwise transferred by the creditor or its affiliates to another person, or that were subject at the time of consummation to a commitment to be acquired by another person; and (3) have, together with its affiliates that regularly extended covered transactions secured by first liens, total assets less than $2 billion (as adjusted for inflation). These tests are assessed based on transactions and assets from the calendar year preceding the current calendar year or from either of the two calendar years preceding the current calendar year if the application for the transaction was received before April 1 of the current calendar year. A balloon-payment qualified mortgage under § 1026.43(f)(1) transferred to a creditor that meets these criteria would retain its qualified mortgage status even if it is transferred less than three years after consummation.

* * * * *

Dated: March 21, 2016.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2016–06834 Filed 3–22–16; 4:15 pm]

BILLING CODE 4810–AM–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket No. OSHA–2014–0024]

RIN 1218–AC87

Updating OSHA Standards Based on National Consensus Standards; Eye and Face Protection

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule.

SUMMARY: On March 13, 2015, OSHA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to revise its eye and face protection standards for general industry, shipyard employment, marine terminals, longshoring, and construction by updating the references to national consensus standards approved by the American National Standards Institute (ANSI). OSHA received no significant objections from commenters and therefore is adopting the amendments as proposed. This final rule updates the references in OSHA's eye and face standards to reflect the most recent edition of the ANSI/International Safety Equipment Association (ISEA) eye and face protection standard. It removes the oldest-referenced edition of the same ANSI standard. It also amends other provisions of the construction eye and face protection standard to bring them into alignment with OSHA's general industry and maritime standards.

DATES: This final rule becomes effective on April 25, 2016. The incorporation by reference of certain standards listed in the rule was approved by the Director of the Federal Register as of April 25, 2016.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), OSHA designates Ann S. Rosenthal, Associate Solicitor of Labor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, to receive petitions for review of the final rule.

The address for OSHA's docket office is: Docket Office, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2350. (OSHA's TTY number is (877) 889–5627)). The hours of operation for the OSHA Docket Office are 8:15 a.m. to 4:45 p.m., e.t. In addition, addresses and phone numbers for OSHA's state and regional offices can be found at *http://www.osha.gov/about.html.*

FOR FURTHER INFORMATION CONTACT:

General information and press inquiries: Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

Technical information: Ken Stevanus, Directorate of Standards and Guidance, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2260; fax: (202) 693–1663; email: *stevanus.ken@dol.gov.*

Copies of this Federal Register notice: Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

This final rule updates eye and face protection requirements in OSHA's general industry, shipyard employment, marine terminals, longshoring, and construction standards. The changes involve incorporation by reference of the latest ANSI/ISEA Z87.1–2010 standard on Occupational and Educational Eye and Face Protection Devices and removal of the oldest ANSI (Z87.1–1989) version of the same standard. In addition, OSHA is modifying the language in its construction standard to make it more consistent with the general and maritime industry standards.

This new rule will allow employers to continue to follow the existing ANSI standards referenced or allow employers to follow the latest version of the same ANSI/ISEA standard. Employers are not required to update or replace protection devices solely as a result of this rule and may continue to follow their current and usual practices for their eye and face protection. Therefore, this rule has no compliance or economic burdens associated with it.

II. Background

A. Overview and Procedural Background

OSHA requires employers to ensure that their employees use eye and face protection where necessary to protect them against flying objects, splashes or droplets of hazardous chemicals, and other workplace hazards that could injure their eyes and face. OSHA's standards state that the protection employers provide must meet specified consensus standards. For operations covered by OSHA's general industry, shipyard employment, longshoring, and marine terminals standards, the protection must comply with one of the following standards: ANSI Z87.1–2003, ANSI Z87.1–1989 (R–1998), and ANSI Z87.1–1989. Alternatively, the employer may show that the devices used are at least as effective as one of these consensus standards (29 CFR 1910.133(b); 29 CFR 1915.153(b); 29 CFR 1917.91(a)(1); 29 CFR 1918.101(a)(1)). The construction standard requires that eye and face protection meet the requirements of ANSI Z87.1–1968 (29 CFR 1926.102(a)(2)).

As a part of its ongoing efforts to update its standards with the latest versions of national consensus standards, (see 69 FR 68283), OSHA last updated its eye and face protection standards in 2009 (74 FR 46350). That effort did not address the eye and face protection requirements in the construction standard, which had been revised in 1993, and during the 2009 rulemaking OSHA received several comments suggesting that the construction requirements be updated as well. After the new ANSI/ISEA 87.1–2010 standard was published, OSHA decided to again update its eye and face protection requirements.

Before publishing a proposal, OSHA consulted the Advisory Committee on Construction Safety and Health (ACCSH) on May 8, 2014, as required by 29 CFR 1911.10. OSHA presented two options to ACCSH. The first option replaced all eye and face protection provisions in the construction standard with those of the general industry and maritime standards, except those that

were unique to the construction industry standard. The second option substituted only the three most current (ANSI/ISEA and ANSI) standards for the outdated ANSI standard currently cited, or allowed the employer to show that the protection was at least as protective as one of those standards. The remaining provisions of the construction standard were unchanged except for the removal of Table E–1, which referenced the outdated ANSI standard. The Committee selected the first option and passed a motion recommending that the Agency move forward in the rulemaking process. (*See* ACCSH meeting minutes, ID: OSHA–2014–0024–0004; *see* also Options presented to ACCSH, ID: OSHA–2014–0024–0003).

On March 13, 2015, OSHA published an NPRM in the **Federal Register** to revise its eye and face protection standards. For the general industry and maritime standards, OSHA proposed updating the ANSI standard references by deleting ANSI Z87.1–1989 and replacing it with ANSI/ISEA Z87.1–2010 (80 FR 13295). In addition, in the NPRM, the Agency proposed deleting the reference to ANSI Z87.1–1968 in its construction standard at 29 CFR 1926.102, and replacing it with the references to the same three consensus standards (including Z87.1–2010) cited in the proposed general industry, shipyard employment, longshoring, and marine terminals standards. As recommended by ACCSH, OSHA also proposed other changes to the construction standard to bring it into greater alignment with OSHA's other eye and face protection requirements, while retaining requirements unique to the construction standard not covered by the ANSI standards. Thus, the NPRM allowed all employers covered by OSHA's standards to follow any of the three most recent versions of the ANSI/ISEA eye and face protection standard.

OSHA received no significant adverse comment to the proposal, and this notice finalizes the rule updates as proposed. This action will ensure consistency among the Agency's standards, and eliminate any confusion, clarify employer obligations, and provide up-to-date protection for workers exposed to eye and face hazards.

B. Incorporation by Reference Under 1 CFR Part 51

1. Summary of the Incorporated Consensus Standards

ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, provides requirements for the selection, testing, use, and maintenance of protectors intended to minimize or prevent eye and face injuries including impact, non-ionizing radiation and chemical exposures, in occupational and educational environments. ANSI Z87.1–2003 and ANSI Z87.1–1989 (R–1998) are prior versions of this standard which are also incorporated by reference as alternative means of compliance with OSHA's eye and face protection requirements.

2. Reasonable Availability of the Incorporated Consensus Standards

OSHA believes that the ANSI/ISEA and ANSI standards are reasonably available to interested parties. The ANSI/ISEA 2010 and ANSI 2003 and 1989 (R–1998) versions of the Z87.1 standard can be purchased as a package from ANSI in pdf form for $57 (*http://webstore.ansi.org/*). They are also available for purchase at either the IHS Standards (*http://global.ihs.com/*) or Techstreet (*http://www.techstreet.com/*) stores. Employers may rely on manufacturer representations that protection is compliant with the indicated standard and therefore are not obligated to incur this expense to comply with the standard. These standards are also available for review in OSHA's docket office and regional offices; see the **ADDRESSES** section of this document for details.

III . Summary and Explanation of the Final Rule

A. Revisions to OSHA's Eye and Face Protection Standards

1. Final Rule for General Industry and Maritime Industry Standards

OSHA adopted the previous revision of the general industry and maritime eye and face protection standards on September 9, 2009 (74 FR 46350). These revisions, which became effective on October 9, 2009, permit compliance with ANSI Z87.1–2003, ANSI Z87.1–1989 (R–1998), or ANSI Z87.1–1989. Since OSHA published the previous revision, ANSI/ISEA Z87.1–2010 became available. This final rule includes ANSI/ISEA Z87.1–2010 in 29 CFR 1910.133(b)(1), 29 CFR 1915.153(b)(1), 29 CFR 1917.91(a)(1)(i) and removes references to ANSI Z87.1–1989. It also updates the general incorporation by reference section for each of these standards (*i.e.,* 29 CFR 1910.6, 1915.5, 1917.3, 1918.3) to reflect the incorporation of ANSI/ISEA Z87.1–2010, ANSI Z87.1–2003, and ANSI Z87.1–1989 (R–1998).

OSHA believes that eye and face protection meeting the 2010 ANSI/ISEA standard is already on the market, and the 2010 standard is not less protective than the previous versions of the standard. Therefore it is amending its standard to allow the use of such protection in the workplace.

2. Final Rule for Construction Industry Standard

The final rule involves: (1) Changes to the ANSI standard references and (2) inclusion of language from the general industry eye and face protection standard. With respect to the consensus standards update, OSHA is amending 29 CFR 1926.6 and 1926.102, which currently incorporate by reference ANSI Z87.1–1968 to include the same three consensus standards incorporated into the general industry and maritime standards, ANSI/ISEA Z87.1–2010, ANSI Z87.1–2003, and ANSI Z87.1–1989 (R–1998). OSHA is modifying certain existing language to make it nearly identical to the language in the general industry standard's eye and face protection provisions. It is retaining provisions unique to the current construction standard that are not covered in the versions of the consensus standards incorporated by the proposal.

Specifically, OSHA is placing language from the general industry standard, sections 1910.133(a)(1) through (a)(4) and 1910.133(b), in sections 1926.102(a)(1) through (a)(3), and (a)(7). Additionally, the Agency is replacing: (1) The scope section in 1926.102(a)(1) with the scope section in 1910.133(a)(1); (2) the reference to the 1968 ANSI standard in 1926.102(a)(2) with the updated list of national consensus standards in 1910.133(b)(1); and (3) the requirements for corrective lenses in 1926.102(a)(3) with the corrective-lens requirements in 1910.133(a)(3). The final rule removes the requirements in section 1926.102(a)(4)—to keep protective equipment clean, in good repair, and free of structural and optical defects—which are addressed by requirements in each of the three versions of the Z87.1 standard. Likewise, it deletes Table E–1, Eye and Face Protector Selection Guide, which is specific to the 1968 version of ANSI Z87.1 and referenced in the current section 1926.102(a)(5), and renumbers Tables E–2 and E–3 under this paragraph as Tables E–1 and E–2, respectively.

The final rule substitutes the marking requirement specified by section 1926.102(a)(7) with the marking requirement in section 1910.133(a)(4). The final rule removes the requirement in 1926.102(a)(8) that employers must transmit information from manufacturers to users about equipment

limitations or precautions and that such limitations and precautions must be strictly observed. It also adds a provision to the construction standard that permits an employer to use eye and face protection not manufactured in accordance with one of the incorporated Z87.1 standards if the employer can demonstrate compliance with one of the incorporated Z87.1 standards (*i.e.,* the equivalent-protection provision). The final rule will redesignate section 1926.102(b) as section 1926.102(c).

OSHA believes these changes are warranted because it will make compliance easier for employers who perform work that is covered both by the construction standard and another of OSHA's standards. Further, OSHA believes that the consensus standard reference should be updated because the new ANSI standards are at least as protective as the 1968 standard, and the Agency does not believe that personal protective equipment (PPE) designed and tested to the 1968 ANSI standard is currently available for purchase.

B. Discussion of Comments

OSHA received twelve comments in response to the NPRM on eye and face protection consensus standards updating. While commenters generally supported OSHA's efforts to update its standards, some raised issues to which OSHA responds below.

Mr. Bruce Donato, a private citizen, Mr. Douglas Greenhaus of the National Automobile Dealers Association (NADA), and Ms. Julie Trembly of 3M commented on OSHA's use of consensus standards. Mr. Donato asked why OSHA uses consensus standards rather than proposing its own standards (ID: OSHA–2014–0024–0006). Mr. Greenhaus advocated for use of a performance-oriented approach and removal of all consensus standard references, believing this approach would free OSHA from the obligation to continuously review and adopt new versions of third-party standards (ID: OSHA–2014–0024–0015). Ms. Trembly mentioned that OSHA may want to allow compliance only with the 2010 ANSI/ISEA standard. She reasoned that this would ease compliance because the 2010 version is the most recent and maintains a hazard-based approach (ID: OSHA–2014–0024–0013).

OSHA disagrees with these commenters. First, the Agency is legally required to consider national consensus standards. The Occupational Safety and Health Act of 1970 (OSH Act) requires OSHA to follow them in promulgating a rule, unless OSHA explains why another requirement will better effectuate the purposes of the act (29 U.S.C. 655(b)(b)). In addition, the National Technology Transfer and Advancement Act of 1995 also requires OSHA (and other Federal agencies) to use voluntary consensus standards unless contrary to applicable law or impractical. Pub. L 104–113 § 12(d), 15 U.S.C.A. 272 note; see also OMB Circular A–119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* 68 FR 8553. Second, voluntary consensus standards contain valuable information about how to address workplace hazards. As Ms. Patricia Ennis from the American Society of Safety Engineers pointed out, since experts with diverse backgrounds produce national consensus standards, the standards reflect their expertise and the latest developments in workplace safety (ID: OSHA–2014–0024–0008).

OSHA disagrees with the suggestion to only incorporate the latest ANSI/ISEA standard, because it believes some employers may be using eye and face protection meeting the ANSI 87.1–2003 and ANSI 87.1–1989 (R–1998) standards. OSHA is unaware of evidence that disallowing the use of PPE meeting those standards would significantly increase safety.

Relatedly, Mr. Donato and Mr. Greenhaus of NADA also expressed concern that the cost of obtaining consensus standards could be prohibitive to small businesses (IDs: OSHA–2014–0024–0006 and 0015). As noted above, all referenced consensus standards are available purchase for a modest sum and may be viewed for free in OSHA's regional offices, among other places.

Ms. Julie Weide, a private citizen, commented that she wanted more mandatory eye protection at worksites, in accordance with equipment manufacturers' warnings (ID: OSHA–2014–0024–0007). Though her suggestion falls outside of the scope of the proposal, OSHA notes that its current eye and face protection standards already require employers to ensure that affected employees use appropriate eye or face protection when exposed to hazards from flying particles, molten metal, liquid chemicals, acids or caustic liquids, chemical gases or vapors, or potentially injurious light radiation. *See* 29 CFR 1910.133(a).

Several commenters supported OSHA's decision to make eye and face protection requirements consistent across all industry standards, stating that consistency makes compliance easier for employers (IDs: OSHA–2014–0024–0009, 0011, and 0012). OSHA agrees with the commenters' assessment.

Mr. Joe Miles of the Northeastern Retail Lumber Association (NRLA) commented that the final rule should provide a transition period so that associations such as the NRLA would have time to notify members of the new standards. Members could then inform their customers of the new PPE requirements, and have sufficient time to order and integrate necessary PPE into the workplace (ID: OSHA–2014–0024–0011). Mr. Greenhaus of NADA agreed, opining that small business employers should be given greater flexibility with respect to compliance (ID: OSHA–2014–0024–0015).

Under the final rule, employers may follow any of the three latest versions of the Z87.1 standards. The new rule places no new obligations, costs, or time constraints on employers. Employers already in compliance with OSHA's eye and face requirements may continue their current usual and customary practice in providing eye and face protection to their employees. The final now allows employers to follow the newest ANSI/ISEA Z87.1–2010 standard—if they choose and at their convenience—or to continue to follow the older versions (ANSI Z87.1–2003 or Z87.1–1989 (R–1998)), which appeared in the previous version of the rule. As Mr. Daniel Shipp of the ISEA commented, the removal of the 1989 version will have no effect on the acceptability of any product because it is identical to the 1989 (R–1998) standard, which remains in the final rule (ID: OSHA–2014–0024–0012). Further, OSHA anticipates that compliance with the 2010 version of the ANSI/ISEA Z87.1 standard will not be burdensome, because as commenters noted, most manufacturers of eye and face protection devices already follow the latest ANSI/ISEA standard (IDs: OSHA–2014–0024–0012 and 0013).

While they supported the proposal, Mr. Faulkner and Ms. Fitch from the United Steelworkers (USW) and Mr. McCann, a private citizen, discussed their concerns about improperly-fitting PPE, especially for women and men of nonstandard body types. They further indicated that OSHA's standardized PPE requirement throughout various industries was insufficient. Instead, OSHA should require employers to: (1) Provide the best fitting PPE available on the market for their workers at no cost, (2) regularly evaluate which PPE is provided to employees, and (3) purchase customized PPE where special orders are needed. They also highlighted a need to protect workers who complain about inadequate PPE from retaliation (ID: OSHA–2014–0024–0016 and 0017).

OSHA thanks the commenters for raising these issues and the agency agrees that PPE must fit properly no matter who is wearing it. A correct, comfortable fit helps to ensure the worker will receive the intended protection for the duration of the exposure. Many of the commenters' concerns are addressed in the existing PPE standard. Specifically, the general industry standard requires employers to select PPE that properly fits each affected employee, at no cost to the employee. *See* 29 CFR 1910.132(d)(1)(iii) (fit); 1910.132 (h)(1) (cost). It also requires employers to conduct a hazard assessment to determine which PPE is necessary. 29 CFR 1910.132(d). Moreover, the standards require employers to ensure their employees wear ''appropriate'' or ''protective'' eye and face protection, which includes proper fit, and preclude the use of defective or damaged PPE. These requirements apply equally for workers of both sexes and all body types. With respect to the need to protect workers from retaliation, the OSH Act currently protects workers who complain to employers about workplace safety issues, including inadequate PPE, from retaliation. 29 U.S.C. 660(c); 29 CFR 1977.9(c). While the specific proposals made by USW and Mr. McCann fall outside the scope of the proposal, OSHA will continue to monitor the issues they raised.

A number of commenters noted a more general need for OSHA to revise its standards to incorporate by reference the most recent versions of consensus standards (*See, e.g.,* IDs: OSHA–2014–0024–0008, 0015, and 0016). OSHA agrees with these commenters, and as part of its mandate to provide a safe and healthful work environment to all employees, the Agency intends to continue in its efforts to adopt the latest consensus standards as soon as possible. However, incorporation by reference can, at times, be a lengthy process because OSHA must evaluate consensus standards to ensure that they are: (1) At least as effective, or meet, the current consensus standards incorporated by reference, and (2) technologically and economically feasible. As a related matter, Mr. Faulkner and Ms. Fitch from the USW suggested that OSHA coordinate with the Mine Safety and Health Administration (MSHA), so that OSHA's standards could also benefit employees in the mining industry (ID: OSHA–2014–0024–0016). OSHA agrees with the importance of interagency cooperation, and in general the Agency attempts to coordinate with other Federal agencies when there is the possibility of duplication, overlap, or conflict. However, OSHA has no jurisdiction over employers regulated by MSHA. Nonetheless, where there may be some benefit for employees in doing so, OSHA will consider working with MSHA on relevant standards updates in the future.

Mr. Shipp from ISEA noted that OSHA incorrectly referenced to the 2010 consensus standard in its NPRM. OSHA appreciates this comment and has corrected the final rule so all references to the 2010 standard reflect the official designation of the consensus standard: ANSI/ISEA Z87.1–2010 (ID: OSHA–2014–0024–0012).

IV. Agency Determinations

A. Legal Considerations

The purpose of the OSH Act is to achieve to the extent possible safe and healthful working conditions for all employees. 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. 654(b), 655(b). A safety or health standard is one ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'' 29 U.S.C. 652(8). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) of the OSH Act when a significant risk of material harm exists in the workplace and the standard would substantially reduce or eliminate that workplace risk. *See Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607 (1980). OSHA already determined that requirements specified by eye and face protection standards, including design requirements, are reasonably necessary or appropriate within the meaning of Section 652(8). *See, e.g.,* 49 FR 49726, 49737 (1978); 51 FR 33251, 33251–59 (1986).

Moreover, this final rule neither reduces employee protection nor alters an employer's obligations under the existing standards. With respect to employee protection, because the final rule will allow employers to continue to provide the same eye and face protection they currently provide, employees' protection will not change. In terms of employers' obligations, the final rule will allow employers additional options for meeting the design-criteria requirements for eye and face protection. Accordingly, this final rule does not require an additional significant risk finding (*cf. Edison Elec. Inst.* v. *OSHA,* 849 F.2d 611, 620 (D.C. Cir. 1988)).

In addition, a safety standard must be technologically feasible. *See UAW* v. *OSHA,* 37 F.3d 665, 668 (D.C. Cir. 1994). A standard is technologically feasible when the protective measures it requires already exist, when available technology can bring the protective measures into existence, or when that technology is reasonably likely to develop. *See Am. Textile Mfrs. Inst.* v. *OSHA,* 452 U.S. 490, 513 (1981); *Am. Iron and Steel Inst.* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991)). The final rule is technologically feasible because: (1) Protectors are already manufactured in accordance with the 2010 ANSI/ISEA standard or the other versions permitted under the revision and (2) employers already comply with the 2003 and 1998 versions of the ANSI standard incorporated by reference into the general industry and maritime standards, which will remain in effect under the final rule.

B. Final Economic Analysis and Regulatory Flexibility Act Certification

OSHA has determined that employers can comply with the final rule by following their current usual and customary practice in providing eye and face protection to their employees. This final rule expands the options available to employers without removing any existing option and thus has no costs. Therefore, OSHA finds that the final rule is not economically significant within the context of Executive Order 12866, or a major rule under the Unfunded Mandates Reform Act or Section 801 of the Small Business Regulatory Enforcement Fairness Act. In addition, this final rule complies with Executive Order 13563 because employers are allowed increased flexibility in choosing eye and face protection for their employees and are not required to update or replace that protection solely as a result of this final rule if the employer's current practice meets the new standards. Because the final rule imposes no costs, OSHA certifies that it will not have a significant economic impact on a substantial number of private or public sector entities. Likewise, it does not meet any of the criteria for an economically significant or major rule specified by the Executive Order or relevant statutes.

C. Paperwork Reduction Act of 1995

As was the case for the NPRM, the Department has determined this rule does not establish new or revise any existing collection of information requirements subject to OMB approval

under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501. The proposed rule invited comments on this determination, and OSHA received no comments.

D. Federalism

OSHA reviewed this final rule in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999), which requires that agencies, to the extent possible, refrain from limiting state policy options, consult with states prior to taking any actions that would restrict state policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. Executive Order 13132 provides for preemption of state law only with the expressed consent of Congress. Agencies must limit any such preemption to the extent possible.

Under Section 18 of the OSH Act, 29 U.S.C. 651 *et seq.,* Congress expressly provides that states may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards (29 U.S.C. 667); OSHA refers to states that obtain Federal approval for such a plan as ''State Plan states.'' Occupational safety and health standards developed by State Plan states must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. 29 U.S.C. 667. Subject to these requirements, State Plan states are free to develop and enforce under state law their own requirements for occupational safety and health standards.

While OSHA developed the final rule to protect employees in every state, Section 18(c)(2) of the OSH Act permits State Plan states and U.S. Territories to develop and enforce their own standards for eye and face protection provided these requirements are at least as effective in providing safe and healthful employment and places of employment as the requirements specified in this final rule.

In summary, this final rule complies with Executive Order 13132. In states without OSHA-approved state plans, this rule limits state policy options in the same manner as other OSHA standards. In State Plan states, this rule does not significantly limit state policy options because, as explained in the following section, State Plan states do not have to adopt this final rule.

E. State Plan States

When Federal OSHA promulgates a new standard or amends an existing standard to be more stringent than it was previously, the 28 states or U.S. Territories with their own OSHA-approved occupational safety and health plans must revise their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary, *e.g.,* because an existing state standard covering this area is at least as effective in protecting workers as the new Federal standard or amendment. 29 CFR 1953.5(a). In this regard, the state standard must be at least as effective as the final Federal rule. State Plan states must adopt the Federal standard or complete their own standard within six months of the publication date of the final Federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than the existing standard, State Plan states need not amend their standards, although OSHA may encourage them to do so. The following 21 states and 1 U.S. Territory have OSHA-approved occupational safety and health plans that apply only to private-sector employers: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. In addition, Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply only to state and local government employees.

With regard to this final rule, it will not impose any additional or more stringent requirements on employers compared to existing OSHA standards. Through this rulemaking, OSHA is updating the references in its regulations to recognize recent editions of the applicable national consensus standards, and deleting a number of outdated editions of the national consensus standards referenced in its existing PPE standards. The final rule does not require employers to update or replace their PPE solely as a result of this rulemaking if the PPE currently in use meets the existing standards. Therefore, the final rule does not require action under 29 CFR 1953.5(a), and States and U.S. Territories with approved State Plans do not need to adopt this rule or show OSHA why such action is unnecessary. However, to the extent these States and Territories have the same standards as the OSHA standards affected by this final rule, OSHA encourages them to adopt the amendments.

F. Unfunded Mandates Reform Act of 1995

OSHA reviewed this final rule according to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501–1571, and Executive Order 12875, 58 FR 58093 (October 26, 1993). As discussed above in Section IV.B (''Final Economic Analysis and Regulatory Flexibility Act Certification'') of this preamble, OSHA determined that the final rule imposes no additional costs on any private-sector or public-sector entity. Accordingly, this final rule requires no additional expenditures by either public or private employers.

As noted above under Section IV.E (''State Plan States'') of this preamble, OSHA standards do not apply to state or local governments except in states that elected voluntarily to adopt an OSHA-approved state plan. Consequently, this final rule does not meet the definition of a ''Federal intergovernmental mandate.'' *See* 2 U.S.C. 658(5). Therefore, for the purposes of the UMRA, OSHA certifies that this final rule does not mandate that state, local, or tribal governments adopt new, unfunded regulatory obligations, or increase expenditures by the private sector of more than $100 million in any year.

G. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed this final rule in accordance with Executive Order 13175, 65 FR 67249 (November 6, 2000), and determined that it does not have ''tribal implications'' as defined in that order. The final rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

List of Subjects in 29 CFR Parts 1910, 1915, 1917, 1918, and 1926

Incorporation by reference, Occupational Safety and Health, Personal Protective Equipment.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210, authorized the preparation of this notice. OSHA is issuing this final rule pursuant to 29 U.S.C. 653, 655, and 657; 40 U.S.C. 3701 *et seq.;* 5 U.S.C. 553; Secretary of Labor's Order 1–2012, 77 FR 3912 (2012); and 29 CFR part 1911.

Signed at Washington, DC, on March 15, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons stated above in the preamble, the Occupational Safety and Health Administration is amending 29 CFR parts 1910, 1915, 1917, 1918, and 1926 as follows:

PART 1910—[AMENDED]

Subpart A—[Amended]

■ 1. The authority citation for subpart A of part 1910 continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657; Secretary of Labor's Order Numbers 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable.

Sections 1910.6, 1910.7, 1910.8 and 1910.9 also issued under 29 CFR 1911. Section 1910.7(f) also issued under 31 U.S.C. 9701, 29 U.S.C. 9a, 5 U.S.C. 553; Public Law 106–113 (113 Stat. 1501A–222); Pub. L. 11–8 and 111–317; and OMB Circular A–25 (dated July 8, 1993) (58 FR 38142, July 15, 1993).

■ 2. Amend § 1910.6 by revising paragraphs (e)(69) through (71) to read as follows:

§ 1910.6 Incorporation by reference.

* * * * *

(e) * * *

(69) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, Approved April 13, 2010; IBR approved for § 1910.133(b). Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(70) ANSI Z87.1–2003, Occupational and Educational Eye and Face Personal Protection Devices Approved June 19, 2003; IBR approved for §§ 1910.133(b). Copies available for purchase from the:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(71) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection, Reaffirmation approved January 4, 1999; IBR approved for § 1910.133(b). Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/*;

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

* * * * *

Subpart I—[Amended]

■ 3. The authority citation for subpart I of part 1910 continues to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable, and 29 CFR part 1911; Sections 1910.132, 1910.134, and 1910.138 of 29 CFR also issued under 29 CFR 1911; Sections 1910.133, 1910.135, and 1910.136 of 29 CFR also issued under 29 CFR 1911 and 5 U.S.C. 553.

■ 4. Amend § 1910.133 by revising paragraph (b)(1) to read as follows:

§ 1910.133 Eye and face protection.

* * * * *

(b) *Criteria for protective eye and face protection.* (1) Protective eye and face protection devices must comply with any of the following consensus standards:

(i) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1910.6;

(ii) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1910.6; or

(iii) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection, incorporated by reference in § 1910.6;

* * * * *

PART 1915—[AMENDED]

■ 5. The authority citation for part 1915 continues to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections. 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; 29 CFR part 1911.

Section 1915.100 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Sections 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

■ 6. Amend § 1915.5 by revising paragraphs (d)(1)(vi) through (viii) to read as follows:

§ 1915.5 Incorporation by reference.

* * * * *

(d)(1) * * *

(vi) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, Approved April 13, 2010; IBR approved for § 1915.153(b). Copies are available for purchase from:

(A) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(B) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(C) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(vii) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, approved June 19, 2003; IBR approved for § 1910.153(b). Copies available for purchase from the:

(A) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(B) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(C) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(viii) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection,

Reaffirmation approved January 4, 1999; IBR approved for § 1910.153(b). Copies are available for purchase from:

(A) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(B) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(C) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

* * * * *

Subpart I—[Amended]

■ 7. Amend § 1915.153 by revising paragraph (b)(1) to read as follows:

§ 1915.153 Eye and face protection.

* * * * *

(b) *Criteria for protective eye and face devices.* (1) Protective eye and face protection devices must comply with any of the following consensus standards:

(i) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1915.5;

(ii) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1915.5; or

(iii) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection, incorporated by reference in § 1915.5;

* * * * *

PART 1917—[AMENDED]

■ 8. The authority citation for part 1917 continues to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912),as applicable; and 29 CFR 1911.

Section 1917.28 also issued under 5 U.S.C. 553.

Section 1917.29 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

* * * * *

■ 9. Amend § 1917.3 by revising paragraphs (b)(6) through (8) to read as follows:

§ 1917.3 Incorporation by reference.

* * * * *

(b) * * *

(6) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, Approved April 13, 2010; IBR approved for § 1917.91(a). Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/*;

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(7) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, Approved April 13, 2010; IBR approved for § 1917.91(a). Copies available for purchase from the:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(8) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection, Reaffirmation approved January 4, 1999; IBR approved for § 1917.91(a). Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

* * * * *

Subpart E—[Amended]

■ 10. Amend § 1917.91 by revising paragraph (a)(1)(i) to read as follows:

§ 1917.91 Eye and face protection.

(a)(1)(i) The employer shall ensure that each affected employee uses protective eye and face protection devices that comply with any of the following consensus standards:

(A) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1917.3;

(B) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1917.3;

or

(C) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection, incorporated by reference in § 1917.3;

* * * * *

PART 1918—[AMENDED]

■ 11. The authority citation for part 1918 is revised to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR 1911.

Section 1918.90 also issued under 5 U.S.C. 553.

Section 1918.100 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

■ 12. Amend § 1918.3 by revising paragraphs (b)(6) through (8) to read as follows:

§ 1918.3 Incorporation by reference.

* * * * *

(b) * * *

(6) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, Approved April 13, 2010; IBR approved for § 1918.101(a). Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(7) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, Approved June 19, 2003; IBR approved for § 1918.101(a). Copies available for purchase from the:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(8) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection, Reaffirmation approved January 4, 1999; IBR approved for § 1918.101(a). Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

* * * * *

Subpart J—[Amended]

■ 13. Amend § 1918.101 by revising paragraph (a)(1)(i) to read as follows:

§ 1918.101 Eye and face protection.

(a) * * *

(1)(i) Employers must ensure that each employee uses appropriate eye and/or face protection when the employee is exposed to an eye or face hazards, and that protective eye and face devices comply with any of the following consensus standards:

(A) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1918.3;

(B) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1918.3; or

(C) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection, incorporated by reference in § 1918.3

* * * * *

PART 1926—[AMENDED]

Subpart A—General [Amended]

■ 14. The authority citation for subpart A of part 1926 continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 15. Amend § 1926.6 as follows:

■ a. Revise paragraph (h)(31);

■ b. Redesignate paragraphs (h)(32) thru (34) as (h)(34) thru (36);

■ c. Add new paragraphs (h)(32) and (h)(33).

The revisions and additions read as follows:

§ 1926.6 Incorporation by reference.

* * * * *

(h) * * *

(31) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, Approved April 3, 2010; IBR approved for § 1926.102(b). Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(32) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, Approved June 19, 2003; IBR approved for § 1926.102(b). Copies available for purchase from the:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

(33) ANSI Z87.1–1989 (R–1998), Practice for Occupational and Educational Eye and Face Protection, Reaffirmation approved January 4, 1999; IBR approved for § 1926.102(b). Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642–4980; Web site: *http://webstore.ansi.org/;*

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413–5184; Web site: *http://global.ihs.com;* or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699–9277; Web site: *http://techstreet.com.*

* * * * *

Subpart E—[Amended]

■ 16. Revise the authority citation for subpart E of part 1926 to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 17. Amend § 1926.102 as follows:

■ a. Revise paragraphs (a)(1) thru (4).

■ b. Remove paragraphs (a)(5), (a)(7), (a)(8), and Tables E–1, E–2, and E–3.

■ c. Redesignate paragraph (a)(6) as (a)(5).

■ d. Revise paragraph (b).

■ e. Add paragraph (c).

The additions and revisions read as follows:

§ 1926.102 Eye and face protection.

(a) *General requirements.* (1) The employer shall ensure that each affected employee uses appropriate eye or face protection when exposed to eye or face hazards from flying particles, molten metal, liquid chemicals, acids or caustic liquids, chemical gases or vapors, or potentially injurious light radiation.

(2) The employer shall ensure that each affected employee uses eye protection that provides side protection when there is a hazard from flying objects. Detachable side protectors (*e.g.* clip-on or slide-on side shields) meeting the pertinent requirements of this section are acceptable.

(3) The employer shall ensure that each affected employee who wears prescription lenses while engaged in operations that involve eye hazards wears eye protection that incorporates the prescription in its design, or wears eye protection that can be worn over the prescription lenses without disturbing the proper position of the prescription lenses or the protective lenses.

(4) Eye and face PPE shall be distinctly marked to facilitate identification of the manufacturer.

* * * * *

(b) *Criteria for protective eye and face protection.* (1) Protective eye and face protection devices must comply with any of the following consensus standards:

(i) ANSI/ISEA Z87.1–2010, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1926.6;

(ii) ANSI Z87.1–2003, Occupational and Educational Personal Eye and Face Protection Devices, incorporated by reference in § 1926.6; or

(iii) ANSI Z87.1–1989 (R–1998), Practice for Occupational and

Educational Eye and Face Protection, incorporated by reference in § 1926.6;

(2) Protective eye and face protection devices that the employer demonstrates are at least as effective as protective eye and face protection devices that are constructed in accordance with one of the above consensus standards will be deemed to be in compliance with the requirements of this section.

(c) *Protection against radiant energy*—(1) *Selection of shade numbers for welding filter.* Table E–1 shall be used as a guide for the selection of the proper shade numbers of filter lenses or plates used in welding. Shades more dense than those listed may be used to suit the individual's needs.

TABLE E–1—FILTER LENS SHADE NUMBERS FOR PROTECTION AGAINST RADIANT ENERGY

Welding operation	Shade number
Shielded metal-arc welding 1/16-, 3/32-, 1/8-, 5/32-inch diameter electrodes	10
Gas-shielded arc welding (nonferrous) 1/16-, 3/32-, 1/8-, 5/32-inch diameter electrodes	11
Gas-shielded arc welding (ferrous) 1/16-, 3/32-, 1/8-, 5/32-inch diameter electrodes	12
Shielded metal-arc welding 3/16-, 7/32-, 1/4-inch diameter electrodes	12
5/16-, 3/8-inch diameter electrodes	14
Atomic hydrogen welding	10–14
Carbon-arc welding	14
Soldering	2
Torch brazing	3 or 4
Light cutting, up to 1 inch	3 or 4
Medium cutting, 1 inch to 6 inches	4 or 5
Heavy cutting, over 6 inches	5 or 6
Gas welding (light), up to 1/8-inch	4 or 5
Gas welding (medium), 1/8-inch to 1/2-inch	5 or 6
Gas welding (heavy), over 1/2-inch	6 or 8

(2) *Laser protection.* (i) Employees whose occupation or assignment requires exposure to laser beams shall be furnished suitable laser safety goggles which will protect for the specific wavelength of the laser and be of optical density (O.D.) adequate for the energy involved. Table E–2 lists the maximum power or energy density for which adequate protection is afforded by glasses of optical densities from 5 through 8. Output levels falling between lines in this table shall require the higher optical density.

TABLE E–2—SELECTING LASER SAFETY GLASS

Intensity, CW maximum power density (watts/cm^2)	Attenuation	
	Optical density (O.D.)	Attenuation factor
10^{-2}	5	10^5
10^{-1}	6	10^6
1.0	7	10^7
10.0	8	10^8

(ii) All protective goggles shall bear a label identifying the following data:

(A) The laser wavelengths for which use is intended;

(B) The optical density of those wavelengths;

(C) The visible light transmission.

[FR Doc. 2016–06359 Filed 3–24–16; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Disestablishment of Danger Zone for Meteorological Rocket Launching Facility, Shemya Island Area, AK

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Direct final rule.

SUMMARY: The U.S. Air Force has requested that the U.S. Army Corps of Engineers (Corps) disestablish the existing danger zone located in the Bering Sea near Shemya Island, Alaska. The danger zone was established on September 28, 1971. The purpose of the danger zone was to protect persons and property from dangers encountered in the area associated with the launching of weather rockets. The facility has not been used for this activity since the mid-1980s. As a result of the discontinued use of this area, the Air Force has requested the danger zone be disestablished.

DATES: This rule is effective May 24, 2016 without further notice, unless the Corps receives adverse comment by April 25, 2016. If we receive such adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: You may submit comments, identified by docket number COE–2016–0003, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Email: david.b.olson@usace.army.mil. Include the docket number, COE–2016–0003, in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW–CO (David B. Olson), 441 G Street NW., Washington, DC 20314–1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Direct your comments to docket number COE–2016–0003. All comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the commenter indicates that the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through regulations.gov or email. The regulations.gov Web site is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to the Corps without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, we recommend that you

include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov.* All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or Ms. Linda Speerstra, U.S. Army Corps of Engineers, Alaska District, Regulatory Division, at 907–747–0658.

SUPPLEMENTARY INFORMATION: By letter dated December 18, 2015, the Chief, Pacific Air Forces Weather Operations Branch, Joint Base Pearl Harbor-Hickam, Hawaii requested the disestablishment of the danger zone at Meteorological Rocket Launching Facility on Shemya Island, Alaska. This request was made because the facility has not been used since the mid-1980s. In response to this request by the Pacific Air Forces Weather Operations Branch, and pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3), the Corps is amending the regulation at 33 CFR part 334 by disestablishing the danger zone in the waters of the Bering Sea, Meteorological Rocket Launching Facility on Shemya Island Area, Alaska.

The Corps is publishing this rule without prior proposal because we view this as a non-controversial amendment and anticipate no adverse comment. The Corps regulations governing restricted areas state that notice of proposed rulemaking and public procedures are not needed before publishing a final rule revoking a danger zone area (see 33 CFR 334.5(b)).

In the ''Proposed Rules'' section of today's **Federal Register**, we are publishing a separate document that will serve as the proposal to disestablish this danger zone if adverse comments are filed. This rule will be effective on May 24, 2016 without further notice unless we receive adverse comment by April 25, 2016. If we receive adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the direct final rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

Procedural Requirements

a. *Review Under Executive Order 12866.* This rule is issued with respect to a military function of the Defense Department and the provisions of Executive Order 12866 do not apply.

b. *Review Under the Regulatory Flexibility Act.* This rule has been reviewed under the Regulatory Flexibility Act (Pub. L. 96–354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (*i.e.,* small businesses and small governments). The Corps has determined that the removal of the danger zone area will have no economic impact on the public because the area has not been used to launch weather rockets since the mid-1980s. The removal of the danger zone will decrease economic impacts on small entities because they will no longer have to comply with that regulation. The proposal will have no significant economic impact on small entities.

c. *Review Under the National Environmental Policy Act.* The Corps expects that the final rule will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement will not be required. An environmental assessment has been prepared and it may be reviewed at the District office listed at the end of the **FOR FURTHER INFORMATION CONTACT**, above. If we receive adverse comment, an environmental assessment will be prepared for the subsequent decision on the final rule.

d. *Unfunded Mandates Act.* The final rule does not impose an enforceable duty among the private sector and, therefore, are not a Federal private sector mandate and are not subject to the requirements of Section 202 or 205 of the Unfunded Mandates Reform Act (Pub. L. 104–4, 109 Stat. 48, 2 U.S.C. 1501 *et seq.*). We have also found under Section 203 of the Act, that small governments will not be significantly or uniquely affected by this rulemaking.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps amends 33 CFR part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

■ 1. The authority citation for 33 CFR part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

§ 334.1290 [Removed]

■ 2. Remove § 334.1290.

Dated: March 18, 2016.

Edward E. Belk, Jr.,

Chief, Operations and Regulatory Division, Directorate of Civil Works.

[FR Doc. 2016–06860 Filed 3–24–16; 8:45 am]

BILLING CODE 3720–58–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0394; FRL–9944–19–Region 7]

Approval of Air Quality State Implementation Plans (SIP); State of Iowa; Infrastructure SIP Requirements for the 2008 Lead National Ambient Air Quality Standard (NAAQS); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; technical amendment.

SUMMARY: The Environmental Protection Agency (EPA) inadvertently approved and codified incorrect entry numbers in the part 52 instructions for the final rule action published on November 2, 2015. This technical amendment amends the part 52 codification instructions.

DATES: This action is effective March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Jan Simpson at (913) 551–7089, or by email at *simpson.jan@epa.gov.*

SUPPLEMENTARY INFORMATION: On November 2, 2015 (80 FR 67335), EPA published a final rule approving a SIP revision for Iowa that approved Iowa's November 4, 2011, submission addressing the requirements of the CAA sections 110(a)(1) and (2) as applicable to the 2008 Lead NAAQS. Specifically, EPA approved the following infrastructure elements: 110(a)(2)(A),

(B), (C), (D), (E), (F), (G), (H), (J), (K), (L), and (M) which are necessary to implement, maintain, and enforce the 2008 Lead NAAQS. EPA also approved Iowa's May 11, 2015, submission to include article 1, section 2 of the Iowa Constitution, and portions of the Iowa code and the Iowa Administrative Code to codify the relevant state laws as applied to conflict of interest requirements of sections 110(a)(2)(E) and 128 of the CAA.

This technical amendment revises the erroneous part 52 instructions published in the **Federal Register** on November 2, 2015 (80 FR 67335) in the third column on page 67336 to read as follows: Amend § 52.820 by adding new entries (e) (40) and (41).

Dated: March 17, 2016.

Mark Hague,

Regional Administrator, Region 7.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart Q—Iowa

■ 2. Amend § 52.820 by adding entries (e)(40) and (41) to read as follows:

§ 52.820 Identification of plan.

* * * * *

(e)* * *

EPA-APPROVED IOWA NONREGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic area or nonattainment area	State submittal date	EPA Approval date	Explanation
*	*	*	* * * *	
(40) Sections 110(a)(1) and (2) Infrastructure Requirements 2008 Lead NAAQS.	Statewide	11/4/11	11/2/15; Correction 3/25/16 [*Insert* ***Federal Register*** *citation*].	This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L), and (M). 110(a)(2)(I) is not applicable.
(41) Section 128 Declaration: Conflicts of Interest Provisions;				
Constitution of the State of Iowa, Article 1, Section 2.	.....	.....	.....	This action addresses the following sections of the Constitution of the State of Iowa, Article 1, section 2;
Iowa Code: 4.4.(5), 7E.4, Chapter 68B	.....	.....	.....	Iowa Code : 4.4 (5), 7e.4, Chapter 68B;
Iowa Administrative Code: 351 IAC 6.11, 351 IAC 6.14(2), 351 IAC 6.19, 351 IAC 7.1-7.2, 567 IAC 1.11 (1–9).	Statewide	5/11/15	11/2/15; Correction 3/25/16 [*Insert* ***Federal Register*** *citation*].	Iowa Administrative Code: 351 IAC 6.11, 351 IAC 6.14(2), 351 IAC 6.19, 351 IAC 7.1–7.2, 567 IAC 1.11(1–9).

[FR Doc. 2016–06705 Filed 3–24–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 130312235–3658–02]

RIN 0648–XE506

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2016 Commercial Accountability Measure and Closure for South Atlantic Vermilion Snapper

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures (AMs) for the commercial sector for vermilion snapper in the exclusive economic zone (EEZ) of the South Atlantic. NMFS projects that commercial landings for vermilion snapper will reach the commercial annual catch limit (ACL) for the January through June, 2016, fishing period by March 29, 2016. Therefore, NMFS closes the commercial sector for vermilion snapper in the South Atlantic EEZ on March 29, 2016, and it will remain closed until July 1, 2016, the start of the July through December fishing period. This closure is necessary to protect the South Atlantic vermilion snapper resource.

DATES: This rule is effective from 12:01 a.m., local time, March 29, 2016, until 12:01 a.m., local time, July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Britni LaVine, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *britni.lavine@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes vermilion snapper and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The commercial ACL (equivalent to the commercial quota) for vermilion snapper in the South Atlantic is divided into separate quotas for two 6-month time periods, January through June and July through December. For the January through June, 2016, fishing season, the commercial quota is 388,703 lb (176,313 kg), gutted weight (431,460 lb (195,707 kg), round weight), as specified in 50 CFR 622.190(a)(4)(i)(D).

On February 26, 2016 (81 FR 9786), NMFS published a temporary rule in the **Federal Register** to reduce the commercial trip limit for vermilion snapper in or from the EEZ of the South Atlantic to 500 lb (227 kg), gutted weight, effective 12:01 a.m., local time, March 2, 2016, until July 1, 2016, or until the quota was reached and the commercial sector closed, whichever would occur first.

In accordance with regulations at 50 CFR 622.193(f)(1), NMFS is required to close the commercial sector for vermilion snapper when the commercial quota for that portion of the fishing year has been reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the commercial quota for South Atlantic vermilion snapper for the January through June fishing period will be reached by March 29, 2016. Accordingly, the commercial sector for South Atlantic vermilion snapper is closed effective 12:01 a.m., local time, March 29, 2016, until 12:01 a.m., local time, July 1, 2016. The commercial quota for vermilion snapper in the South Atlantic is 388,703 lb (176,313 kg), gutted weight (431,460 lb (195,707 kg), round weight), for the July 1 through December 31, 2016, fishing period, as specified in 50 CFR 622.190(a)(4)(ii)(D).

The operator of a vessel with a valid commercial vessel permit for South Atlantic snapper-grouper having vermilion snapper on board must have landed and bartered, traded, or sold such vermilion snapper prior to 12:01 a.m., local time, March 29, 2016. During the closure, the bag limit specified in 50 CFR 622.187(b)(5) and the possession limits specified in 50 CFR 622.187(c)(1), apply to all harvest or possession of vermilion snapper in or from the South Atlantic EEZ. During the closure, the sale or purchase of vermilion snapper taken from the EEZ is prohibited. As specified in 50 CFR 622.190(c)(1)(i), the prohibition on sale or purchase does not apply to the sale or purchase of vermilion snapper that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, March 29, 2016, and were held in cold storage by a dealer or processor. For a person on board a vessel for which a Federal commercial or charter vessel/headboat permit for the South Atlantic snapper-grouper fishery has been issued, the bag and possession limits and the sale and purchase provisions of the commercial closure for vermilion snapper would apply regardless of whether the fish are harvested in state or Federal waters, as specified in 50 CFR 622.190(c)(1)(ii).

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of South Atlantic vermilion snapper and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.193(f)(1) and is exempt from review under Executive Order 12866.

This action responds to the best scientific information available. The Assistant Administrator for Fisheries, NOAA (AA), finds that the need to immediately implement this action to close the commercial sector for vermilion snapper constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such procedures would be unnecessary and contrary to the public interest. Such procedures would be unnecessary because the rule itself has been subject to notice and comment, and all that remains is to notify the public of the closure. Allowing prior notice and opportunity for public comment is contrary to the public interest because of the need to immediately implement this action to protect vermilion snapper since the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment would require time and could result in a harvest well in excess of the established commercial quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 21, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–06737 Filed 3–22–16; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE532

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod in the Aleutian Islands Subarea of the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod, except for the Community Development Quota program (CDQ), in the Aleutian Islands subarea of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the non-CDQ allocation of the 2016 Pacific cod total allowable catch (TAC) in the Aleutian Islands subarea of the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), March 22, 2016, through 2400 hrs, A.l.t., December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7269.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The non-CDQ allocation of the 2016 Pacific cod TAC in the Aleutian Islands subarea of the BSAI is 11,465 metric tons (mt) as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016). In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS, has determined that the non-CDQ allocation of the 2016 Pacific cod TAC in the Aleutian Islands subarea of the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 9,000 mt, and is setting aside the remaining 2,465 mt as

incidental catch in directed fishing for other species. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod in the Aleutian Islands subarea of the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of non-CDQ Pacific cod in the Aleutian Islands subarea of the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of March 21, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 22, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–06831 Filed 3–22–16; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE518

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pollock in the Bering Sea and Aleutian Islands

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule.

SUMMARY: NMFS is reallocating the projected unused amounts of the Aleut Corporation's pollock directed fishing allowance and the Community Development Quota from the Aleutian Islands subarea to the Bering Sea subarea directed fisheries. These actions are necessary to provide opportunity for harvest of the 2016 total allowable catch of pollock, consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), March 25, 2016, until 2400 hrs, A.l.t., December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

In the Aleutian Islands subarea, the portion of the 2016 pollock total allowable catch (TAC) allocated to the Aleut Corporation's directed fishing allowance (DFA) is 14,700 metric tons (mt) and the Community Development Quota (CDQ) is 1,900 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016).

As of March 18, 2016, the Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that 5,000 mt of Aleut Corporation's DFA and 1,900 mt of pollock CDQ in the Aleutian Islands subarea will not be harvested. Therefore, in accordance with § 679.20(a)(5)(iii)(B)(*4*), NMFS reallocates 5,000 mt of Aleut Corporation's DFA and 1,900 mt of pollock CDQ from the Aleutian Islands subarea to the 2016 Bering Sea subarea allocations. The 1,900 mt of pollock CDQ is added to the 2016 Bering Sea CDQ DFA. The remaining 5,000 mt of pollock is apportioned to the AFA Inshore sector (50 percent), AFA catcher/processor sector (40 percent), and the AFA mothership sector (10 percent). The 2016 pollock incidental catch allowance remains at 48,240 mt. As a result, the harvest specifications for pollock in the Aleutian Islands subarea included in the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) are revised as follows: 9,700 mt to Aleut Corporation's DFA and 0 mt to CDQ pollock. Furthermore, pursuant to § 679.20(a)(5), Table 4 of the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) is revised to make 2016 pollock allocations consistent with this reallocation. This reallocation results in adjustments to the 2016 Aleut Corporation and CDQ pollock allocations established at § 679.20(a)(5).

TABLE 4—FINAL 2016 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]

[Amounts are in metric tons]

Area and sector	2016 Allocations	2016 A season [1]		2016 B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Bering Sea subarea TAC [1]	1,346,900	n/a	n/a	n/a
CDQ DFA	135,900	54,360	38,052	81,540
ICA [1]	48,240	n/a	n/a	n/a
AFA Inshore	581,380	232,552	162,786	348,828
AFA Catcher/Processors [3]	465,104	186,042	130,229	279,062
Catch by C/Ps	425,570	170,228	n/a	255,342
Catch by CVs [3]	39,534	15,814	n/a	23,720

TABLE 4—FINAL 2016 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]—Continued

[Amounts are in metric tons]

Area and sector	2016 Allocations	2016 A season [1]		2016 B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Unlisted C/P Limit [4]	2,326	930	n/a	1,395
AFA Motherships	116,276	46,510	32,557	69,766
Excessive Harvesting Limit [5]	203,816	n/a	n/a	n/a
Excessive Processing Limit [6]	349,398	n/a	n/a	n/a
Total Bering Sea DFA	1,162,760	465,104	325,573	697,656
Aleutian Islands subarea ABC	32,227	n/a	n/a	n/a
Aleutian Islands subarea TAC [1]	12,100	n/a	n/a	n/a
CDQ DFA	0	0	n/a	0
ICA	2,400	1,200	n/a	1,200
Aleut Corporation	9,700	9,700	n/a	0
Area harvest limit: [7]				
541	9,668	n/a	n/a	n/a
542	4,834	n/a	n/a	n/a
543	1,611	n/a	n/a	n/a
Bogoslof District ICA [8]	500	n/a	n/a	n/a

[1] Pursuant to § 679.20(a)(5)(i)(A), the BS subarea pollock, after subtracting the CDQ DFA (10 percent) and the ICA (4.0 percent), is allocated as a DFA as follows: Inshore sector—50 percent, catcher/processor sector (C/P)—40 percent, and mothership sector—10 percent. In the BS subarea, 40 percent of the DFA is allocated to the A season (January 20–June 10) and 60 percent of the DFA is allocated to the B season (June 10–November 1). Pursuant to § 679.20(a)(5)(iii)(B)(*2*)(*i*) and (*ii*), the annual AI pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second the ICA (2,400 mt), is allocated to the Aleut Corporation for a pollock directed fishery. In the AI subarea, the A season is allocated 40 percent of the ABC and the B season is allocated the remainder of the pollock directed fishery.

[2] In the BS subarea, no more than 28 percent of each sector's annual DFA may be taken from the SCA before April 1.

[3] Pursuant to § 679.20(a)(5)(i)(A)(*4*), not less than 8.5 percent of the DFA allocated to listed catcher/processors shall be available for harvest only by eligible catcher vessels delivering to listed catcher/processors.

[4] Pursuant to § 679.20(a)(5)(i)(A)(*4*)(*iii*), the AFA unlisted catcher/processors are limited to harvesting not more than 0.5 percent of the catcher/processors sector's allocation of pollock.

[5] Pursuant to § 679.20(a)(5)(i)(A)(*6*), NMFS establishes an excessive harvesting share limit equal to 17.5 percent of the sum of the non-CDQ pollock DFAs.

[6] Pursuant to § 679.20(a)(5)(i)(A)(*7*), NMFS establishes an excessive processing share limit equal to 30.0 percent of the sum of the non-CDQ pollock DFAs.

[7] Pursuant to § 679.20(a)(5)(iii)(B)(*6*), NMFS establishes harvest limits for pollock in the A season in Area 541 no more than 30 percent, in Area 542 no more than 15 percent, and in Area 543 no more than 5 percent of the Aleutian Islands pollock ABC.

[8] The Bogoslof District is closed by the final harvest specifications to directed fishing for pollock. The amounts specified are for ICA only and are not apportioned by season or sector.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of AI pollock. Since the pollock fishery is currently open, it is important to immediately inform the industry as to the final Bering Sea subarea pollock allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery; allow the industry to plan for the fishing season and avoid potential disruption to the fishing fleet as well as processors; and provide opportunity to harvest increased seasonal pollock allocations while value is optimum. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of March 15, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 22, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–06832 Filed 3–24–16; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 58
Friday, March 25, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

2 CFR Subtitle B, Chapter IV

5 CFR Chapter LXXIII

7 CFR Subtitle A; Subtitle B, Chapters I–XI, XIV–XVIII, XX, XXV–XXXVIII, and XLII

9 CFR Chapters I–III

36 CFR Chapter II

48 CFR Chapter 4

Identifying and Reducing Regulatory Burdens

AGENCY: Office of Budget and Program Analysis, USDA.

ACTION: Request for Information (RFI); extension of comment period.

SUMMARY: On January 26, 2016, the Office of the Secretary, USDA, published a document in the **Federal Register** in accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review,'' and Executive Order 13610, ''Identifying and Reducing Regulatory Burdens'' inviting public comment on which regulations should be modified, expanded, streamlined, or repealed to make the USDA's regulatory program more effective or less burdensome in achieving the regulatory objectives. USDA's planned regulatory actions and retrospective review efforts were made available in the 2015 Fall Unified Regulatory Agenda. Written comments were to be received by March 28, 2016. USDA is extending the public comment period until April 27, 2016.

DATES: The notice published January 26, 2016, at 81 FR 4213, is extended. Comments and information are requested on or before April 27, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this notice. All submissions must refer to ''Retrospective Review'' to ensure proper delivery.

• *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal: *http://www.regulations.gov.* USDA strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, and ensures timely receipt by USDA. Commenters should follow the instructions provided on that site to submit comments electronically.

• *Submission of Comments by Mail, Hand delivery, or Courier.* Paper, disk, or CD–ROM submissions should be submitted to Michael Poe, Office of Budget and Program Analysis, USDA, Jamie L. Whitten Building, Room 101–A, 1400 Independence Ave. SW., Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Michael Poe, Telephone Number: (202) 720–3257.

SUPPLEMENTARY INFORMATION: USDA remains committed to minimizing the burdens on individuals, businesses, and communities for participation in and compliance with USDA programs that promote economic growth, create jobs, and protect the health and safety of the American people.

USDA programs are diverse and far reaching, as are the regulations and legislation that implement their delivery. The regulations range from nutrition standards for the school lunch program, natural resources and environmental measures governing national forest usage and soil conservation, emergency producer assistance as a result of natural disasters, to protection of American agriculture from the ravages of plant or animal pestilence. USDA regulations extend from farm to supermarket to ensure the safety, quality, and availability of the Nation's food supply. Regulations also specify how USDA conducts its business, including access to and eligibility for USDA programs. Finally, regulations specify the responsibilities of businesses, individuals, and State and local governments that are necessary to comply with their provisions.

I. Executive Orders 13563 and 13610

The overall intention of Executive Orders 13563 and 13610 is to create a continuing process of scrutiny of regulatory actions.

Executive Order 13563, ''Improving Regulation and Regulatory Review,'' was issued to ensure that Federal regulations use the best available tools to promote innovation that will reduce costs and burden while allowing public participation and an open exchange of ideas. These principles enhance and strengthen Federal regulations to allow them to achieve their regulatory objectives, most important among them protecting public health, welfare, safety, and the environment. In consideration of these principles, and as directed by the Executive Order, Federal agencies and departments need to periodically review existing regulations that may be outmoded, ineffective, insufficient, or excessively burdensome and to modify, streamline, expand, or repeal them in accordance with what has been learned.

In addition, Executive Order 13610, ''Identifying and Reducing Regulatory Burdens,'' directed Federal agencies to conduct retrospective analyses of existing rules to examine whether they remain justified and whether they should be modified or streamlined in light of changed circumstances, including the availability of new technologies. Executive Order 13610 directs Federal agencies to give priority, consistent with law, to those initiatives that will produce significant quantifiable monetary savings or significant quantifiable reductions in paperwork burdens while protecting public health, welfare, safety, and the environment. For the regulatory requirements imposed on small businesses, it directs Federal agencies to give special consideration to initiatives that would simplify or harmonize the regulatory requirements.

II. Request for Information

USDA is seeking public comment on our effort: To identify and reduce regulatory burdens; to remove unintended regulatory obstacles to participation in and compliance with USDA programs; and to improve current regulations to help USDA agencies advance the USDA mission. USDA is particularly interested in public comments that speak to areas in which we can reduce costs and reporting burdens on the public, through technological advances or other modernization efforts, and comments on regulatory flexibility.

III. Regulatory Flexibility

USDA is also seeking public input on measures that can be taken to reduce burdens and increase flexibility and freedom of choice for the public. Regulatory flexibility includes a variety of regulatory techniques that can help avoid unnecessary costs on regulated entities and avoid negative impacts. Regulatory flexibility techniques could include:

- Pilot projects, which can be used to test regulatory approaches;
- Safe harbors, which are streamlined modes of regulatory compliance and can serve to reduce compliance costs;
- Sunset provisions, which terminate a rule after a certain date;
- Trigger provisions, which specify one or more threshold indicators that the rule is designed to address;
- Phase-ins, which allow the rule to be phased-in for different groups at different times;
- Streamlined requirements, which provide exemptions or other streamlined requirements if a particular entity (for example, a small business) may otherwise experience disproportionate burden from a rule;
- State flexibilities, which provide greater flexibility to States or other regulatory partners, for example, giving them freedom to implement alternative regulatory approaches; and
- Exceptions, which allow exceptions to part of the rule, or the entire rule in cases where there is a potential or suspected unintended consequence.

IV. Existing USDA Regulations

In addition to retrospective review actions and other regulatory reforms identified in USDA's 2015 Fall Regulatory Agenda, we welcome comments from the public on any of USDA's existing regulations and ways to improve them to help USDA agencies advance the mission of the Department consistent with the Executive Order. USDA notes that this RFI is issued solely for information and program-planning purposes. While responses to this RFI do not bind USDA to any further actions, all submissions will be reviewed by the appropriate program office, and made publicly available on *http://www.regulations.gov.*

Michael Poe,

Office of Budget and Program Analysis, United States Department of Agriculture.

[FR Doc. 2016–06852 Filed 3–24–16; 8:45 am]

BILLING CODE 3410–90–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–5247; Directorate Identifier 2015–SW–008–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Airbus Helicopters Deutschland GmbH (Airbus Helicopters) Model BO–105LS A–3 helicopters. This proposed AD would require inspecting the helicopter records to determine if there is a life limit for the tension-torsion (TT) straps installed in the helicopter lifting system, establishing a life limit if there is not one, and replacing each TT strap that has met or exceeded its life limit. This proposed AD is prompted by an error in the Airworthiness Limitations section of the Model BO–105LS A–3 maintenance manual. The proposed actions are intended to prevent failure of a TT strap and subsequent loss of control of a helicopter.

DATES: We must receive comments on this proposed AD by May 24, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5247; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.airbushelicopters.com/techpub.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, Texas 76177.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, Texas 76177; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, issued EASA AD No. 2015–0042, dated March 9, 2015, to correct an unsafe condition for Airbus Helicopters Model BO105 LS A–3 helicopters.

EASA advises that life limits have been introduced for TT strap part number (P/N) 2604067 and P/N 117–14110 installed on the helicopter lifting system. During a revision of the Airworthiness Limitations section of the Model BO105LS A–3 maintenance manual, the life limit for the TT strap was inadvertently deleted. Accordingly, EASA issued AD No. 2015–0042 to correct this error. EASA AD No. 2015–0042 requires replacing TT straps upon reaching their life limit and entering the life limit into the aircraft maintenance manual. EASA states that failure to comply with the life limit could result in an unsafe condition.

FAA's Determination

These helicopters have been approved by the aviation authority of Germany and are approved for operation in the United States. Pursuant to our bilateral agreement with Germany, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information

Airbus Helicopters issued Alert Service Bulletin ASB BO105LS–10A–013, Revision 0, dated March 9, 2015 (ASB). The ASB specifies adding a life limit for the TT strap P/N 2604067 or 117–14110 of 25,000 flights or 10 years, whichever occurs first, in the list of life-limited parts and corresponding log cards. The ASB also states TT straps that have exceeded the retirement time must be replaced and that only TT straps that have not exceeded the retirement time may be installed.

Proposed AD Requirements

This proposed AD would require, within 20 hours time-in-service:

- Inspecting the Airworthiness Limitations section of the applicable maintenance manual or Instructions for Continued Airworthiness (ICA) and the component history card or equivalent record for each TT strap and determining whether those records specify a life limit of 25,000 flights or 10 years since the date of manufacture, whichever occurs first.

○ If the records do not specify a life limit for each TT strap or if they specify a different life limit than required, revising the Airworthiness Limitations section of the applicable maintenance manual or ICA by establishing a life limit of 25,000 flights or 10 years since date of manufacture, whichever occurs first.

○ Creating a component history card or equivalent record for each TT strap, if one does not exist, and recording a life limit of 25,000 flights or 10 years since date of manufacture, whichever occurs first.

- Removing from service each TT strap that has reached or exceeded its life limit.

Differences Between This Proposed AD and the EASA AD

This proposed AD would require compliance within 20 hours TIS. The EASA AD allows 2 months to calculate the flight cycles or calendar time of each TT strap.

Costs of Compliance

We estimate that this proposed AD would affect 8 helicopters of U.S. Registry. Labor costs are estimated at $85 per hour. We estimate that it would take 2 work hours to inspect and revise the Airworthiness Limitations section and to calculate and record a life limit for the TT strap for a total cost of $170 per helicopter and $1,360 for the fleet. If a TT strap is replaced, we estimate it would take 8 work hours and $16,617 for required parts for a total cost of $17,297 per helicopter per TT strap.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus Helicopters Deutschland GmbH Helicopters: Docket No. FAA–2016–5247; Directorate Identifier 2015–SW–008–AD.

(a) Applicability

This AD applies to Model BO–105LS A–3 helicopters with a tension torsion (TT) strap part number (P/N) 2604067 or P/N 117–14110 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a TT strap remaining in service beyond its fatigue life. This condition could result in failure of a TT strap and loss of control of a helicopter.

(c) Comments Due Date

We must receive comments by May 24, 2016.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 20 hours time-in-service:

(1) Inspect the Airworthiness Limitations section of the applicable maintenance manual or Instructions for Continued Airworthiness (ICA) and the component history card or equivalent record for TT strap P/N 2604067 and P/N 117–14110. Determine whether those records specify a life limit of 25,000 flights or 10 years since the date of manufacture, whichever occurs first.

(2) If the Airworthiness Limitations section of the applicable maintenance manual or ICA or the component history card or equivalent record do not specify a life limit for the TT strap, or if they specify a different life limit than in paragraph (e)(1), do the following:

(i) Revise the Airworthiness Limitations section of the applicable maintenance manual or ICA by establishing a life limit of 25,000 flights or 10 years since date of manufacture, whichever occurs first, for each TT strap P/N 2604067 and P/N 117–14110 by making pen-and-ink changes or by inserting a copy of this AD into the Airworthiness Limitations section of the maintenance manual or the ICA. For purposes of this AD, a flight would be counted anytime the helicopter lifts off into the air and then lands again regardless of the duration of the landing and regardless of whether the engine is shut down.

(ii) Create a component history card or equivalent record for each TT strap P/N 2604067 and P/N 117–14110, if one does not exist, and record a life limit of 25,000 flights or 10 years since date of manufacture, whichever occurs first.

(3) Remove from service each TT strap that has reached or exceeded its life limit.

(f) Special Flight Permit

Special flight permits are prohibited.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, Texas 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

(1) Airbus Helicopters Alert Service Bulletin ASB BO105LS–10A–013, Revision 0, dated March 9, 2015, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.airbushelicopters.com/techpub.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2015–0042, dated March 9, 2015. You may view the EASA AD on the Internet at *http://www.regulations.gov* in the AD Docket.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6200 Main Rotor System.

Issued in Fort Worth, Texas, on March 16, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–06530 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Disestablishment of Danger Zone for Meteorological Rocket Launching Facility, Shemya Island Area, AK

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Proposed rule.

SUMMARY: The U.S. Air Force has requested that the U.S. Army Corps of Engineers (Corps) disestablish the existing danger zone located in the Bering Sea near Shemya Island, Alaska. The danger zone was established on September 28, 1971. The purpose of the danger zone was to protect persons and property from dangers encountered in the area associated with the launching of weather rockets. The facility has not been used for this activity since the mid-1980s. As a result of the discontinued use of this area, the Air Force has requested the danger zone be disestablished. In the ''Rules and Regulations'' section of **Federal Register**, we are publishing the restricted area disestablishment as a direct final rule without prior proposal because we view this as a non-controversial adjustment to our restricted area regulations and anticipate no adverse comment. We have explained our reasons for this approval in the preamble to the direct final rule. If we receive no adverse comment, we will not take further action on this rule and it will go into effect. If we receive adverse comment, we will withdraw the direct final rule and it will not take effect. We will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: Written comments must be received by April 25, 2016.

SUPPLEMENTARY INFORMATION:

This document concerns the ''Disestablishment of Danger Zone for Meteorological Rocket Launching Facility, Shemya Island Area, AK.'' For further information, including instructions on how to submit comments, please see the information provided in the direct final rule that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: March 18, 2016.

Edward E. Belk, Jr.,

Chief, Operations and Regulatory Division, Directorate of Civil Works.

[FR Doc. 2016–06861 Filed 3–24–16; 8:45 am]

BILLING CODE 3720–58–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Docket No. EPA–R02–OAR–2016–0059; FRL–9944–21–Region]

Approval of Air Quality Implementation Plans; New Jersey, Carbon Monoxide Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the New Jersey Department of Environmental Protection. This revision will establish an updated ten-year carbon monoxide (CO) maintenance plan for the New Jersey portion of the New York-Northern New Jersey-Long Island (NYNNJLI) CO area which includes the following areas: Hudson, Essex, Bergen, and Union Counties, and the municipalities of Clifton, Passaic and Paterson in Passaic County. EPA is also proposing to approve the 2007 Attainment/Base Year CO emissions inventory. In addition, EPA proposes to approve the shutdown of 5 CO maintenance monitors in New Jersey. The New Jersey portion of the NYNNJLI CO area was redesignated to attainment of the CO National Ambient Air Quality Standard (NAAQS) on August 23, 2002 and the maintenance plan was also approved at that time. By

this action, EPA is proposing to approve the second maintenance plan for this area because it provides for continued attainment for an additional ten years of the CO NAAQS.

DATES: Comments must be received on or before April 25, 2016.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R02–OAR–2016–0059, at *http://www.regulations.gov.* Follow the on-line instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Henry Feingersh *feingersh.henry@epa.gov* for general questions, Raymond Forde *forde.raymond@epa.gov* for emissions inventory questions, or Matthew Laurita *laurita.matthew@epa.gov* for mobile source related questions at the U.S. Environmental Protection Agency, Air Programs Branch, 290 Broadway, 25th Floor, New York, NY 10007–1866, telephone number (212) 637–4249, fax number (212) 637–3901.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

Table of Contents

I. What is the nature of the EPA's action?

The EPA is proposing to approve an updated ten-year carbon monoxide (CO) maintenance plan for the New Jersey portion of the New York–Northern New Jersey–Long Island (NYNNJLI) CO area. On August 23, 2002, the EPA approved a request from New Jersey to redesignate the New Jersey portion of the NYNNJLI CO area to attainment of the CO National Ambient Air Quality Standard (NAAQS) (67 FR 54574). In addition, the EPA also approved at that time a ten-year CO maintenance plan for the area. The Clean Air Act (the Act) requires that an area redesignated to attainment of the CO NAAQS must submit a second ten-year CO maintenance plan to show how the area will continue to attain the CO standard for an additional ten years. On June 11, 2015, New Jersey submitted a second ten-year CO maintenance plan for the New Jersey portion of the NYNNJLI CO area and requested that EPA approve the plan. This plan also included a request and the justification for shutting down 4 CO maintenance monitors. On February 8, 2016, New Jersey submitted an addendum to the plan which provides additional information to justify the shutdown of one additional CO maintenance monitor. The following sections describe how the EPA made its determination proposing to approve the second ten-year maintenance plan. Additionally, the EPA is proposing to approve the 2007 Attainment/Base Year CO emissions inventory. Finally, the EPA proposes to approve the shutdown of 5 CO maintenance monitors in New Jersey. A more detailed discussion of the EPA's review and proposed action is found in the Technical Support Document (TSD) available in the Docket for this action, and by contacting the individuals in the For Further Information Section.

II. What is the Carbon Monoxide Limited Maintenance Plan for the New Jersey portion of the New York–Northern New Jersey–Long Island Carbon Monoxide area?

A maintenance plan is a SIP revision that must demonstrate continued attainment of the applicable NAAQS in the maintenance area for at least ten years. The Act requires that a second ten-year plan be submitted in order to assure that the area will continue to stay in compliance with the relevant NAAQS. For the NYNNJLI CO area, the New Jersey Department of Environmental Protection is proposing to utilize EPA's limited maintenance plan approach, as detailed in the EPA guidance memorandum, ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas'' from Joseph Paisie, Group Leader, Integrated Policy and Strategies Group, Office of Air Quality and Planning Standards, dated October 6, 1995. Pursuant to this approach, the EPA will consider the maintenance demonstration satisfied for areas if the monitoring data show the design value is at or below 7.65 parts per million (ppm), or 85 percent of the level of the 8-hour CO NAAQS. The design value must be based on eight consecutive quarters of data. For such areas, there is no requirement to project emissions of CO over the maintenance period. EPA believes if the area begins the maintenance period at, or below, 85 percent of the CO 8 hour NAAQS, the applicability of Prevention of Significant Deterioration (PSD) requirements, the control measures already in the SIP, and Federal measures, should provide adequate assurance of maintenance over the 10-year maintenance period.

III. What is included in a maintenance plan?

Section 175A of the Act sets forth the elements of maintenance plans for areas seeking redesignation from nonattainment to attainment. The initial and subsequent ten-year plans must each demonstrate continued attainment of the applicable NAAQS for at least ten years after approval. EPA is proposing action on the second ten-year maintenance plan which covers the period from 2015 through 2024. The specific elements of a maintenance plan are:

A. Attainment Inventory

EPA's October 6, 1995 Limited Maintenance Plan guidance states that for inventory purposes the state is only required to submit an attainment inventory to EPA that is based on monitoring data which shows attainment. There is no requirement to project emissions over the maintenance period. The calendar year inventory selected for the attainment inventory is 2007. This means if 2007 is a calendar year which has monitoring data which demonstrates attainment of the standard, the 2007 base year inventory can be used as the attainment year

inventory and no projection inventories are required over the years of the maintenance period. Only calendar year 2007 summary emissions data (based on a winter season day) are required. In addition, the inventory should be consistent with EPA's most recent guidance on emission inventories for nonattainment areas available at the time and should include emissions during the time period associated with the monitoring data showing attainment.

New Jersey submitted a limited maintenance plan which included a 2007 base year emissions inventory. The 2007 inventory is also classified as the attainment year inventory for the limited maintenance plan. New Jersey has elected 2007 because it is the attainment base year that will be used for the limited maintenance plan and 2007 represents one of the years of violation free monitored data in the area. The inventory included peak winter season daily emissions from stationary point, stationary area, non-road mobile, and on-road mobile sources of CO. These emission estimates were prepared in accordance with EPA guidance.

The EPA is proposing to approve the CO inventory for Hudson, Essex, Bergen, and Union Counties, and the municipalities of Clifton, Passaic and Paterson in Passaic County. Details of the inventory review are located in section IV of this action. A more detailed discussion of how the emission inventory was reviewed and the results of EPA's review are presented in the TSD.

Table 1 presents a summary of the 2007 CO peak winter season daily emissions estimates in tons per day for the NYNNJLI CO area. Again, under the Limited Maintenance Plan guidance, there is no requirement to project emissions over the maintenance period.

TABLE 1—2007 BASE YEAR/ATTAINMENT EMISSIONS INVENTORY NYNNJLI CO AREA

[Tons/Peak Winter Season Day]

County	Point sources	Area sources	Onroad mobile sources	Nonroad mobile sources	Total
Bergen	1.82	14.75	346.29	139.60	502.47
Essex	5.52	12.93	198.99	75.20	292.64
Hudson	2.46	10.05	111.77	35.70	159.97
Passaic	0.32	6.52	144.70	42.30	193.84
Union	4.18	8.31	169.18	53.60	23.27
Total	14.30	52.56	970.93	346.50	1,384.19

B. Maintenance Demonstration

New Jersey has met the Limited Maintenance Plan air quality criteria requirement by demonstrating that its highest monitored design value is less than 85 percent (7.65 parts per million) of the CO standard of 9.0 parts per million. The highest monitored design value in the NYNNJLI CO area for the 2013–2014 design year was 2.5 parts per million at two monitoring sites in New Jersey. In addition, New Jersey commits to continued implementation of all other Federal and State measures already implemented as part of its CO SIP. Thus, according to the Limited Maintenance Plan Guidance, emission projections are not required.

C. Monitoring Network

New Jersey continues to operate its CO monitoring network and will continue to work with the EPA through the air monitoring network review process as required by 40 CFR part 58 to determine the adequacy of its network.

On August 8, 2011, New Jersey submitted their ''New Jersey Ambient Air Monitoring Network Plan 2011'' to the EPA. This document described New Jersey's ambient air monitoring network and also detailed proposed changes and the rationale for them.[1] The reasoning behind the requested CO maintenance monitor shutdowns are included in that submittal. In a letter dated October 27, 2011, the EPA told New Jersey that it will make a determination on New Jersey's analysis in a revision to a CO SIP. Based on the EPA's review, the EPA is proposing approval of these CO maintenance monitor shutdowns. The EPA's review of the New Jersey analysis is included in the accompanying TSD and in Section V of this notice.

New Jersey will continue annual reviews of its data in order to verify continued attainment of the NAAQS. As mentioned earlier, all of New Jersey's 8-hour design values are well below the 9.0 ppm 8-hour NAAQS for CO with the highest monitors in the New Jersey portion of the NYNNJLI reading 2.5 ppm, as shown in Table 2.

TABLE 2—DESIGN VALUES FOR CO IN NEW JERSEY

[8-hour standard—9 parts per million]

Monitoring location	2013–2014 Design value (parts per million)
East Orange	2.5
Camden Spruce Street	1.2
Elizabeth	2.2
Elizabeth lab	1.8
Jersey City	1.8
Newark Firehouse	2.5

In its SIP revision, New Jersey submitted design values from 2006–2007 through 2012–2013. The EPA reviewed more recent data in addition to the submitted data and found the maximum 2013–2014 design value for New Jersey to be 2.5 ppm, which continues to show attainment of the NAAQS.

D. Verification of Continued Attainment

New Jersey will verify that the New Jersey portion of the NYNNJLI CO area continues to attain the CO NAAQS through an annual review of its monitoring data. If any design value exceeds 7.65 ppm, New Jersey will coordinate with EPA Region 2 to verify and evaluate the data and then, if warranted, develop a full maintenance plan for the affected maintenance area.

[1] New Jersey has submitted subsequent 2012, 2013, 2014, and 2015 Monitoring Network Plans. The EPA is only discussing the 2011 Plan because of its relevance to the CO Limited Maintenance Plan.

E. Contingency Plan

Section 175A(d) of the Act requires that a maintenance plan include a contingency plan which includes contingency measures, as necessary, to promptly correct any violation of the NAAQS that occurs after redesignation of the area. Contingency measures do not have to be fully adopted at the time of redesignation. However, the contingency plan is considered to be an enforceable part of the SIP and should ensure that the contingency measures are adopted expeditiously once they are triggered by a specified event. In addition, the contingency plan includes a requirement that the State continue to implement all control measures used to bring the area into attainment.

The triggers specified in New Jersey's previous maintenance plan are included in this Limited Maintenance Plan. If design values in any maintenance area in New Jersey exceeds 7.65 parts per million (ppm), New Jersey will coordinate with the EPA to verify the validity of the data, evaluate the data, and analyze available air quality and meteorological data and related activities in the area. If design values show noncompliance with the 9 ppm standard, New Jersey will implement the appropriate contingency measures.

1. Control Measures

New Jersey has implemented a number of measures to control motor vehicle CO emissions. Emission reductions achieved through the implementation of these control measures are enforceable. These measures include the Federal Motor Vehicle Control Program, Federal reformulated gasoline, New Jersey's pre-1990 modifications to its inspection and maintenance (I/M) program, and local control measures relied on in the SIP.

The State of New Jersey has demonstrated that actual enforceable emission reductions are responsible for the air quality improvement and that the CO emissions in the base year are not artificially low due to local economic downturn. The EPA finds that the combination of existing EPA approved-SIP and Federal measures contribute to the permanence and enforceability of reductions in ambient CO levels that have allowed the New Jersey portion of the NYNNJLI CO area to attain the NAAQS since 1995.

New Jersey commits to continue implementation of all control measures used to bring the area into attainment.

2. Contingency Measures

The State plans to continue to use the contingency measure from the original maintenance plan. The plan included implementation of an enhanced I/M program. This program is fully operational and the State commits to meet the performance standard for an enhanced I/M program in an effort to maintain the CO NAAQS. Although the plan is currently in place, EPA guidance allows for it to act as a contingency measure. We approved this measure in the previous maintenance plan and are proposing to approve it in this action. If, in the future, it becomes necessary to reduce CO levels further, New Jersey will work with the local Transportation Planning Organizations or Metropolitan Planning Organizations to identify and implement transportation control measures such as Transportation Demand Management measures, signal improvement projects, bicycle projects, and various transit related projects as necessary.

F. Conformity

Section 176(c) of the Act defines conformity as meeting the SIP's purpose of eliminating or reducing the severity and number of violations of the NAAQS and achieving expeditious attainment of such standards. The Act further defines conformity to mean that no Federal activity will: (1) Cause or contribute to any new violation of any standard in any area; (2) increase the frequency or severity of any existing violation of any standard in any area; or (3) delay timely attainment of any standard or any required interim emission reductions or other milestones in any area.

The Federal transportation conformity rule, 40 CFR part 93 subpart A, sets forth the criteria and procedures for demonstrating and assuring conformity of transportation plans, programs and projects which are developed, funded or approved by the U.S. Department of Transportation, and by metropolitan planning organizations or other recipients of federal funds under Title 23 U.S.C. or the Federal Transit Laws (49 U.S.C. chapter 53). The transportation conformity rule applies within all nonattainment and maintenance areas. As prescribed by the Rule, once an area has an applicable SIP with motor vehicle emissions budgets, the expected emissions from planned transportation activities must be consistent with (''conform to'') such established budgets for that area.

In the case of the NYNNJLI, CO limited maintenance plan area, however, the emissions budgets may be treated as essentially not constraining for the length of this second maintenance period as long as the area continues to meet the limited maintenance criteria, because there is no reason to expect that these areas will experience so much growth in that period that a violation of the CO NAAQS would result. In other words, emissions from on-road transportation sources need not be capped for the maintenance period because it is unreasonable to believe that emissions from such sources would increase to a level that would threaten the air quality in this area for the duration of this maintenance period. Therefore, for the limited maintenance plan CO maintenance area, all Federal actions that require conformity determinations under the transportation conformity rule are not required to satisfy the regional emissions analysis requirements in 40 CFR 93.118 or 93.119 of the rule (40 CFR 93.109(e)).

Since limited maintenance plan areas are still maintenance areas, however, transportation conformity determinations are still required for transportation plans, programs and projects. Specifically, for such determinations, transportation plans, transportation improvement programs, and projects must still demonstrate that they are fiscally constrained (40 CFR part 108) and must meet the criteria for consultation and Transportation Control Measure (TCM) implementation in the conformity rule (40 CFR 93.112 and 40 CFR 93.113, respectively). In addition, projects in limited maintenance areas will still be required to meet the criteria for CO hot spot analyses to satisfy ''project-level'' conformity determinations (40 CFR 93.116 and 40 CFR 93.123) which must incorporate the latest planning assumptions and models that are available. All aspects of transportation conformity (with the exception of satisfying the emission budget test) will still be required. Approval of the limited maintenance plan does not supersede the current 2014 motor vehicle emissions budget. However, conformity determinations conducted now and in the future would not need to conduct an emission budget test.

If the area should monitor CO concentrations at or above the limited maintenance eligibility criteria or 7.65 parts per million then that maintenance area would no longer qualify for a limited maintenance plan and would revert to a full maintenance plan. In this event, the limited maintenance plan would remain applicable for conformity purposes only until the full maintenance plan is submitted and the EPA has found its motor vehicle emissions budget adequate for conformity purposes or the EPA approves the full maintenance plan SIP revision. At that time regional emissions

analyses would resume as a transportation conformity criteria.

On July 27, 2015, the EPA posted New Jersey's CO limited maintenance plan on its Adequacy Review Web site: *http://www.epa.gov/otaq/stateresources/transconf/adequacy.htm.* We did not receive any comments by the August 26, 2015, deadline. The EPA may now elect to proceed with finding the CO limited maintenance plan adequate for transportation conformity purposes either as part of the SIP's final approval or in a separate notice of adequacy. The EPA's adequacy review process is described in 40 CFR part 93.118(f).

In addition to transportation conformity, approval of the CO limited maintenance plan would have implications for general conformity (40 CFR part 93 Subpart B). Federal actions subject to general conformity would be presumed to conform under a limited maintenance plan as actions in this area will automatically satisfy the budget test of 40 CFR 93.158(a)(5)(i)(A), as described in the October 1995 EPA memo ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas'' from Joseph Paisie, Group Leader, Integrated Policy and Strategies Group, Office of Air Quality and Planning Standards.

IV. What is the New Jersey Attainment/ Base Year CO Inventory?

Section 182(a)(3) and 172(c)(3) of the Act requires the periodic submission of a base inventory for SIP planning processes to address the pollutants for the eight hour-ozone, $PM_{2.5}$ and CO national ambient air quality standard. Identifying the base year gives certainty to states that requires submission of the ozone, $PM_{2.5}$ and CO emission inventories periodically. These requirements allow the EPA, based on the states' progress in reducing emissions, to periodically reassess its policies and air quality standards and revise them as necessary. Most important, the ozone, $PM_{2.5}$ and CO inventories will be used to develop and assess new control strategies that the states will need to submit in their attainment demonstration SIPs for the new national ambient air quality standards for ozone, $PM_{2.5}$ and for CO. The base year inventory may also serve as part of statewide inventories for purposes of regional modeling in transport areas. The base year inventory plays an important role in modeling demonstrations for areas classified as nonattainment and outside transport regions. For the reasons stated above, ideally the EPA would therefore emphasize the importance and benefits of developing a comprehensive, current, and accurate emission inventory (similar to the 1990 base year inventory effort). In this case, the 2007 base year has been selected as the inventory that will be used for planning purposes for the NYNNJLI CO area.

There are specific components of an acceptable emission inventory. The emission inventory must meet certain minimum requirements for reporting each source category. Specifically, the source requirements are detailed below.

The review process, which is described in the accompanying TSD, is used to determine that all components of the base year inventory are present. This review also evaluates the level of supporting documentation provided by the state, assesses whether the emissions were developed according to current EPA guidance, and evaluates the quality of the data.

The review process is outlined here and consists of 8 points that the inventory must include. For a base year emission inventory to be acceptable, it must pass all of the following acceptance criteria:

1. Evidence that the inventory was quality assured by the state and its implementation documented.
2. The point source inventory was complete.
3. Point source emissions were prepared or calculated according to the current EPA guidance.
4. The area source inventory was complete.
5. The area source emissions were prepared or calculated according to the current EPA guidance.
6. Non-road mobile emissions were prepared according to the current EPA guidance for all of the source categories.
7. The method (*e.g.,* Highway Performance Monitoring System or a network transportation planning model) used to develop VMT estimates followed the EPA guidance.
8. On-road mobile emissions were prepared according to the current EPA guidance.

Based on the EPA's review, New Jersey satisfied all of the EPA's requirements for purposes of providing a comprehensive, accurate, and current inventory of actual emissions for CO areas. Where applicable, CO peak winter season daily emissions are provided for the CO nonattainment area. The inventory was developed in accordance with *Emission Inventory Guidance for Implementation of Ozone and Particulate Matter NAAQS and Regional Haze Regulation,* dated August 2005. *Using MOVES to Prepare Emission Inventories in State Implementation Plans and Transportation Conformity: Technical Guidance for MOVES2010, 2010a and 2010b,* April 2012, and *Example Documentation Report for 1990 Base Year for Ozone and CO SIP Emissions Inventories, March 1992.*

A summary of the EPA's review is given below:

1. The Quality Assurance (QA) plan was implemented for all portions of the inventory. The QA plan included a QA/Quality control (QC) program for assessing data completeness and standard range checking. Critical data elements relative to the inventory sources were assessed for completeness. QA checks were performed relative to data collection and analysis, and double counting of emissions from point, area and mobile sources. QA/QC checks were conducted to ensure accuracy of units, unit conversions, transposition of figures, and calculations. The inventory is well documented. New Jersey provided documentation detailing the methods used to develop emissions estimates for each category. In addition, New Jersey identified the sources of data used in developing the inventory.
2. The point source emissions are complete and in accordance with the EPA guidance.
3. The point source emissions were prepared/calculated in accordance with the EPA guidance.
4. The area source emissions are complete and in accordance with the EPA guidance.
5. Area source emissions were prepared/calculated in accordance with the EPA guidance.
6. Emission estimates for the non-road mobile source categories are correctly based on the latest non-road mobile model or other appropriate guidance and prepared in accordance with the EPA guidance.
7. The method used to develop VMT estimates is in accordance with the EPA guidance and was adequately described and documented in the inventory report.
8. The latest MOVES model was used in accordance with the EPA's guidance.

The 2007 base year inventory has been developed in accordance with EPA guidance. Therefore, EPA is proposing to approve the 2007 base year CO emission inventory. A more detailed discussion of how the emission inventory was reviewed and the results of the review are presented in the TSD. Detailed emission inventory development procedures can be found in the following document: *Emission Inventory Guidance for Implementation of Ozone and Particulate Matter NAAQS and Regional Haze Regulation,* dated August 2005; *Using MOVES to Prepare Emission Inventories in State*

Implementation Plans and Transportation Conformity: Technical Guidance for MOVES2010, 2010a and 2010b, April 2012; and *Example Documentation Report for 1990 Base Year for Ozone and CO SIP Emissions Inventories, March 1992.* See Table 1 for a summary of 2007 CO peak winter season daily emission estimates by source sector and by county for the NYNNJLI CO area.

V. Why is New Jersey shutting down 5 CO Maintenance Monitors?

In order to conserve resources, the State is seeking to discontinue monitoring in Burlington, Freehold, Morristown, Perth Amboy, and East Orange since current air quality levels do not warrant the additional expense of running CO monitors in those areas. The State has committed to continue CO monitoring in Camden and Elizabeth, and will reestablish CO monitoring in Burlington, Freehold, Morristown, Perth Amboy, and East Orange if air quality in Camden and Elizabeth degrade significantly. The Camden and Elizabeth sites have been judged to be representative of these 5 CO maintenance monitor sites and are thus acting as their surrogate sites. Starting in the early 1970's, EPA has set national standards that have considerably reduced emissions of CO and other pollutants from motor vehicles, including tailpipe emissions, new vehicle technologies, and clean fuels programs. Because of this, the EPA believes that it is unlikely that the maintenance area will exceed the CO NAAQS again. Thus, we believe that the revisions that New Jersey has made to its maintenance plan will continue to protect the citizens of New Jersey from high CO concentrations, and also conserve resources. Additional detail can be seen in the accompanying TSD to this notice.

VI. What action is the EPA proposing to take?

The EPA has evaluated New Jersey's submittals for consistency with the Act and Agency regulations and policy. The EPA is proposing to approve New Jersey's CO limited maintenance plan because it meets the requirements set forth in section 175A of the Act and continues to demonstrate that the NAAQS for CO will continue to be met for the next ten years. The EPA is also proposing to approve the 2007 Attainment/Base Year CO emissions inventory. Finally, the EPA also proposes to approve the shutdown of 5 CO maintenance monitors in New Jersey, since CO monitoring will continue at other representative locations across the State.

The EPA views the SIP revisions proposed in today's proposal as separable actions. This means that if the EPA receives adverse comments on particular portions of this notice and not on other portions, the EPA may choose not to take final action at the same time in a single notice on all of these SIP revisions. Instead, the EPA may choose to take final action on these SIP revisions in separate notices.

Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA Region 2 Office by the method discussed in the **ADDRESSES** section of this action.

VII. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and the EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: March 14, 2016.

Judith A. Enck,

Regional Administrator, Region 2.

[FR Doc. 2016–06704 Filed 3–24–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 580

[Docket No. NHTSA–2016–0037]

RIN 2127–AL39

Odometer Disclosure Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This notice is being issued pursuant to the Moving Ahead for Progress in the 21st Century Act of 2012 requiring NHTSA to prescribe regulations permitting States to adopt schemes for electronic odometer disclosure statements. To permit States to allow electronic odometer disclosures, NHTSA is proposing to amend the existing requirements to clarify that most of those requirements apply regardless of the technology used for the disclosure. NHTSA is further

proposing to add a new section containing specific additional requirements that would apply only to electronic disclosures to ensure the secure creation and maintenance of the electronic records. Through this proposal NHTSA seeks to allow odometer disclosures in an electronic medium while maintaining and protecting the existing system(s) that ensure accurate odometer disclosures and aid law enforcement in prosecuting odometer fraud. NHTSA is also proposing to extend an existing exemption for vehicles more than 10 years old to 25 years.

DATES: You should submit comments early enough to ensure that Docket Management receives them not later than May 24, 2016.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. Eastern Standard Time, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Regardless of how you submit your comments, you should mention the docket number of this document.

You may call the Docket at (202) 366–9324.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act discussion below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Confidential Information: If you wish to submit any information under a claim of confidentiality, you should submit two copies of your complete submission, including the information you claim to be confidential business information, and one copy with the claimed confidential business information deleted from the document, to the Chief Counsel, NHTSA, at the address given below under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should follow the procedures set forth in 49 CFR part 512 and include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR part 512.)

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and follow the online instructions for accessing the dockets or go to the street address listed above.

FOR FURTHER INFORMATION CONTACT:

For policy and technical issues: Mr. David Sparks, Director, Office of Odometer Fraud, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: (202) 366–5953. Email: *David.Sparks@dot.gov.*

For legal issues: Ms. Arija Flowers, Trial Attorney, Office of the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: (202) 366–5263.

SUPPLEMENTARY INFORMATION:

I. Background

A. Executive Summary

This document is being issued pursuant to the Moving Ahead for Progress in the 21st Century Act of 2012 (MAP–21, or Pub. L. 112–141), which amended Section 32705 of Title 49, United States Code, by adding the following subsection:

> (g) ELECTRONIC DISCLOSURES.—Not later than 18 months after the date of enactment of the Motor Vehicle and Highway Safety Improvement Act of 2012, in carrying out this section, the Secretary shall prescribe regulations permitting any written disclosures or notices and related matters to be provided electronically.

§ 31205, 126 Stat. 761 (2012).

To permit States to allow electronic odometer disclosures, NHTSA is proposing to amend the existing requirements to clarify that most of those requirements apply regardless of the technology used for the disclosure. NHTSA is further proposing to add a new section containing specific additional requirements that would apply only to electronic disclosures to ensure the secure creation and maintenance of the electronic records. Through this proposal NHTSA seeks to allow odometer disclosures in an electronic medium while maintaining and protecting the existing system(s) that ensure accurate odometer disclosures and aid law enforcement in prosecuting odometer fraud. The new issues addressed by the new requirements are electronic signatures, security of the hardware in an electronic odometer disclosure system, determination of official document, power of attorney and record retention. NHTSA is also proposing to modify an existing exemption for vehicles more than 10 years old to 25 years.

B. The Cost Savings Act, the Truth in Mileage Act and Subsequent Amendments

1. The Cost Savings Act

In 1972, Congress enacted the Motor Vehicle Information and Cost Savings Act (Cost Savings Act) to, among other things, protect purchasers of motor vehicles from odometer fraud. See Public Law 92–513, 86 Stat. 947, 961–63 (1972).

To assist purchasers in knowing the true mileage of a motor vehicle, Section 408 of the Cost Savings Act required the transferor of a motor vehicle to provide written disclosure to the transferee in connection with the transfer of ownership of the vehicle. See Public Law 92–513, 408, 86 Stat. 947 (1972). Section 408 required the Secretary to issue rules requiring the transferor to give a written disclosure to the transferee in connection with the transfer of the vehicle. 86 Stat. 962–63. The written disclosure was to include the cumulative mileage registered on the odometer, or disclose that the actual mileage is unknown, if the odometer reading is known to the transferor to be different from the number of miles the vehicle has actually traveled. The rules were to prescribe the manner in which information is disclosed under this section and in which such information is retained. Id. Section 408 further stated that it shall be a violation for any transferor to violate any rules under this section or to knowingly give a false statement to a transferee in making any disclosure required by such rules. Id. The Cost Savings Act also prohibited disconnecting, resetting, or altering motor vehicle odometers. Id. The statute

subjected violators to civil and criminal penalties and provided for Federal injunctive relief, State enforcement, and a private right of action.

Despite these protections, there were shortcomings in the odometer provisions of the Cost Savings Act. Among others, in some States, the odometer disclosure statement was not on the title; instead, it was a separate document that could easily be altered or discarded and did not travel with the title. Consequently, the separate disclosure statement did not effectively provide information to purchasers about the vehicle's mileage. In some States, the title was not on tamper-proof paper. The problems were compounded by title washing through States with ineffective controls. In addition, there were considerable misstatements of mileage on vehicles that had formerly been leased vehicles, as well as on used vehicles sold at wholesale auctions.

2. The Truth in Mileage Act

In 1986, Congress enacted the Truth in Mileage Act (TIMA), which added provisions to the odometer provisions of the Cost Savings Act. See Public Law 99–579, 100 Stat. 3309 (1986). The TIMA amendments expanded and strengthened Section 408 of the Cost Savings Act.

Among other requirements, TIMA precluded the licensing of vehicles, the ownership of which was transferred, in any State unless several requirements were met by the transferee and transferor. The transferee, in submitting an application for a title, is required to provide the transferor's (seller's) title, and if that title contains a space for the transferor to disclose the vehicle's mileage, that information must be included and the statement must be signed and dated by the transferor.

TIMA also precluded the licensing of vehicles, the ownership of which was transferred, in any State unless several titling requirements were met. Titles must be printed by a secure printing process or other secure process. They must indicate the mileage and contain space for the transferee to disclose the mileage in a subsequent transfer. As to lease vehicles, the Secretary was required to publish rules requiring the lessor of vehicles to advise its lessee(s) that the lessee is required by law to disclose the vehicle's mileage to the lessor upon the lessor's transfer of ownership of the vehicle. In addition, TIMA required that auction companies establish and maintain records on vehicles sold at the auction, including the name of the most recent owner of the vehicle, the name of the buyer, the vehicle identification number and the odometer reading on the date the auction took possession of the vehicle.

As amended by TIMA, Section 408(f)(1) of the Cost Savings Act provided that its provisions on mileage statements for licensing of vehicles (and rules involving leased vehicles) apply in a State, unless the State has in effect alternate motor vehicle mileage disclosure requirements approved by the Secretary. Section 408(f)(2) stated that ''[t]he Secretary shall approve alternate motor vehicle mileage disclosure requirements submitted by a State unless the Secretary determines that such requirements are not consistent with the purpose of the disclosure required by subsection (d) or (e), as the case may be.''

3. Amendments Following the Truth in Mileage Act and the 1994 Recodification of the Cost Savings Act

In 1988, Congress amended section 408(d) of the Cost Savings Act to permit the use of a secure power of attorney in circumstances where the title was held by a lienholder. The Secretary was required to publish a rule to implement the provision. See Public Law 100–561 § 40, 102 Stat. 2805, 2817 (1988), which added Section 408(d)(2)(C). In 1990, Congress amended section 408(d)(2)(C) of the Cost Savings Act. The amendment addressed retention of powers of attorneys by States and provided that the rule adopted by the Secretary not require that a vehicle be titled in the State in which the power of attorney was issued. See Public Law 101–641 § 7(a), 104 Stat. 4654, 4657 (1990).

In 1994, in the course of the 1994 recodification of various laws pertaining to the Department of Transportation, the Cost Savings Act, as amended by TIMA, was repealed. It was reenacted and recodified without substantive change. See Public Law 103–272, 108 Stat. 745, 1048–1056, 1379, 1387 (1994). The statute is now codified at 49 U.S.C. 32705 *et seq.* In particular, Section 408(a) of the Cost Savings Act was recodified at 49 U.S.C. 32705(a). Sections 408(d) and (e), which were added by TIMA (and later amended), were recodified at 49 U.S.C. 32705(b) and (c). The provisions pertaining to approval of State alternate motor vehicle mileage disclosure requirements were recodified at 49 U.S.C. 32705(d).

4. FAST Act Amendments

Section 24111 of the Fixing America's Surface Transportation Act of 2015 (FAST Act, or Public Law 114–94), signed into law on December 4, 2015, allows States to adopt electronic odometer disclosure systems without prior approval of the Secretary (''the Secretary'') of the Department of Transportation. Any such system must comply with applicable State and Federal laws regarding electronic signatures under 15 U.S.C. 7001 *et seq.,* meet the requirements of 49 U.S.C. 32705 and provide for ''appropriate authentication and security measures,'' Public Law 114–94 § 24111. States may only adopt electronic odometer systems without prior approval of the Secretary until the effective date of the rules proposed in this notice. Id.

In providing States with the opportunity to implement electronic odometer disclosure systems until the effective date of the regulations now being proposed, the FAST Act amendments do not alter existing statutory odometer disclosure requirements or modify the intent of those requirements. Effective odometer disclosure systems are essential to protecting consumers from odometer fraud and must reduce or eliminate opportunities for such fraud to the greatest practicable extent. Federal and State governments have an interest in preventing such fraud.

The agency's proposed regulations, as contained in this notice, as well as our prior responses to State petitions for approval of alternative disclosure schemes (discussed below) contain guidance on the potential strengths and weaknesses of electronic odometer disclosure schemes and may serve as a resource for States implementing electronic odometer disclosure systems under the FAST Act. NHTSA respectfully requests that States adopting electronic odometer disclosure schemes under the authority granted by the FAST Act be mindful of the persistence and ingenuity of those who would commit odometer fraud as well as their propensity to find and exploit weaknesses in the disclosure requirements of particular jurisdictions. The agency therefore suggests that the issues considered in this notice and the accompanying regulatory proposals be carefully considered in the formulation of any electronic odometer disclosure system.

C. Overview of NHTSA's Odometer Disclosure Regulations

The implementing regulations for the odometer provisions of the Cost Savings Act, as amended, are found in Part 580 of Title 49 of the Code of Federal Regulations (CFR). These regulations establish the minimum requirements for odometer disclosure, the form of certain documents employed in disclosures, and the security of title documents and power of attorney forms. The regulations also set the rules for

transactions involving leased vehicles, set recordkeeping requirements including those for auctions, and authorize the use of powers of attorney in limited circumstances. In addition, Part 580 also contains provisions exempting certain classes of vehicles from the disclosure regulations and provides a petition process by which a State may obtain approval of alternate disclosure requirements. The following paragraphs summarize some of the important aspects of the regulations.

Regulations governing disclosures are codified in 49 CFR 580.5, 580.7 and 580.13. Section 580.5(c) requires, in connection with the transfer of ownership of a motor vehicle, the odometer disclosure by the transferor to the transferee on the title. Following the initial execution
on a title, reassignment documents may be used. As provided by the regulations, in the case of a transferor in whose name the vehicle is titled, the transferor shall disclose the mileage on the title, and not on a reassignment document. Section 580.5(c) requires a transferor to sign, and to print his/her name on an odometer disclosure statement with the following information: (1) The odometer reading at the time of transfer (not to include tenths of miles); (2) the date of transfer; (3) the transferor's name and current address; (4) the transferee's name and current address; and (5) the identity of the vehicle, including its make, model, year, body type, and VIN. The transferor must also, under § 580.5(e), certify whether the odometer reading reflects the vehicle's actual mileage, disclose whether the odometer reading reflects mileage in excess of the odometers mechanical limit or, if the odometer does not reflect the actual mileage, must state that the odometer reading should not be relied on. The transferee must sign the statement. Each title, at the time it is issued to the transferee, must contain the mileage disclosed by the transferor.

To ensure that vehicles subject to leases of 4 months or more have accurate odometer readings executed on titles at the time of transfer, § 580.7(a) requires lessors to provide written notice to the lessee of the lessee's obligation to disclose the mileage of the leased vehicle and the penalties for failure to disclose the information. In connection with the transfer of ownership of a leased vehicle, lessees are required by § 580.7(b) to provide disclosures comparable to those required by §§ 580.5(c) and (e), noted above, to the lessor along with the date the lessor notified the lessee of disclosure requirements. Additionally, the lessor must state the date the lessor received the lessee's completed disclosure statement and must also sign it. Under § 580.7(d) a lessor transferring ownership of a vehicle (without obtaining possession) may indicate the mileage disclosed by the lessee on the vehicle's title unless lessor has reason to believe the lessee's disclosure is inaccurate.

If allowed by State law, the transferor may give the transferee a power of attorney to execute the mileage disclosure on the title, as provided by § 580.13(a) when the title is physically held by a lienholder or has been lost and the transferee obtains a duplicate title on behalf of a transferor. Sections 580.13(b) and (d) provide that the transferor must disclose information identical to that required by §§ 580.5(c) and (e) on part A of the secure power of attorney form. The transferee is required to sign the power of attorney form part A and print his/her name. See § 580.13(e). In turn, § 580.13(f) requires the transferee, upon receipt of the transferor's title, to make on the title exactly the mileage disclosure as disclosed by the transferor on the power of attorney.

After part A of the power of attorney form has been used, part B may be executed when a vehicle addressed on part A is resold. Part B of the secure power of attorney form, if permitted by State law, allows a subsequent transferee to give a power of attorney to his transferor to review the title and any reassignment documents for mileage discrepancies, and if no discrepancies are found, to acknowledge disclosure on the title, while maintaining the integrity of the first seller's disclosure. The disclosure required to be made by the transferor to the transferee for this transaction on part B of the power of attorney form tracks information required to be made by the transferor to the transferee on the title when ownership of a vehicle is transferred on a title under 49 CFR 580.5. Among other things, the power of attorney must contain a space for the transferor to disclose the mileage to the transferee and sign and date the form, and a space for the transferee to sign and date the form.

To ensure that disclosures made through a power of attorney are accurate, § 580.15 requires the person exercising the power of attorney to certify, on part C of the form, that the disclosures made on a title or reassignment document on behalf of the original seller are identical to those found on part A of the power of attorney. This section also requires a certification, when part B is used, that the mileage disclosed and acknowledged under part B is greater than the mileage disclosed in part A.

Odometer disclosures may only be made on certain documents. These specified documents are a vehicle title (§ 580.5(a)), a reassignment document when used by transferors other than those in whose name the vehicle is titled (§§ 580.5(b) and (c)), a disclosure statement made by a lessee (§ 580.7(b)), and a power of attorney when the title is held by a lienholder or is lost (§ 580.13(a)). When the power of attorney authorized by § 580.13(a) is used, a further power of attorney authorized by § 580.14(a) may be employed to allow a subsequent transferee to approve the seller's disclosure, per § 580.16. Both of the aforementioned powers of attorney must be on the same form.

Section 580.4 requires titles, reassignment documents, and the power of attorney form described §§ 580.13 and 580.14 to be protected against counterfeiting and tampering by a secure printing process or other secure process. These titles, reassignment documents, and powers of attorney must contain a statement referring to Federal odometer law and a warning that failure to complete the form or providing false information may result in fines or imprisonment pursuant to §§ 580.5(d), 580.13(c), and 580.14(c). For a leased vehicle, the lessor is obligated to provide the lessee with written notice of the obligation to make a mileage disclosure and that notice must contain the same warnings (§ 580.7(a)). Except in the limited context of the proper use of the power of attorney forms, no person shall sign an odometer disclosure statement as both the transferor and transferee in the same transaction (§ 580.5(h)).

Part 580 establishes minimum requirements for record retention, which ensures that adequate records exist to create a ''paper trail'' sufficient to support detection and prosecution of odometer fraud. Section 580.8(a) requires motor vehicle dealers and distributors who are required to issue an odometer disclosure to retain copies of each odometer statement they issue and receive for five years. Lessors of leased vehicles must retain the odometer statement they receive from their lessee for five years from the date they transfer ownership of the leased vehicle (§ 580.8(b)). If a power of attorney authorized by §§ 580.13 and/or 580.14 has been used, dealers must retain copies of the document for five years (§ 580.8(c)). Section 580.9 requires auction companies to retain the name of the most recent owner on the date the auction took possession of the motor

vehicle, the name of the buyer, the vehicle identification number and the odometer reading on the date the auction company took possession of the motor vehicle for five years from the date of sale. States are required, under § 580.13(f) to retain the original copy of the power of attorney authorized by § 580.13(a) or (b) and the title for a period of three years or a time period equal to the State's titling record retention period, whichever is shorter.

In addition to the recordkeeping requirements, Part 580 also requires that subsequent buyers of a vehicle that was transferred to their seller through a disclosure made with a Part A power of attorney under § 580.13(a) have access to that power of attorney if they elect not to use Part B and return to the seller to acknowledge disclosure on the title itself (§ 580.16).

Other sections of Part 580 establish a petition process by which States may seek assistance in revising their odometer laws (§ 580.10), may seek approval of alternative odometer disclosure schemes (§ 580.11), and establish exemptions from the disclosure requirements of § 580.5 and § 580.7 (§ 580.17). The exemptions in 580.17 apply to transfers or leases for: (1) Vehicles with a Gross Vehicle Weight Rating (GVWR) over 16,000 pounds; (2) vehicles that are not self-propelled; (3) vehicles manufactured in a model year beginning ten years before January 1 of the calendar year in which the transfer occurs; (4) certain vehicles sold by the manufacturer to any agency of the United States; and (5) a new vehicle prior to its first transfer for purposes other than resale.

D. Previous State Petitions for Approval of Electronic Odometer Disclosure Schemes

The Cost Savings Act, as amended by TIMA in 1986, contains a specific provision on approval of State alternative odometer disclosure programs. Subsection 408(f)(2) of the Cost Savings Act (now recodified at 49 U.S.C. 32705(d)) provides that NHTSA shall approve alternate motor vehicle mileage disclosure requirements submitted by a State unless NHTSA determines that such requirements are not consistent with the purpose of the disclosure required by subsection (d) or (e) as the case may be. (Subsections 408(d), (e) of the Costs Savings Act were recodified to 49 U.S.C. 32705(b) and (c).)

Six States—Virginia, Wisconsin, Florida, New York, Texas, and Arizona—have filed petitions with NHTSA seeking approval of electronic alternative odometer programs under 49 U.S.C. 32705(d)). NHTSA has approved, in whole or in part, five of these six petitions and has not yet taken final action on the sixth and most recent petition. A review of these petitions and the agency's responses is instructive regarding the various concerns raised by the implementation of electronic odometer disclosure systems.

1. Virginia

In December 2006, the Commonwealth of Virginia petitioned NHTSA to approve the Commonwealth's proposed electronic odometer disclosure requirements for intrastate transactions involving vehicles not subject to a lien. Virginia's proposal contemplated a paperless system where users would enter data directly into a State electronic system. To authenticate the identity of the participants, Virginia's petition stated that a unique personal identification number (PIN) and a unique customer number that would both be physically mailed to the individual would be used in conjunction with the customer's date of birth (DOB) to allow creation of an electronic odometer disclosure statement and signature. For dealers, the Virginia proposal stated that each dealer would provide the State with a list of employees authorized to make disclosures for the dealership. These individuals would be provided customer number PINS by mail and would use these identifiers in the same fashion as a private individual to verify their identity so they could complete transactions. In addition, transactions involving dealerships would require that the dealership enter a dealer number to complete the transaction.

Virginia's proposed electronic odometer disclosure would be made in the same way a paper disclosure would be made. The transferor would fill out the electronic form that contained the same entries and warnings as those found on a paper title and then sign it electronically. The transferee would then examine the odometer disclosure executed by the transferor and either accept it or reject it. The disclosure statement would be linked to the electronic title and the transferor would be instructed to mail any existing paper title to the State for destruction. The proposal also stated that the transferee could obtain a paper copy of the title upon request.

After finding that the Virginia proposal would properly verify the identity of users, would provide an equivalent level of security to the paper system, and would create an adequate system of records, NHTSA granted Virginia's request on January 7, 2009 (74 FR 643).

2. Texas

Texas filed a petition seeking approval of alternative odometer disclosure requirements in June 2008. The State proposal would transfer vehicles' titles electronically for in-state transactions between residents where there are no security interests in the vehicle. The proposal did not encompass leased vehicles, the use of a power of attorney, or interstate transactions. Texas's system would eliminate paper titles (except as requested) by creating an electronic title and require transfers of vehicle title for in-state transactions to be made using the internet. The identities of the parties, who would have to be Texas residents holding a valid State identification credential, would be verified by matching four personal data elements and two forms of identification against a State database. Odometer mileage disclosures would be made by requiring the seller and buyer to separately log into a secure Web site and each enter the odometer mileage. Upon successful completion of the transaction, the seller would mail the paper title to the State for destruction. The title would remain as an electronic record and the transferee could receive a paper title on request.

NHTSA's initial determination, published on November 18, 2009, 74 FR 59503, preliminarily granted the Texas petition on the condition that Texas amend its program to enable transferees to obtain a paper copy of the title that met the requirements of TIMA, require dealers to retain a copy of all odometer disclosures that they issue and receive, and require disclosure of the brand (the brand states whether the odometer reflects the actual mileage, reflects the mileage in excess of the designated odometer limit or differs from the actual mileage and is not reliable.) Id. at 59506. Following submission of comments by Texas clarifying features of its proposal, NHTSA granted the Texas petition in a final determination issued on April 22, 2010. 75 FR 20925. The final determination noted that the Texas petition and comments indicated that the proposed system contained sufficient safeguards and record keeping requirements to meet the purposes of TIMA. Further, the agency noted that since Texas would require persons with an electronic title to submit any paper titles to the State for destruction, the proposal would prevent potential mischief caused by duplicate titles. Id. at 20929.

3. Wisconsin

In September 2009, Wisconsin filed a petition seeking approval of an electronic odometer disclosure system limited to intrastate transactions involving motor vehicle dealers. Identity verification would be based on customers entering a minimum of three personal identifiers—name, address, date of birth, product number, Driver License/ID number, and a Federal Employer Identification Number or partial Social Security Number—in the State system. Once the user is verified under this scheme, the user could begin the title transaction. As with the earlier petitions, Wisconsin proposed that electronic odometer disclosures be linked to, and become part of, the title record in the State's database and a title transfer could not be completed unless an electronic odometer disclosure had been completed. Also, if a paper title is needed, the Wisconsin DMV would print the title on secure paper with the odometer disclosure statement in the proper location and format under existing rules.

In April 2010, NHTSA published an Initial Determination proposing to approve Wisconsin's program, subject to the resolution of certain concerns. 75 FR 20965 (Apr. 22, 2010). In particular, NHTSA raised questions about how the Wisconsin program would manage odometer disclosures for leased vehicles. In response to NHTSA's concerns, Wisconsin submitted comments stating that lessee odometer disclosures would be addressed in the future.

NHTSA published a Final determination approving a revised Wisconsin electronic odometer disclosure plan on January 10, 2011. 76 FR 1367. The Agency found the Wisconsin proposal to be consistent with the odometer disclosure requirements. The verification scheme and form of the electronic disclosure provided adequate assurances that the persons executing the disclosure were the actual transferor and transferee. Thereafter the odometer disclosure statement would reside as an electronic record in the Wisconsin database and would be linked to the vehicle's title. NHTSA also noted that the electronic title would, under Wisconsin law, be the official title and that paper titles would be issued only if needed for an interstate transaction or a transfer that could not be completed electronically.

4. Florida

In December 2009, Florida proposed a hybrid electronic disclosure system in which the electronic transactions would be performed through authorized tag agents. Because the electronic data entries would only be made through terminals located at tag agent locations, Florida proposed that the required odometer disclosures for certain transactions would be made on physical documents that would then be delivered to tag agents who would then enter disclosure information into the State system. Under Florida's proposal a seller with a vehicle having an electronic title wishing to sell the car would visit a tag office with the buyer. After providing adequate identification to the tag agent, the buyer and seller would sign, in the presence of the tag agent, a secure reassignment form transferring ownership and disclosing the odometer reading. A title would then be issued in the buyer's name and stored electronically, or the buyer could choose to have the title printed as a physical document.

For transactions involving dealers, Florida proposed that a seller with e-title would bring the vehicle to a dealership. The seller and dealer would complete a secure reassignment form with odometer disclosure. When the dealer sold the vehicle to another buyer, the dealer and buyer would complete another secure reassignment form with odometer disclosure. The dealer would take both of the secure reassignment forms to a tag agency. The vehicle title would then be transferred to the buyer and the buyer would have the option to obtain a paper title or have Florida's Department of Transportation hold the title electronically.

Under Florida's proposal, the lessor of a leased vehicle would hold an e-title. When the lease ends, the lessee would bring the vehicle to a dealership. The lessee would sign an odometer disclosure statement on a secure physical document. The lessor would then sign a secure physical power of attorney to the dealer authorizing the dealer to execute the odometer disclosure. The dealer would then sign a physical secure reassignment form agreeing with the odometer disclosure. When the dealer sold the vehicle to another buyer, the dealer would take the various physical documents (bill of sale, reassignment document, and power of attorney) to the tag agency, where the title would be transferred to the buyer. The buyer would then have the option of obtaining a new paper title or having the Florida Department of Transportation hold the vehicle title electronically.

NHTSA's final determination granted the Florida petition in part and denied it in part. 77 FR 36935 (June 20, 2012). Florida's request was granted for electronic transactions involving transfers between private parties but was denied for transactions involving dealers and leased vehicles. Among other things, NHTSA's final determination observed that transactions involving dealers relied on a number of odometer disclosures being made on documents other than the title itself. This, in the Agency's view, was inconsistent with TIMA's command that disclosures be made on the title and not on a separate document. Further, the Florida scheme for dealer transactions would result in new registrations being issued after submission of a disclosure statement made on a physical reassignment document rather than on the title itself, thereby violating the requirement that a vehicle may only be registered if the new owner submits a title containing the odometer disclosure statement. NHTSA denied Florida's proposed requirements for leased vehicles on similar grounds. Because of the proposed system's reliance on tag agents as the only point of data entry, completion of a transaction and execution of the required disclosure statements required that the disclosures be made on a number of documents, none of which were the actual title. These documents also did not meet other content and security requirements. Moreover, the use of a power of attorney in an instance where the lessor would have access to the title, was viewed by the Agency as inconsistent with the narrow set of circumstances under which such a power of attorney could be used under TIMA.

5. New York

The State of New York filed a petition with NHTSA in November 2010, seeking approval of alternative odometer disclosure requirements. The New York petition sought to convert the State's existing paper process for dealer transactions to an electronic process in which an authorized dealership user would sign on to the State's planned system and enter the vehicle's identifying information. The vehicle's odometer reading, disclosed on the title in the case of a consumer trading in or selling a vehicle to the dealer, would be recorded in the system by the dealer. Access to the system itself would occur only at dealerships by specific dealer employees whose identity would be verified by State issued credentials.

If that dealer sold a vehicle to another licensed New York dealer, the selling dealer would sign on to the proposed electronic system and enter current vehicle information, including the current odometer reading, as well as seller and purchaser information. The

purchasing dealer would subsequently sign on to the system and review the vehicle's identifying information, including the odometer disclosure statement made by the selling dealer, and either accept or reject the transaction. If the purchasing dealer accepted the transaction it would be considered complete. The original pre-dealer title (still in the prior owner's name) would be surrendered to the purchasing dealer at the time of sale. Subsequent transfers between licensed New York dealers would be recorded in the same manner. The history of the vehicle's identifying information entered into the system at each transfer would be maintained on the system.

Under the New York proposal, when a vehicle owned by a New York dealer is sold to a retail purchaser, salvage dealer, out-of-state buyer or other non-New York dealer purchaser, the selling dealer would access the vehicle information on the system. The selling dealer would enter current vehicle information, including the current odometer reading, and would enter seller and purchaser information. A two-part sales receipt/odometer statement would be created on the system. The purchaser would then review the information, including the odometer statement, on the draft receipt displayed on the computer screen. If the purchaser agrees with the odometer statement and other information, the authorized dealer representative would save the data in the system and then print a two-part sales receipt. Both parties would then sign the odometer disclosure statement printed on each of the two parts of the receipt. The dealer would retain the dealer part of the receipt for its files, while the purchaser would be given the purchaser's copy of the receipt along with the original title acquired by the dealer when it purchased the vehicle.

NHTSA's initial determination denied the New York petition because it used a non-secure receipt for odometer disclosure in transfers between New York dealers and out-of-state buyers and was therefore inconsistent with Federal odometer law. 76 FR 65487, 65491 (Oct. 21, 2011). New York subsequently amended its proposal by replacing the non-secure document with a secure State issued paper, New York State MV–50 (Retail Certificate of Sale) form. The result of this change was that a consumer purchasing a vehicle from a dealer would then receive the original title and odometer statement executed by the owner who sold the vehicle to the dealer and the secure MV–50 form with an odometer disclosure. In addition, the mileage disclosed at the time of the sale to the dealer and the mileage disclosed at the time the dealer sold the vehicle to the subsequent retail purchaser would be recorded in New York's system and available for viewing through a web portal.

The Agency's final determination, 77 FR 50381 (Aug. 12, 2012), granted the New York petition as amended. NHTSA found that the employment of the secure State issued and numbered MV–50 form, in conjunction with the odometer disclosure on the original seller's title and the recording of these disclosures in New York's electronic system, met the purposes of TIMA.

6. Arizona

In December 2011, Arizona filed a petition with NHTSA seeking approval of alternative odometer disclosure requirements. The Arizona proposal was limited to transactions involving licensed Arizona dealers and did not encompass interstate transactions. Under this proposal, dealers would electronically scan and upload documents to the State. Dealers would scan documents using a specified format and resolution, encrypt the scanned images and transmit the images to a secure system using account codes, user/group profiles, and passwords. The State would retain electronic files in a document management system, and dealers would be required to retain hard copies of the documents. The disclosures would not be made on a title but on a form described as a Secure Odometer Disclosure. This form would be completed and signed by hand and submitted to Arizona along with other documents after being scanned. The petition appears to propose that the title would not be among the documents submitted to Arizona, and it may be that this procedure would be followed if the seller's title is an electronic title. If the dealer sells the vehicle, that dealer would again scan and electronically submit a Secure Odometer Disclosure, but not the title, to Arizona after selling the vehicle. The dealer would retain the original Secure Odometer Disclosure forms for the retention periods specified by Federal and Arizona law.

In instances where a dealer sought to sell a vehicle that had been purchased from an owner with a paper title, Arizona also proposed that the vehicle would be resold by a dealer using the paper title from the transferor. It appears, based on this description and the requirements of Arizona law that a dealer's name shall be recorded on a title certificate as transferee or purchaser and that a title include space for dealer reassignment information, that the dealer would make an odometer disclosure on the paper title at the time it resells the vehicle. However, the petition also specifies that if the dealer applies for a new title in the name of the vehicle purchaser, the dealer and purchaser would complete a Secure Odometer Disclosure form. The dealer would then scan and electronically submit a title application, the paper title, the Secure Odometer Disclosure form, and supporting documents to Arizona. The dealer would retain the original documents (including the original paper title) for the retention periods specified by Federal and Arizona law. According to the petition, a new title would be sent to the buyer if there is no lien on the vehicle. If there is a lien, both the lien and the title would be maintained as electronic records by the Arizona Department of Transportation.

NHTSA issued an initial determination denying the Arizona petition on August 20, 2012. 77 FR 50071. In this initial determination, the Agency stated that the Arizona petition did not meet 49 CFR 580.11(b), which establishes the requirements for alternative disclosure requirement petitions. The petition did not, in NHTSA's view, set forth the motor vehicle disclosure requirements in effect in the State or adequately demonstrate that the proposal was consistent with the purposes of the Motor Vehicle Information and Cost Savings Act. In regard to the latter, the agency found that making disclosures on documents other than the title, the proposed use of non-secure forms, the failure to address record keeping requirements, and the potential for alterations posed by the use of scanned documents were all inconsistent with the purposes of TIMA.

7. Ongoing Concerns Regarding Electronic Odometer Disclosures in Light of Previous State Petitions

NHTSA's experience in processing State petitions for alternative electronic odometer disclosure schemes illustrates a number of concerns that remain relevant for the purposes of this rulemaking. First and foremost, any electronic odometer disclosure system must be conceived with a full appreciation of the importance of following the command found in TIMA that odometer disclosures must be made on the title itself, or the electronic equivalent of that title, and not, except for a very limited number of exceptions, on any other document. In particular, an electronic odometer disclosure system should minimize or eliminate odometer disclosures made on physical documents instead of promoting the use of such documents as some proposals

examined by NHTSA have done. Similarly, an electronic odometer disclosure system may not rely on a method of transmitting secure paper documents if that method does not preserve the security features now present in physical titles, reassignments, and powers of attorney. A low resolution scan of such a document is not secure and such a scan may not reveal forgeries or alterations.

In addition, as addressed below, any electronic odometer disclosure system must provide adequate means for verifying the identity of transferors and transferees. In the absence of such verification, unauthorized and inaccurate disclosures could easily be entered into State systems by imposters, defeating the purposes of the Cost Savings Act and enhancements established in TIMA and the subsequent amendments. Electronic title and odometer disclosure systems must also foreclose the possibility that a seemingly valid physical paper title and an electronic title may co-exist. The presence of two such ''valid'' titles invites fraud and creates opportunities for confusion and deception. While States are under no obligation to implement electronic odometer disclosure systems that accommodate transactions involving leased vehicles, any system that proposes to do so must employ measures that meet the existing regulatory requirements without employing physical forms such as a power of attorney that are not authorized under agency regulations. Finally, all electronic odometer disclosure systems must be designed not to impede interstate vehicle sales while providing consumers with protection against odometer fraud. Unless and until electronic odometer disclosure is implemented in all States, Territories, and the District of Columbia, secure paper titles or their equivalent will be needed for the purposes of making odometer disclosures in interstate transactions.

II. e-Manifest

In developing this proposal, NHTSA reviewed the experience of the Environmental Protection Agency (EPA) during the development of its requirements for electronic manifests for hazardous waste. See 79 FR 7517 (Feb. 7, 2014). While the authority EPA was operating under is different from NHTSA's current authority, and the existing system differed from the current odometer disclosure system, NHTSA believes there are lessons to be learned from EPA's experience transitioning from a paper to electronic environment.

The EPA proposal envisioned the agency setting minimum standards for an e-manifest system and various private entities stepping forward to develop and make available such systems. The ''EPA proposed standards in 3 distinct areas: (1) Standard electronic data exchange formats for the manifest; (2) electronic signature methods that could be used to execute manifest signatures electronically; and (3) standard system security controls and work flow procedures to ensure the reliable and consistent processing of manifest data by electronic manifest systems, as well as to ensure the availability and integrity of manifest data submitted through the electronic systems.'' [1] Commenters expressed concern that this proposal could lead to numerous inconsistent approaches to e-manifest, a particular problem for companies with large numbers of inter-state transactions. Others criticized the rigor of the standards proposed which set a higher bar than existed for paper documents. Still others noted that such detailed requirements could frustrate technology in an area which was constantly changing.

The EPA's ultimate solution was to develop a centralized system controlled by the EPA and funded by user fees. This option is not available to NHTSA for odometer disclosures. Nevertheless, we are mindful of the comments EPA received. Vehicle transactions cross State boundaries and the need for various State systems to interact must be considered. Further, both traditional paper-based and electronic systems are likely to exist in neighboring States for some time and must facilitate interstate transactions while providing protection against odometer fraud. The MAP–21 mandate to permit electronic odometer disclosures could be frustrated by requirements that set an unnecessarily higher bar than currently exists for paper documents. However, NHTSA believes that achieving the objectives of the statute—to ensure that consumers receive valid representations of the actual vehicle mileage at the time of transfer and to detect, prevent, and aid in prosecuting odometer fraud—some aspects of the specific disclosure requirements may need to differ for traditional and electronic systems. It is also neither helpful to the public nor wise to create rules that NHTSA must regularly amend to adapt to technological changes. Accordingly, NHTSA has been, and remains, aware of these lessons in developing this proposal.

[1] 79 FR 7517, 7519 (Feb. 7, 2014).

III. Current Proposal

A. Purpose of Odometer Disclosure Requirements

The overall purpose of the odometer disclosure provisions of the Cost Savings Act, as amended, is to protect consumers by assuring that they receive valid representations of a vehicle's actual mileage at the time of transfer. An additional purpose is to create a system of records and a ''paper trail'' to facilitate detection and prosecution of odometer fraud. The statutory scheme and the current regulations adopted by NHTSA aim to achieve these overall purposes.

In developing the current proposal for electronic odometer disclosures pursuant to MAP–21, NHTSA desires a regulation that continues to achieve these purposes without imposing overly burdensome requirements that are not necessary to achieve these purposes in an electronic environment. That is, electronic disclosures must be made accurately by the actual parties to the transaction to protect consumers and provide assurances that a transferee receives a valid representation of a vehicle's actual mileage at the time of transfer. In addition, electronic disclosure schemes must have retention requirements to create a secure and reliable electronic trail to facilitate detection and prosecution of odometer fraud. Unique issues the agency considered were the ability of different State electronic systems to share data, and the security of that information sharing, as well as the ability to issue secure paper documents for use in States which do not choose to adopt electronic disclosure requirements.

An additional issue considered by the agency was the possibility that, if NHTSA were to adopt only minimum requirements necessary to achieve the above stated purposes, States that voluntarily chose to permit electronic odometer disclosures could do so in ways which could eventually create enough variation to hinder on-going efforts among the States to develop a national system for electronic titling of motor vehicles. However, NHTSA determined that its authority under MAP–21 was intended only to facilitate the change to electronic odometer disclosures, not to impose additional requirements for odometer disclosures. NHTSA requests comments, however, on whether it should go further than proposed in this notice in order to prevent, or limit, variation among the various State systems.

B. Odometer Disclosure Requirements

As noted earlier, NHTSA believes that meeting the objectives of the statute will require some variation in the requirements for traditional and electronic systems. To achieve this, NHTSA is proposing to restructure the requirements to accommodate both ''physical'' and ''electronic'' documents. Therefore we are proposing to amend 580.1 to add the option of electronic disclosures; 580.3 to add new definitions and amend existing definitions to accommodate physical and electronic filings; 580.4 to clarify separate requirements for the security of physical disclosures and electronic disclosures; 580.5 to clarify methods of disclosure for physical and electronic systems; 580.7 to add provisions allowing for the option of electronic disclosures for leased motor vehicles; 580.8 to include electronic copies among the forms of disclosures that must be retained and general requirements for that retention; 580.10 to update the address for NHTSA; 580.11 to add the newly created 580.6 to the sections a State may seek exemption from via petition for alternative disclosure requirements and update the address for NHTSA; 580.13 and 580.14 to revise the provisions relating to the use of a power of attorney to address the potential that transferors from an electronic title State wishing to convey a vehicle to a transferee in a physical title State may not have an opportunity to obtain a State issued secure physical title before transferring ownership of the vehicle and to correct a typographical error that would bring the disclosure requirements into conformity with the disclosure requirements under 580.5 and 580.7; 580.15 to add language clarifying that power of attorney certification is limited to physical document disclosures; and 580.17 to extend the disclosure exemption from ten years to twenty-five years and provide an updated example. NHTSA is proposing to strike the regulatory text in section 580.12 as the provision is obsolete and to reserve the section. Finally, NHTSA is proposing to create a new section 580.6 (previously reserved) which would contain unique requirements for electronic odometer disclosures.

1. Definitions

The most basic proposed change NHTSA is making is to add new definitions for the terms ''Electronic Document,'' ''Physical Document,'' and ''Sign or Signature,'' which are necessary to provide clarity in the requirements for each, taking into account the different security concerns and practical challenges that arise under the different disclosure systems. NHTSA requests comments on whether the following new definitions are appropriate and properly identify the items and actions intended.

a. Electronic Document. NHTSA proposes to add ''Electronic Document'' to the defined terms in part 580.3. This addition is necessary to provide clarity for the requirements and procedures applicable to these documents, as opposed to documents in paper format. NHTSA proposes to define ''Electronic Document'' to mean ''a title, reassignment document or power of attorney that is maintained in electronic form by a state, territory or possession that meets all the requirements of this part.''

b. Physical Document. NHTSA proposes to add ''Physical Document'' to the defined terms in part 580.3. This addition is necessary to provide clarity for the requirements and procedures applicable to these documents, as opposed to documents in electronic format. NHTSA proposes to define ''Physical Document'' to mean ''a title, reassignment document or power of attorney printed on paper that meets all the requirements of this part.''

c. Sign or Signature. NHTSA proposes to add definitions for ''Sign or Signature'' applicable to physical document disclosures and to electronic document disclosures to the terms defined in part 580.3. This addition is necessary to clarify the actions and requirements that qualify as a signature or the signing of a document in the different contexts of physical and electronic disclosures. Further, electronic records of contractual agreements are capable of verification through methods other than written words, and may include sounds, other symbols, or processes. *See* 15 U.S.C. 7006(5) (providing a definition of ''electronic signature''). NHTSA proposes to define ''Sign or Signature'' as meaning ''[f]or a paper odometer disclosure, a person's name, or a mark representing it, as hand written personally'' and ''[f]or an electronic odometer disclosure, an electronic sound, symbol, or process using an authentication system equivalent to or greater than Level 3 as described in National Institute of Standards and Technology (NIST) Special Publication 800–63–2, *Electronic Authentication Guideline,* which identifies a specific individual.''

2. Identity of Parties to a Motor Vehicle Transfer and Security of Signatures

One issue NHTSA considered was the electronic equivalent of the existing requirements for physical signatures on odometer disclosures and how to securely authenticate an electronic signature. This is particularly important because in an electronic environment documents may be ''signed'' remotely. To address this issue, NHTSA reviewed the guidance in the National Institute of Standards and Technology (NIST) Special Publication 800–63–2, *Electronic Authentication Guideline.* The publication defines four levels of assurance, Levels 1 to 4, in terms of the consequences of authentication errors and misuse of credentials, with Level 1 being the lowest assurance level, and Level 4 as the highest. Based on the level, different levels of authentication are recommended to help ensure the security of the information. NHTSA also reviewed a December 16, 2003 memorandum from the Director of the Office of Management and Budget (OMB) to the Heads of all Federal Departments and Agencies.[2] This memorandum guidance was issued by OMB under the Government Paperwork Elimination Act of 1998, 44 U.S.C. 3504 in light of the NIST publication. Attachment A to this memorandum supplements OMB Circular A–130, Management of Federal Information Resources, Appendix II, Implementation of the Government Paperwork Elimination Act (GPEA). While both the NIST publication and the OMB memorandum are directed towards Federal Departments and Agencies, NHTSA believes they provide good guidance in this instance also.

NHTSA is aware that the American Association of Motor Vehicle Administrators (AAMVA) published a report from its Electronic Odometer Task Force in December 2014 (E-Odometer Task Force Report).[3] In this report AAMVA recommends that States implement an electronic signature verification system that complies with at least NIST Level 2, however it also notes that some of the identification discussed would comply with NIST Level 3. As discussed below, NHTSA has made a preliminary determination that at least NIST Level 3 verification should be required, both to prevent the potential harm of fraudulent disclosures and to aid in their prosecution.

Attachment A to the OMB memorandum sets out six potential

[2] OMB Memorandum M–04–04, 12/16/03, *https://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy04/m04-04.pdf.*

[3] *http://www.aamva.org/e-Odometer-Task-Force/.*

impact categories, and then, depending on whether the impact is low, moderate, or high, assigns a NIST assurance level. The Attachment does not provide specific guidance for how to assign an overall assurance level if potential impact categories fall in different levels. The impact categories are:

- Inconvenience, distress or damage to standing or reputation.
- Financial loss or agency liability.
- Harm to agency programs or public interests.
- Unauthorized release of sensitive information.
- Personal Safety.
- Civil or criminal violations.

In reviewing these impact categories, NHTSA notes a definite potential for financial loss. The purpose of odometer fraud is to induce consumers to pay more for a used vehicle than they would if they knew the accurate mileage. For an individual consumer, it is important that the value of the vehicle reasonably match the price agreed to, and paid, based upon the information available to the consumer and provided by the seller. In addition, odometer fraud is often committed by the same individual(s) or entities multiple times, resulting in high dollar amounts of damages. State electronic title and odometer disclosure systems will also contain sensitive personal information that could be subject to unauthorized release if the system were not sufficiently secure. Last, odometer fraud is a criminal offense that victimizes innocent consumers. NHTSA and other enforcement agencies use odometer disclosure documents to prove these criminal violations.

Therefore, after reviewing this document, NHTSA has made a preliminary decision that a high level of assurance in the accuracy of the identity of the person making an odometer disclosure is necessary, and therefore the appropriate level of security for odometer disclosures is Level 3 according to the NIST guidelines. NHTSA is therefore proposing that any State which allows electronic odometer disclosures require security protocols at this level or higher. Under the NIST guidelines (*http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf*), a Level 3 system must have certain minimum attributes. These attributes include verification of the name associated with the user, issuance of a credential to the user through a separate channel such as postal mail, text message or telephone call directed at an address or number confirmed through examination of different independent databases and use of that credential to gain access to the Level 3 system. For example, a person wishing to make odometer disclosures electronically without having to appear in person at a State motor vehicle agency would need to have a valid Government ID number and a financial institution or utility account number that could be confirmed through examining records containing those numbers. The State entity providing the e-title and odometer disclosure service would then check the information provided by the individual and confirm that the name, date of birth, and other personal information in the examined records are consistent and sufficient to identify a unique individual. The State entity would then issue a credential by postal mail or some other means that would direct the credential to the proper person. The issued credential would then be employed by the user to obtain access to the electronic odometer and title system. As outlined in the NIST guidelines, other methods may be employed to attain Level 3 authentication but the important principle, in NHTSA's view, is that Level 3 requires multi-factor identification of an individual applicant who, once their identity has been verified, is provided with a unique credential in order to access the system.

NHTSA is therefore proposing that the requirement for Level 3 authentication be incorporated in the definition of ''signature'' for electronic disclosures. However, this also will require the use of computers by all parties for all transfers in electronic title States. NHTSA requests comments on the appropriate NIST level and if specific identification verification(s) should be required, and further requests comments on how such a system should be implemented, including whether dealers should be required to provide secure computing services to transferors and transferees and what security measures should be mandatory for such services.

Next, NHTSA is proposing to require that each ''signature'' in an electronic environment apply only to a single individual, not to an organization. For example, if a dealership wished to allow multiple employees to execute odometer disclosures on behalf of the dealership, each employee would be required to have and maintain a distinct access identity or code to the electronic odometer system so that the actual individual making the disclosure, not just the dealership, is identified by the ''signature.'' The dealer or entity on whose behalf the individual is making the disclosure must also be identified in the transaction and the dealer(s) and entity on whose behalf the individual works must be recorded as part of the individual's distinct access identity or code.

NHTSA also considered the existing requirements that various parties provide copies of documents as part of the odometer disclosure process, and what would qualify as an equivalent in an electronic environment. For example, section 580.5(f) requires the transferee to return a copy of the odometer disclosure document to the transferor after it is signed. Under the current system, the transferee may apply for a new title for the vehicle, and generally, a State will not title a vehicle without an odometer disclosure statement that contains the signatures of both the transferor and the transferee. However, the State does not usually verify that a copy of the document was returned to the transferor or that the transferor retained it. For this reason, NHTSA is concerned about imposing any requirement in the electronic environment that would be more restrictive than these current requirements. NHTSA therefore proposes to specify only that the requirement to provide a document is satisfied by electronically transmitting the document, provided that the State allows the parties to the transaction access to the completed disclosure statements.

As discussed previously, one purpose of the signature requirement is to aid in the prosecution of odometer fraud. For this reason, NHTSA proposes requiring an electronic ''signature'' to identify an individual, not a business, for example. NHTSA requests comment on whether any other requirements are necessary to ensure that investigators can back trace an electronic ''signature'' to identify the individual and/or computer used in the electronic equivalent of a ''paper trail.'' Conversely, if an odometer disclosure is altered, do the proposed system requirements develop an adequate ''paper trail'' to lead investigators to the IP address or computer used to alter the disclosure, and if not, what additional system requirements are necessary?

3. Security of Title Documents

Currently, § 580.4 requires that titles, which are necessarily all physical documents except in the five jurisdictions with approved petitions for electronic systems pursuant to 49 U.S.C. 32705(d), be printed using a secure printing or other secure process. Further, currently any power of attorney forms and all documents used to reassign title must be issued by the State and be created using a secure process. It is central to the integrity and efficacy of the motor vehicle titling systems and

odometer disclosure laws that the authenticity and security of title documents, at a minimum, be maintained at their current levels in moving to electronic disclosure and titling systems. Currently, investigators are able to examine physical documents and observe indicators of tampering. Unlike paper documents, however, alterations to electronic documents are much more difficult to detect from a visual inspection. Further, while electronic documents and transactions provide opportunity to enhance security, as with physical documents, these systems are still susceptible to manipulation and attacks.

The proposed changes and additions to § 580.4 seek to clarify that the existing requirements apply to physical documents, moving the language to a new paragraph (a), and set forth requirements for electronic documents, in a new paragraph (b), to ensure comparable levels of security and authenticity in electronic documents as exist currently for paper documents. Such requirements are necessary to protect both the financial interests of motor vehicle owner's and potential buyers, as well as to aid law enforcement in preventing, detecting, and prosecuting odometer fraud. NHTSA seeks comments as to whether the proposed changes and additions to § 580.4 appropriately match the security and authenticity requirement for electronic documents to the existing requirements, which apply to paper documents.

a. Electronic Odometer Disclosure System Security

As discussed previously, § 580.4 requires the title, power of attorney or reassignment documents used for odometer disclosures to have certain security safety features to inhibit altering the disclosure and to aid in the detection of alterations.

NHTSA contemplated proposing specific minimum requirements for system security, but has preliminarily determined that it would be counter-productive, and thus inappropriate, to do so. NHTSA based this decision on the knowledge that the rulemaking process is typically slow, while developments in technology are fast and frequent. While proactive changes to enhance cyber security are constantly evolving and improving, cyber-attacks and efforts to undermine the security of electronic data systems are also changing rapidly and frequently. The rulemaking process would not be able to keep pace with these technological changes and it is foreseeable that, if NHTSA imposed specific system requirements, the specific requirements could become obsolete, yet remain the requirements while a new rulemaking is undertaken. Alternatively, to the extent that rulemaking by NHTSA would be able to keep up with the dynamic technological landscape, such constant revisions to the regulations would result in an ever-changing set of specific requirements for States to adhere to.

Further, the potential risks to property interests and commerce presented by insecure vehicle titling and odometer disclosure systems are obvious, since it is critical that the owners, buyers, and sellers of motor vehicles have certainty in their ownership status and avoid being defrauded in the fundamental details about the vehicle they own or are buying.

By NHTSA's adoption of more general minimum requirements, any State that choses to adopt an electronic disclosure system will be able to select the specific system requirements it believes are most appropriate, while ensuring information security for motor vehicle owners, buyers, and law enforcement.

While NHTSA's expectation is that any State implementing an electronic disclosure system would take these various risks into account and establish appropriate safeguards, NHTSA nonetheless requests comments on whether it should establish minimum specific security requirements in this rulemaking and, if so, what requirements would be appropriate. NHTSA requests comment on whether requirements should be included for the hardware used in an electronic odometer system to protect the system from threats which could disrupt the electronic records, either from natural or manmade sources and, if so, what requirements should be included in a final rule. For example, the Federal Information Security Management Act (FISMA) defines a framework to protect Federal government information systems from such threats. Should NHTSA, for example, require any computer or server attached to an electronic odometer system comply with FISMA?

4. Odometer Disclosures

NHTSA considered the issue of what odometer information disclosures and procedures should be required for paper and electronic disclosures, and what appropriate modifications can and should be made for electronic disclosures. In an effort to track the electronic disclosure requirements to the existing requirements, NHTSA makes the following proposals regarding the odometer disclosures and procedures.

In § 580.5 paragraph (a), NHTSA proposes to add the phrase ''whether a physical or electronic document'' to make clear that the disclosure requirements specified in § 580.5 apply to all titles issued. The requirements currently apply to all title transfers and, as a practical matter, this results in no change in the disclosure requirements whether made on a physical document or electronically.

Paragraph § 580.5(c) sets forth certain specific disclosures that must be made as part of a transaction transferring title of a vehicle, including that the odometer disclosure must be made on the title, or on a document being used to reassign the title. As currently written, this requirement necessarily implies the ability to affix information onto a document. To clarify this requirement, NHTSA proposes to add language specifying ''physical document'' in instances of paper title transfers and ''electronic form incorporated into the electronic title'' for instances of electronic title transfers. The requirement for making electronic disclosures on an electronic form incorporated into the electronic title means that paper disclosures would become the rare exception when electronic disclosure and titling is available. Further, the electronic systems would need to be designed to contain or otherwise embed the electronic odometer disclosure in the electronic title. Finally, for electronic transfers where the transferor is the individual in whose name the vehicle is titled, reassignment documents would not be necessary. NHTSA seeks comments on the proposal that disclosures be made on an electronic form incorporated into the electronic title.

NHTSA also considered the issue of how to provide the warnings currently contained in § 580.5(d) to parties conducting electronic transfers. NHTSA proposes to extend these existing requirements to electronic transfers by amending § 580.5(d), specifying that in instances of electronic transfer, the required information must be displayed on the screen, and acknowledged as understood by that party, before any signature can be applied to the transaction. This proposed requirement is intended to ensure that the information is provided in a size and location that is clearly viewable and readable to individuals making electronic transfers, and that transferors do not unintentionally bypass this information without having an opportunity to review it. NHTSA envisions that the acknowledgement would typically be a box for the party

to click acknowledging having seen and understood the information, not unlike the boxes often seen on Web sites and computer programs today acknowledging service limits or contractual rights prior to gaining access to content or services.

NHTSA considered the existing requirements of § 580.5(f), that a transferee print his or her name on the disclosure and return a copy to the transferor and believes that the requirement on a transferee to ''print'' their name is inappropriate for electronic transfers, but that any electronic system should be able to provide some record of the disclosure for the transferor and transferee. NHTSA proposes to not extend the printed name requirement to electronic disclosures because the purpose of the printed name is to provide hand writing exemplars for use in fraud investigations and prosecutions. However, at present, NHTSA is not aware of electronic systems that capture handwriting with the level of clarity and precision that exists when applying hand-writing to paper. As a result, unlike physical handwriting exemplars, NHTSA does not currently believe that electronic handwriting exemplars would provide the intended investigatory and prosecution tools to law enforcement. The requirement that the transferee print his or her name on the disclosure therefore need not be extended to electronic disclosures. In contrast, it remains important for both parties to the transaction to have access to a record showing the disclosure that was made, and it is appropriate to extend the current requirement that the transferee provide a copy of the disclosure to the transferor to electronic transfers.

In an electronic disclosure jurisdiction, the parties would not have physical control of the disclosure documents and the responsibility to provide copies of the disclosure must fall to the operator(s) of the disclosure system. Thus, NHTSA proposes to amend § 580.5(f) to require that jurisdictions with electronic disclosure systems provide a way for the transferor and transferee to obtain copies, in the form of some detailed record, of the disclosure. These records not only provide assurance to the parties of what information was relied upon in the transaction, but could also aid law enforcement in investigations and prosecutions. NHTSA requests comments on the proposal to not extend the printed name requirement to electronic disclosures, including technologies that provide comparable electronic hand-writing exemplars as paper document exemplars, and on the proposal to require that any electronic system be capable of providing the transferor and transferee with a copy or record of the disclosure made.

NHTSA has considered how to handle odometer disclosure for a vehicle that has not been titled or for which the title does not contain a space for the information required. Under the existing paper disclosure systems, in such instances the parties execute the odometer disclosure as a separate paper document. This system would not make sense in an electronic disclosure system since the first time a title was obtained for any given vehicle the odometer disclosure would be incorporated into that electronic title at the time of creation and no electronic title system would be created that did not provide space for the required information. The option relating to insufficient space on the title is a holdover from when odometer disclosures were first required on the title and jurisdictions needed time to bring titles into conformity with the new regulation. That concern is not applicable here since electronic disclosure systems will be designed and implemented using the requirements established in this rule. Similarly, no special provision is needed for providing the information in the first instance of titling in an electronic disclosure jurisdiction, since any electronic system will include the execution of an electronic disclosure that is incorporated into the electronic title upon creation. NHTSA thus proposes to amend § 580.5(g) to add language clarifying that the existing regulation allowing for disclosure on a separate document for first title and instances where the title does not contain space for the disclosure is limited to transactions conducted using physical documents while disclosures for first title issuance in an electronic disclosure system must be made in the electronic system. NHTSA requests comments on the proposal to limit the current separate document disclosures for first title issuance and when the title does not contain sufficient space for the disclosure requirements to paper title jurisdictions, and requiring disclosures for first title issuance to be conducted within the electronic title system in electronic disclosure jurisdictions.

5. Requirements for Electronic Transactions

NHTSA has considered the differences between disclosures made on physical documents and those made on electronic documents and preliminarily determined that additional requirements are necessary to ensure the accuracy and authenticity of electronic disclosures. NHTSA has also considered the complications that could arise, including competing claims of vehicle ownership, if both paper and electronic titles co-exist as an official form of title issued within a jurisdiction. To address these issues, NHTSA is proposing to add a new § 580.6 (previously reserved), to provide requirements that apply only to electronic transactions.

a. Document Integrity

First, NHTSA proposes to add § 580.6(a)(1), requiring that any electronic record be retained in a format that cannot be altered and, further, that indicates any attempts to alter it. This proposed requirement adds as an explicit condition for electronic disclosures an implicit reality of disclosures on physical documents. Disclosures on physical documents provide some method for detection of alterations or attempts to alter the document. While techniques for altering the physical documents evolve over time, they nonetheless leave an indicator, however hard to detect, of that alteration or attempt. Electronic documents thus present a different challenge since many documents are easily altered, and some of the techniques used can be difficult to trace. A system that prevents alteration is critical for consumer confidence in the disclosure system and information relating to the alteration of disclosure documents is critical to the enforcement of the odometer disclosure laws and in preventing odometer fraud. NHTSA requests comments on this proposed additional requirement for electronic disclosures and what, if any, more specific requirements would be appropriate to ensure that electronic records are not altered and indicate any attempts to alter them.

b. Individual Identity Assigned to all Unique Electronic Signatures

Currently, each person signs their own name to a physical document when completing an odometer disclosure and is uniquely identified as an individual. Or at least that is presumed for non-fraudulent transactions. Similarly, in an electronic disclosure system, each individual person will need to be uniquely identified by their own unique electronic signature. This is necessary to protect the financial interests of vehicle owners and purchasers, providing certainty that the vehicle title remains with the lawful owner and that odometer disclosures are made by the appropriate individuals, who can be located, if needed.

As a practical matter, this is particularly necessary for transactions involving individuals who complete portions of disclosures on behalf of others, like an employer. For example, when a vehicle owner seeks to trade in a car at a car dealership in an electronic disclosure jurisdiction the parties would no longer need to provide power of attorney and reassignment documents for the dealer to use in selling the vehicle at a later date, but instead would simply transfer title from the vehicle owner to the car dealer and make the odometer disclosure on the electronic form which is incorporated into the title. This will require an individual at a car dealership to enter information into the electronic disclosure system on behalf of the business or entity on whose behalf that individual is operating.

NHTSA has considered the importance of maintaining confidence that the parties are who they claim to be for ownership and law enforcement purposes. NHTSA has also considered challenges created in fraud investigation and prosecution if both the individual and business, or entity, are not identified by the code or signature associated with an individual acting in this capacity to input data into the system. Accordingly, NHTSA is proposing to add § 580.6(a)(2) requiring that any electronic signature identify an individual and, further, that if the individual is acting in a business capacity or otherwise on behalf of any other individual or entity, that the business or entity also be identified as part of that unique electronic signature. NHTSA requests comments on this proposal.

c. Availability of Documentation in Electronic Disclosure Systems

The physical document disclosure system currently established in § 580 generally requires in various places that individuals be provided with specific documentation. However, in an electronic system, in many cases there will not be any document to provide, and instead, information can be made available to the parties via the electronic system. Moreover, part of the rationale for using an electronic disclosure and titling system is to reduce the amount of paper being used. It would defeat one of the purposes of electronic disclosure to require the printing and delivery of documentation at various stages. It could also add unnecessary complications to the electronic delivery of documentation if specific electronic delivery mechanisms were required. Having considered this factors, NHTSA proposes to add § 580.6(a)(3), providing that any requirement in the regulations to disclose, issue, execute, return, notify, or otherwise provide information to another person is satisfied when a copy of the electronic disclosure or statement is electronically transmitted or otherwise electronically accessible to the party required to receive the disclosure. NHTSA requests comments on the usefulness of this proposal.

d. Physical Documents Used in Making Electronic Disclosures

The continued use of physical documents to accomplish transfer of title or odometer disclosure in an electronic disclosure jurisdiction is strongly discouraged, as each different document presents a new opportunity for fraudulent activity to occur. However, to the extent that the continued use of physical documents is necessary in an electronic system, any physical documents used must comply with all requirements of this part. NHTSA thus proposes the new § 580.6(a)(7) to require that any physical documents used to make electronic disclosures comply with the existing applicable requirements.

e. Co-Existing Physical and Electronic Disclosures and Titles

NHTSA considered the issue of which title and/or odometer disclosure is, and should be, the official document in certain situations. In a written environment it is possible to determine which document has an original signature and, therefore, to distinguish original (or official) documents from copies. This method of determining the original/official document is not available when the original document was created electronically. In addition, when a print copy is made of an electronic odometer disclosure, what should be done to specify whether the print document is now the official document or the electronic document remains the official document? This issue could arise when a vehicle titled with an electronic odometer disclosure is moved to a State which either does not participate in electronic odometer disclosures or which has an electronic odometer system that cannot communicate directly with the system in the State in which the vehicle is currently titled. It could also occur if a vehicle owner in an electronic disclosure State would like a paper copy of a title and/or odometer disclosure for record-keeping purposes.

First, NHTSA is proposing that once an odometer disclosure is incorporated in the electronic title, the electronic title containing the disclosure is the official record of ownership and mileage. The electronic disclosure does not continue as a record separate from the electronic title as that would be contrary to TIMA and would provide additional opportunity for fraud. If an electronic title (containing an odometer disclosure) must be converted to a paper document as the official document, NHTSA is proposing additional requirements. First, only a State or State-authorized entity can create the new official document. Second, the paper document must be set forth by means of a secure printing method as a physical, paper document. As a practical matter, this may present certain logistical challenges, particularly for individuals in an electronic title State who seek to buy a new car, and trade-in their old car, in another State. This issue is discussed at greater length below regarding Power of Attorney, and NHTSA requests comments on how this logistical challenge can be avoided or mitigated. Third, the electronic record must be altered to clearly indicate that an official paper document has been issued, to whom, and the date of issuance.

Second, NHTSA is proposing to allow States to authorize the issuance of some type of record of ownership document that would contain the information on a title and/or odometer disclosure but would not replace the official document. This document could be used for persons who would like a paper copy but would not like the official document to be converted to a paper document. In the proposed § 580.6(a)(5) jurisdictions with electronic title and odometer disclosure systems would be allowed to provide vehicle owners with a paper record of ownership including the odometer disclosure information so long as the document clearly indicates that it is not an official title or odometer disclosure for that vehicle. NHTSA requests comments on the benefits and drawbacks of such a record and whether the option of obtaining such a document should be required under the regulations.

Finally, in reverse situations where a vehicle titled in a State that does not participate in an electronic odometer system is moved to a State with an electronic odometer system, NHTSA is proposing a new § 580.6(a)(4) to require that the prior title and odometer disclosure be copied electronically for retention by the electronic system State and that the paper document(s) be destroyed at the time they are converted to electronic documents. NHTSA further proposes that the electronic copy of the physical document be retained for a minimum of five years, in an order that

permits systematic retrieval, and in a format that cannot be altered and that indicates any attempts to alter it. The five year retention requirement proposed in this paragraph matches the retention period of similar documentation held by dealers and distributors of motor vehicles and auction companies. Finally, NHTSA is also proposing that any paper documents scanned or copied electronically for storage in an electronic system be converted through a process providing a minimum resolution of 600 dots per inch (dpi) to ensure the preservation of security features during the conversion process.

NHTSA requests comments on what standards should be used for scanning and maintaining the documents including whether the scan must be in color, be made at a minimum resolution (and if so, what required minimum resolution should be), or preserve the security features of the original to ensure that fraud or alteration could be detected, should it occur.

C. Leased Vehicles

Section 580.7 deals with the disclosure obligations and requirements for leased vehicles. NHTSA is not aware of any reason why electronic disclosures could not be made for leased vehicles, though lessors wishing to utilize such a system for communications between themselves and lessees would need to develop an electronic system complying with the technological requirements established in § 580.4(b) of this part unless the jurisdiction where the leased vehicle is titled provides such a system. These requirements are necessary as security and authenticity of disclosure information is fundamental to all types of disclosures within the odometer disclosure system. Otherwise, disclosures regarding leased vehicles would continue on physical documents. As with all other electronic disclosures, it is appropriate and necessary that individuals making the disclosure be provided with the notice of Federal law and possible penalties for providing false information. The substantive disclosures would not change for electronic disclosure except that, as with all other electronic disclosures, the person making the disclosure need not provide their ''printed name'' for the reasons previously discussed.

Having considered the issues involved in lessor-lessee communications regarding odometer disclosure statements, NHTSA proposes to add language to § 580.7(a) specifying that legal notices given on paper odometer disclosure documents must be provided to, and acknowledged by, an individual making an electronic disclosure; add language to § 580.7(b) clarifying that a printed name need not be provided for electronic disclosures; and add a new § 580.7(e) requiring any electronic system maintained by a lessor for the purpose of complying with this section meet the requirements set forth in proposed § 580.4(b) or this part. NHTSA requests comments as to whether electronic disclosures of leased vehicles should be a required part of the electronic system established by a jurisdiction or are best left to individual companies/lessors to establish and whether the current proposal would sufficiently aid law enforcement in detecting altered documents.

D. Record Retention

Sections 580.8 and 580.9 include requirements for odometer disclosure record retention by motor vehicle dealers and distributors and by auction companies, respectively. Section 580.8(a) specifies that dealers and distributors must retain a ''Photostat, carbon copy or other facsimile copy of each odometer mileage statement which they issue and receive.'' An electronic odometer disclosure system that does not allow for dealers and distributors to maintain records in electronic format would undermine the purpose for moving to such a system. NHTSA is therefore proposing to amend this requirement to include electronic copies or electronic documents as an acceptable form of record.

Under both sections, records must be stored for five years in a manner and method so they are accessible to NHTSA investigators and other law enforcement personnel. The records must also be stored so they are difficult or impossible to modify. As previously discussed, unlike paper documents, alterations to electronic documents are much more difficult to detect from a visual inspection. Therefore, NHTSA is proposing to add a specific requirement in a new § 580.8(d) and in § 580.9 that electronic records kept by motor vehicle dealers and distributors and by auction companies must be stored in a format that cannot be altered and which indicates any attempts to alter the document, consistent with the standards set forth in proposed § 580.4(b). NHTSA requests comment on whether this requirement would be sufficient to allow law enforcement to detect altered documents.

E. Power of Attorney

NHTSA is proposing to modify the power of attorney provisions. A power of attorney generally should not be needed for transfers and disclosures within jurisdictions using electronic systems since there will not be a ''lost'' title, as the State system will hold the title record with the odometer disclosure, and any lienholder will not physically hold the title since the title will be on file in the State's electronic system. However, NHTSA proposes to amend § 580.13(a) and (b), to allow an individual with a vehicle titled in an electronic title State to use a power of attorney to sell a vehicle in a paper title State. In this way, the electronic title with the required odometer disclosure is equivalent to a lost title or a title held by a lienholder. Without this additional permitted use of power of attorney, the seller from an electronic title State cannot trade-in his old car and buy a new car in a paper title State unless the seller first remembers, and plans ahead, to obtain a printed title from the electronic title State before going car shopping. For example, assume Mr. Smith lives in an e-title State but goes to a paper title State to trade-in his old car and buy a new car. He must either get his paper title first or there must be some means for him to make his odometer disclosure without a title. Electronic title States will not likely be in a position to provide secure paper titles on demand. This means Mr. Smith cannot buy a new car unless he gets his electronic title printed as a physical title first. The agency believes this is unlikely to happen in many, if not most, instances.

While the use of power of attorney provides an additional step in the transfer process, and thus another opportunity for fraud to occur, the agency believes as a practical matter that there must be some other way for a vehicle owner from an electronic title State to sell the vehicle in a paper title State without first obtaining a converted official paper title from the electronic title State. However, power of attorney laws vary from State to State, so even with this modification there may still be States that retain paper title systems where vehicles registered in electronic title States could not be sold without the converted official paper title. NHTSA requests comments on the benefits and drawbacks of this proposal as well as other ideas to address this challenge while maintaining adequate safeguards of accurate disclosures and a paper-trail.

NHTSA also proposes to add the word ''physical'' in multiple places in § 580.13(f), § 580.14(a), (e), and (f), and in § 580.15(a). In § 580.13(f) this is necessary to make clear that the title being referenced at the two specified points is a physical title and not an electronic title, unlike the other references to ''title'' within paragraph

(f), which apply to either a physical or electronic title depending on in which format the transferor's title is currently held. The word ''physical'' is needed to clarify three documents in § 580.14(a) that must be physical documents for the purposes of using reassignment documents and power of attorney since these documents will only be utilized in transactions outside of electronic disclosure systems. Similarly, the word ''physical'' is also needed in § 580.14(e) and (f) to make clear that power of attorney forms would be physical documents, since power of attorney would not be needed or utilized in electronic title and disclosure jurisdictions. Finally, the addition of the word ''physical'' is necessary in six instances in § 580.15(a) to clarify that the disclosures made and documents reviewed involved physical documents, since the use of power of attorney, and related documents, would not be necessary to accomplish transfers within electronic title and disclosure jurisdictions.

NHTSA requests comments on whether power of attorney would be necessary in an electronic odometer system for intra-state transfers. Second, NHTSA notes that the requirements in section 580.13 permitting disclosures by power of attorney assume that the power of attorney document itself is a physical document. Therefore, NHTSA requests comments on whether odometer disclosure by power of attorney would be made on other than a paper document, *i.e.* electronically, in these situations and, if so, explanation of how that would work. Further, NHTSA has concerns that the validity of power of attorney may vary from State to State and the possible implications of that variability in interstate transactions and requests comment on this issue.

NHTSA proposes to correct a typographical error that appears in both § 580.13(b)(5) and § 580.14(b)(5) by adding a comma between ''model year,'' which would bring the disclosure requirements for power of attorney forms into conformity with standard transfer disclosures and leased vehicle disclosures. This typographical error in the regulation creates inconsistency within the reporting scheme. Accordingly, NTHSA proposes to change ''model year'' to ''model, year'' in these two reporting provisions.

F. Exemptions

Section 580.17(3) currently exempts any vehicle which is more than 10 years old from the odometer disclosure requirements. The average age of the United States vehicle fleet has been trending upward and recently reached 11.5 years.[4] Because of this, NHTSA is proposing to raise this exemption to 25 years. NHTSA also requests comments on whether this exemption should be eliminated.

G. Miscellaneous Amendments

The agency is no longer located at the address currently provided in § 580.10. Accordingly, NHTSA is proposing to amend § 580.10(b)(2) to provide the correct address for applications for assistance to, which is the Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., W41–326, Washington, DC 20590.

Section 580.11 provides States with procedures by which to petition NHTSA for approval of disclosure requirements differing from those required by 49 CFR part 580, specifically § 580.5, § 580.7, and § 580.13(f). NHTSA is proposing to amend § 580.11(a) to add the new § 580.6 to the sections for which a State may petition the agency to utilize different disclosure requirements and to add § 580.6 to the explanation of the effect of a grant or denial of a petition contained in § 580.11(c). NTHSA requests comments on whether a State should be permitted to use alternative disclosure requirements to those proposed in § 580.6.

Section 580.11 also provides the prior address for the agency, and NHTSA is proposing to amend § 580.11(b)(2) to provide the current address, which is the Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., W41–326, Washington, DC 20590.

The petition provided for in § 580.12, allowing a State to seek an extension of time beyond the April 29, 1989 deadline to bring its laws into conformity with the requirements of Part 580, was due to the agency by February 28, 1989. These dates having long ago passed and States having brought applicable laws into compliance, the provisions within § 580.12 are now obsolete. Accordingly, NHTSA proposes to strike the regulatory text of § 580.12 and replace it with ''[Remove and Reserve]'' to reserve the section.

IV. Public Participation

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary supporting documents to your comments. There is no limit on the length of the attachments.

Comments may be submitted to the docket electronically by logging onto the Docket Management System Web site at *http://www.regulations.gov.* Follow the online instructions for submitting comments.

You may also submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at: *http://www.whitehouse.gov/omb/fedreg/reproducible.html.* DOT's guidelines may be accessed at: *http://www.bts.gov/programs/statistical_policy_and_research/data_quality_guidelines.*

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information

[4] *Average age of U.S. fleet hits record 11.5 years, IHS says,* Autonews.com (July 29, 2015), *http://www.autonews.com/article/20150729/RETAIL/150729861/average-age-of-u.s.-fleet-hits-record-11.5-years-ihs-says* (last visited March 14, 2016).

specified in our confidential business information regulation. 49 CFR part 512.

Will the agency consider late comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date. If Docket Management receives a comment too late for us to consider in developing a final rule (assuming that one is issued), we will consider that comment as an informal suggestion for future rulemaking action.

How can I read the comments submitted by other people?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location. You may also see the comments on the Internet. To read the comments on the Internet, go to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets.

Please note that, even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

V. Regulatory Notices and Analyses

A. Executive Orders 12866 and 13563 and DOT Regulatory Policies and Procedures

Executive Order 12866, Executive Order 13563, and the Department of Transportation's regulatory policies require this agency to make determinations as to whether a regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the aforementioned Executive Orders. Executive Order 12866 defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

We have considered the potential impact of this proposal under Executive Order 12866, Executive Order 13563, and the Department of Transportation's regulatory policies and procedures, and have determined that it is not significant. This proposal amends existing requirements to allow States a new alternative means of complying with those requirements. It does not impose any new regulatory burdens. Therefore, this document was not reviewed by the Office of Management and Budget under E.O. 12866 and E.O. 13563.

B. National Environmental Policy Act

We have reviewed this rule for the purposes of the National Environmental Policy Act and determined that it would not have a significant impact on the quality of the human environment.

C. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of proposed rulemaking or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions). The Small Business Administration's regulations at 13 CFR part 121 define a small business, in part, as a business entity ''which operates primarily within the United States.'' 13 CFR 121.105(a). No regulatory flexibility analysis is required if the head of an agency certifies the proposal would not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a proposal would not have a significant economic impact on a substantial number of small entities.

In compliance with the Regulatory Flexibility Act, NHTSA has evaluated the effects of this proposed rule on small entities. The head of the agency has certified that the proposed rule would not have a significant economic impact on a substantial number of small entities. This proposal is only allowing States the option of an alternative means of complying with an existing requirement and therefore would not impose any new impact on any small entities.

D. Executive Order 13132 (Federalism)

NHTSA has examined today's NPRM pursuant to Executive Order 13132 (64 FR 43255, August 10, 1999). Executive Order 13132 requires agencies to determine the federalism implications of a proposed rule. The agency has determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. The proposed rule merely adds another option to the way States are allowed to process and issue existing odometer disclosure requirements, and does not alter the effect on the States of existing statutory or regulatory requirements.

E. Executive Order 12988 (Civil Justice Reform)

When promulgating a regulation, Executive Order 12988 specifically requires that the agency must make every reasonable effort to ensure that the regulation, as appropriate: (1) Specifies in clear language the preemptive effect; (2) specifies in clear language the effect on existing Federal law or regulation, including all provisions repealed, circumscribed, displaced, impaired, or modified; (3) provides a clear legal standard for affected conduct rather than a general standard, while promoting simplification and burden reduction; (4) specifies in clear language the retroactive effect; (5) specifies whether administrative proceedings are to be required before parties may file suit in court; (6) explicitly or implicitly defines key terms; and (7) addresses other important issues affecting clarity and general draftsmanship of regulations.

Pursuant to this Order, NHTSA notes as follows. The preemptive effect of this proposal is discussed above in connection with Executive Order 13132. NHTSA has also considered whether this rulemaking would have any retroactive effect. This proposed rule does not have any retroactive effect. NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceeding before they may file suit in court.

F. Executive Order 13609: Promoting International Regulatory Cooperation

The policy statement in section 1 of Executive Order 13609 provides, in part:

The regulatory approaches taken by foreign governments may differ from those taken by U.S. regulatory agencies to address similar issues. In some cases,

the differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts might not be necessary and might impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

NHTSA requests public comment on whether (a) ''regulatory approaches taken by foreign governments'' concerning the subject matter of this rulemaking, and (b) the above policy statement, have any implications for this rulemaking.

G. National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113), all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments, except when use of such a voluntary consensus standard would be inconsistent with the law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies, such as the SAE International. The NTTAA directs NHTSA to provide Congress, through OMB, explanations when the agency decides not to use available and applicable voluntary consensus standards. NHTSA is proposing to reference the standards provided in NIST Special Publication 800–63–2, *Electronic Authentication Guideline,* to determine the appropriate level of security to authenticate electronic signatures.

H. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation with base year of 1995). In 2011 dollars, this threshold is $139 million.[5]

This proposed rule would not result in the expenditure by State, local, or tribal governments, in the aggregate, or more than $139 million annually, and would not result in the expenditure of that magnitude by the private sector.

I. Paperwork Reduction Act

Under the procedures established by the Paperwork Reduction Act of 1995 (PRA), a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. Today's NPRM does not propose any new information collection requirements, it merely allows States to provide an alternative means of collecting information they already collect.

J. Plain Language

Executive Order 12866 requires each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

If you have any responses to these questions, please include them in your comments on this proposal.

K. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

L. Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an organization, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://www.dot.gov/privacy.html.*

List of Subjects in 49 CFR Part 580

Consumer protection, Motor vehicles, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, NHTSA proposes to amend 49 CFR part 580 as follows:

PART 580—ODOMETER DISCLOSURE REQUIREMENTS

■ 1. Revise the authority citation to read as follows:

Authority: 49 U.S.C. 32705; Pub. L. 112–141; delegation of authority at 49 CFR 1.95.

■ 2. Revise § 580.1 to read as follows:

§ 580.1 Scope.

This part prescribes rules requiring transferors and lessees of motor vehicles to make electronic or written disclosure to transferees and lessors respectively, concerning the odometer mileage and its accuracy as directed by sections 408 (a) and (e) of the Motor Vehicle Information and Cost Savings Act as amended, 15 U.S.C. 1988 (a) and (e). In addition, this part prescribes the rules requiring the retention of odometer disclosure statements by motor vehicle dealers, distributors and lessors and the retention of certain other information by auction companies as directed by sections 408(g) and 414 of the Motor Vehicle Information and Cost Savings Act as amended, 15 U.S.C. 1990(d) and 1988(g).

■ 3. Amend § 580.3 by adding in alphabetical order, definitions for ''*Electronic Document*'', ''*Physical Document*'' and ''*Sign or Signature*'' to read as follows:

§ 580.3 Definitions.

* * * * *

Electronic Document means a title, reassignment document or power of attorney that is maintained in electronic form by a state, territory or possession that meets all the requirements of this part.

* * * * *

Physical Document means a title, reassignment document or power of attorney printed on paper that meets all the requirements of this part.

* * * * *

[5] Adjusting this amount by the implicit gross domestic product price deflator for the year 2011 results in $139 million (113.361/81.606 = 1.39).

Sign or Signature means either:

(a) For a paper odometer disclosure, a person's name, or a mark representing it, as hand written personally.

(b) For an electronic odometer disclosure, an electronic sound, symbol, or process using an authentication system equivalent to or greater than Level 3 as described in National Institute of Standards and Technology (NIST) Special Publication 800–63–2, *Electronic Authentication Guideline,* which identifies a specific individual.

* * * * *

■ 4. Revise § 580.4 to read as follows:

§ 580.4 Security of title documents and power of attorney forms.

(a) Each physical title shall be set forth by means of a secure printing process or other secure process. In addition, physical power of attorney forms issued pursuant to §§ 580.13 and 580.14 and physical documents which are used to reassign the title shall be issued by the State and shall be set forth by a secure process.

(b) Each electronic title shall be maintained in a secure environment so it is protected from unauthorized modification, alteration or disclosure. In addition, electronic power of attorney forms maintained and made available pursuant to §§ 580.13 and 580.14 and electronic documents which are used to reassign the title shall maintained by the State in a secure environment so that it is protected from unauthorized modification, alteration and disclosure. Any system employed to create, store and maintain the aforementioned electronic documents shall record the dates and times when the electronic document is created, the odometer disclosures contained within are signed and when the documents are accessed, including the date and time any attempt is made to alter or modify the electronic document and any alterations or modifications made.

■ 5. Amend § 580.5 by revising paragraphs (a), (c), (d), (f), and (g) to read as follows:

§ 580.5 Disclosure of odometer information.

(a) Each title, whether a physical or electronic document, at the time it is issued or made available to the transferee, must contain the mileage disclosed by the transferor when ownership of the vehicle was transferred and contain a space for the information required to be disclosed under paragraphs (c), (d), (e) and (f) of this section at the time of future transfer.

* * * * *

(c) In connection with the transfer of ownership of a motor vehicle using a physical document, each transferor shall disclose the mileage to the transferee on the physical title or, except as noted below, on the physical document being used to reassign the title. In connection with the transfer of ownership of a motor vehicle using an electronic document, each transferor shall disclose the mileage to the transferee on an electronic form incorporated into the electronic title. In the case of a transferor in whose name the vehicle is titled, the transferor shall disclose the mileage on an electronic form incorporated into the electronic title or on the physical title, and not on a reassignment documents. This disclosure must be signed by the transferor and if made on a physical title, must contain the transferor's printed name. In connection with the transfer of ownership of a motor vehicle in which more than one person is a transferor, only one transferor need sign the disclosure. In addition to the signature of the transferor, the disclosure must contain the following information:

* * * * *

(d) In addition to the information provided under paragraph (c) of this section, the statement shall refer to the Federal law and shall state that failure to complete or providing false information may result in fines and/or imprisonment. Reference may also be made to applicable State law. If the transaction at issue is electronic, the information specified in this paragraph shall be displayed, and acknowledged as understood by the party, prior to the execution of any electronic signatures.

* * * * *

(f) The transferee shall sign the disclosure statement, and in the case of a disclosure made on a physical title, shall print his name, and return a copy to his transferor. If the disclosure is incorporated into an electronic title, the electronic system shall provide a means for making copies of the disclosure statement available to the transferee and transferor.

(g) In jurisdictions employing paper title and odometer disclosure schemes, if the vehicle has not been titled or if the physical title does not contain a space for the information required, the written disclosure shall be executed as a separate physical document. In jurisdictions maintaining electronic title and odometer disclosure systems, the system shall provide a means for making the disclosure electronically and incorporating this disclosure into the electronic title when the title is created.

* * * * *

■ 6. Revise § 580.6 to read as follows:

§ 580.6 Requirements for Electronic Transactions.

(a) Additional Requirements for Electronic Odometer Disclosures

(1) Any electronic record shall be retained in a format which cannot be altered, and which indicates any attempts to alter it.

(2) Any signature shall identify an individual, and not solely the organization the person represents or is employed by. If the individual executing the electronic signature is acting in a business capacity or otherwise on behalf of another individual or entity, the business or other individual or entity shall also be identified when the signature is made.

(3) Any requirement in these regulations to disclose, issue, execute, return, notify or otherwise provide information to another person is satisfied when a copy of the electronic disclosure or statement is electronically transmitted or otherwise electronically accessible to the party required to receive the disclosure.

(4) Upon creation of an electronic title to replace an existing physical title, an electronic copy of the physical title shall be created and retained, for not less than five years, by the State issuing the electronic title and the physical title shall be destroyed immediately following the successful creation of the electronic record. The electronic copy of the paper record shall be retained

(i) in a format which cannot be altered, and which indicates any attempts to alter it; and

(ii) in an order that permits systematic retrieval.

(5) A State allowing electronic odometer disclosures may provide for a paper record of ownership which includes the odometer disclosure information, provided the document clearly indicates it is not an official title, nor official odometer disclosure, for the vehicle.

(6) States maintaining an electronic title and odometer disclosure system shall retain the capacity to issue physical titles meeting all the requirements of this part. Once a physical title is created by a State with an electronic title and odometer disclosure statement system, the electronic record must indicate that a physical title has been issued and the electronic title and disclosure statement have been superseded by the physical title as the official title. The State electronic title and odometer disclosure

system shall record the date on which the physical title was issued and record the identity of the recipient of the physical title as well as the owner(s) named on the physical title.

(7) Any physical documents employed by transferors and transferees to make electronic odometer disclosures shall comply with all requirements of this part.

(8) Any conversion of physical documents to electronic documents employed to comply with any of the requirements of this part must maintain and preserve the security features incorporated in the physical document so that any alterations or modifications to the physical document can be detected in the physical document's electronic counterpart. Scanning of physical documents must be made in color at a resolution of not less than 600 dots per inch (dpi).

■ 7. Amend § 580.7 by revising paragraphs (a) and (b), and add paragraph (e), to read as follows:

§ 580.7 Disclosure of odometer information for leased motor vehicles.

(a) Before executing any transfer of ownership document, each lessor of a leased motor vehicle shall notify the lessee in writing on a physical document or within an electronic document stating that the lessee is required to provide a written disclosure to the lessor regarding the mileage. This notice shall contain a reference to the Federal law and shall state that failure to complete or providing false information may result in fines and/or imprisonment. Reference may also be made to applicable State law. If the transaction at issue is electronic, the information specified in this paragraph shall be displayed, and acknowledged as understood by the party, prior to the execution of any electronic signatures.

(b) In connection with the transfer of ownership of the leased motor vehicle, the lessee shall furnish to the lessor a written statement regarding the mileage of the vehicle. This statement must be signed by the lessee. If executed using a physical document, this statement, in addition to the information required by paragraph (a) of this section, shall contain the information in paragraphs 1 through 9 as set forth below. If executed using an electronic document, this statement, in addition to the information required by paragraph (a) of this section, shall contain the name of the person making the disclosure and the information contained in paragraphs 2 through 9 as set forth below.

(1) The printed name of the person making the disclosure;

(2) The current odometer reading (not to include tenths of miles);

(3) The date of the statement;

(4) The lessee's name and current address;

(5) The lessor's name and current address;

(6) The identity of the vehicle, including its make, model, year, and body type, and its vehicle identification number;

(7) The date that the lessor notified the lessee of disclosure requirements;

(8) The date that the completed disclosure statement was received by the lessor; and

(9) The signature of the lessor if executed using a physical document or the electronic signature of the lessor if statement is made electronically.

* * * * *

(e) Any electronic system maintained by a lessor for the purpose of complying with the requirements of this section shall meet the requirements of § 580.4(b) of this part.

■ 8. Amend § 580.8 by revising paragraph (a) and to add paragraph (d) to read as follows:

§ 580.8 Odometer disclosure statement retention.

(a) Dealers and distributors of motor vehicles who are required by this part to execute an odometer disclosure statement shall retain for five years a photostat, carbon, other facsimile copy or electronic copy or document of each odometer mileage statement which they issue and receive. They shall retain all odometer disclosure statements at their primary place of business in an order that is appropriate to business requirements and that permits systematic retrieval.

* * * * *

(d) Any electronic record shall be retained in a format which cannot be altered, and which indicates any attempts to alter it.

■ 9. Amend § 580.9 by revising the introductory text to read as follows:

§ 580.9 Odometer record retention for auction companies.

Each auction company shall establish and retain in physical document form, or electronic document form that complies with the requirement of § 580.4(b), at its primary place of business in an order that is appropriate to business requirements and that permits systematic retrieval, for five years following the date of sale of each motor vehicle, the following records:

* * * * *

■ 10. Amend § 580.10 by revising paragraph (b)(2) as follows:

§ 580.10 Application for assistance.

* * * * *

(b) * * *

(2) Be submitted to the Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., W41–326, Washington, DC 20590;

* * * * *

■ 11. Amend § 580.11 by revising paragraphs (a), (b)(2), and (c) to read as follows:

§ 580.11 Petition for approval of alternate disclosure requirements.

(a) A State may petition NHTSA for approval of disclosure requirements which differ from the disclosure requirements of § 580.5, § 580.6, § 580.7, or § 580.13(f) of this part.

(b) * * *

(2) Be submitted to the Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., W41–326, Washington, DC 20590;

* * * * *

(c) Notice of the petition and an initial determination pending a 30-day comment period will be published in the **Federal Register**. Notice of final grant or denial of a petition for approval of alternate motor vehicle disclosure requirements will be published in the **Federal Register**. The effect of the grant of a petition is to relieve a State from responsibility to conform the State disclosure requirements with § 580.5, § 580.6, § 580.7, or § 580.13(f), as applicable, for as long as the approved alternate disclosure requirements remain in effect in that State. The effect of a denial is to require a State to conform to the requirements of § 580.5, § 580.6, § 580.7, or § 580.13(f), as applicable, of this part until such time as the NHTSA approves any alternate motor vehicle disclosure requirements.

■ 12. Remove and reserve § 580.12.

§ 580.12 [Removed and Reserved]

■ 13. Amend § 580.13 by revising paragraphs (a), (b), and (f) to read as follows:

§ 580.13 Disclosure of odometer information by power of attorney.

(a) If the transferor's title is physically held by a lienholder, if the transferor's title exists in electronic form and the transferee is located in a State that does not create or maintain electronic titles, or if the transferor to whom the title was issued by the State has lost his title and the transferee obtains a duplicate title on behalf of the transferor, and if otherwise permitted by State law, the transferor may give a power of attorney to his transferee for the purpose of

mileage disclosure. The power of attorney shall be on a form issued by the State to the transferee that is set forth by means of a secure printing process or other secure process, and shall contain, in part A, a space for the information required to be disclosed under paragraphs (b), (c), (d), and (e) of this section. If a State permits the use of a power of attorney in the situation described in § 580.14(a), the form must also contain, in part B, a space for the information required to be disclosed under § 580.14, and, in part C, a space for the certification required to be made under § 580.15.

(b) In connection with the transfer of ownership of a motor vehicle, each transferor to whom a title was issued by the State whose title is physically held by a lienholder, whose title exists in electronic form and the transferee is located in a State that does not create or maintain electronic titles or whose title has been lost, and who elects to give his transferee a power of attorney for the purpose of mileage disclosure, must appoint the transferee his attorney-in-fact for the purpose of mileage disclosure and disclose the mileage on the power of attorney form issued by the State. This written disclosure must be signed by the transferor, including the printed name, and contain the following information:

(1) The odometer reading at the time of transfer (not to include tenths of miles);

(2) The date of transfer;

(3) The transferor's name and current address;

(4) The transferee's name and current address; and

(5) The identity of the vehicle, including its make, model, year, body type and vehicle identification number.

* * * * *

(f) Upon receipt of the transferor's title, the transferee shall complete the space for mileage disclosure on the title exactly as the mileage was disclosed by the transferor on the power of attorney form. The transferee shall submit the original power of attorney form to the State that issued it, with a copy of the transferor's physical title or with the actual physical title when the transferee submits a new title application at the same time. The State shall retain the power of attorney form and title for three years or a period equal to the State titling record retention period, whichever is shorter. If the mileage disclosed on the power of attorney form is

lower than the mileage appearing on the title, the power of attorney is void and the dealer shall not complete the mileage disclosure on the title.

■ 14. Amend § 580.14 by revising paragraphs (a), (b), (e), and (f) to read as follows:

§ 580.14 Power of attorney to review title documents and acknowledge disclosure.

(a) In circumstances where part A of a secure power of attorney form has been used pursuant to § 580.13 of this part, and if otherwise permitted by State law, a transferee may give a power of attorney to his transferor to review the physical title and any physical reassignment documents for mileage discrepancies, and if no discrepancies are found, to acknowledge disclosure on the physical title. The power of attorney shall be on part B of the form referred to in § 580.13(a), which shall contain a space for the information required to be disclosed under paragraphs (b), (c), (d), and (e) of this section and, in part C, a space for the certification required to be made under § 580.15.

(b) The power of attorney must include a mileage disclosure from the transferor to the transferee and must be signed by the transferor, including the printed name, and contain the following information:

(1) The odometer reading at the time of transfer (not to include tenths of miles);

(2) The date of transfer;

(3) The transferor's name and current address;

(4) The transferee's name and current address; and

(5) The identity of the vehicle, including its make, model, year, body type and vehicle identification number.

* * * * *

(e) The transferee shall sign the physical power of attorney form, and print his name.

(f) The transferor shall give a copy of the physical power of attorney form to his transferee.

■ 15. Amend § 580.15 by revising paragraph (a) to read as follows:

§ 580.15 Certification by person exercising powers of attorney.

(a) A person who exercises a power of attorney under both §§ 580.13 and 580.14 must complete a certification that he has disclosed on the physical title document the mileage as it was provided to him on the physical power of attorney form, and that upon examination of the physical title and any physical reassignment documents, the mileage disclosure he has made on the physical title pursuant to the power of attorney is greater than that previously stated on the physical title and reassignment documents. This certification shall be under part C of the same form as the powers of attorney executed under §§ 580.13 and 580.14 and shall include:

* * * * *

■ 16. Amend § 580.17 by revising paragraph (a)(3) and example to paragraph (a)(3) to read as follows:

§ 580.17 Exemptions.

* * * * *

(a) * * *

(3) A vehicle that was manufactured in a model year beginning at least twenty five years before January 1 of the calendar year in which the transfer occurs; or

Example to paragraph (a)(3): For vehicle transfers occurring during calendar year 2016, model year 1991 or older vehicles are exempt.

* * * * *

Issued in Washington, DC, on March 18, 2016. Under authority delegated in 49 CFR part 1.95

Mark R. Rosekind,

Administrator.

[FR Doc. 2016–06665 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–59–P

Notices

Federal Register
Vol. 81, No. 58
Friday, March 25, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Submission for OMB Review; Comment Request

March 21, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by April 25, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Supplemental Nutrition Assistance Program Requirement for National Directory of New Hires Employment Verification and Annual Program Activity Reporting

OMB Control Number: 0584–NEW.

Summary Of Collection: In an interim final rule, FNS will amend the SNAP regulations at 7 CFR 272 to require State agencies to access employment data through the National Directory of New Hires (NDNH) at the time of certification, including recertification, to determine eligibility status and appropriate benefit amount for SNAP applicants. This requirement codifies Section 4013 of the Agricultural Act of 2014 (Pub. L. 113–79).

Need And Use Of The Information: National Directory of New Hires, State agencies are required to compare identifiable information about each household member against data from the NDNH at the time of certification and recertification. This comparison will be used to determine the eligibility status of the household and determine the correct benefit amount the household should receive.

The data reported on the Program Activity Statement (FNS 366B) enables FNS to identify areas that may need improvement and to provide more effective technical assistance to State agencies. An increase in reporting frequency will allow for greater access to timely program data. It will help States, FNS, and other stakeholders identify trends, inconsistencies and inefficiencies earlier in each fiscal year. FNS uses the data to monitor State agency activity levels and performance and to target technical assistance to State agencies in need of performance improvements.

Description of Respondents: State, Local, or Tribal Government; Individual or households.

Number of Respondents: 891,125.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Annually.

Total Burden Hours: 252,432.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–06821 Filed 3–24–16; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Inviting Applications for Rural Cooperative Development Grants

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: This Notice announces that the Rural Business-Cooperative Service (Agency) is accepting fiscal year (FY) 2016 applications for the Rural Cooperative Development Grant (RCDG) program as authorized by the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Approximately $5.8 million is available to be competitively awarded. The purpose of this program is to provide financial assistance to improve the economic condition of rural areas through cooperative development. Eligible applicants include a non-profit corporation or an institution of higher education. The Agency is encouraging applications that direct grants to projects based in or serving census tracts with poverty rates greater than or equal to 20 percent. This emphasis will support Rural Development's (RD) mission of improving the quality of life for Rural Americans and its commitment to directing resources to those who most need them.

DATES: Completed applications must be submitted on paper or electronically according to the following deadlines:

Paper applications must be postmarked and mailed, shipped, or sent overnight no later than June 23, 2016. You may also hand carry your application to one of our field offices, but it must be received by close of business on the deadline date. Late applications are not eligible for funding under this Notice and will not be evaluated.

Electronic applications must be received by June 20, 2016 to be eligible for grant funding. Please review the Grants.gov Web site at *http://www.grants.gov/web/grants/applicants/organization-registration.html.* For

instructions on the process of registering your organization as soon as possible to ensure you are able to meet the electronic application deadline. Late applications are not eligible for funding under this Notice and will not be evaluated.

ADDRESSES: You should contact a USDA Rural Development State Office (State Office) if you have questions. You are encouraged to contact your State Office well in advance of the application deadline to discuss your project and ask any questions about the application process. Contact information for State Offices can be found at *http://www.rd.usda.gov/contact-us/state-offices.*

Program guidance as well as application and matching funds templates may be obtained at *http://www.rd.usda.gov/programs-services/rural-cooperative-development-grant-program.* If you want to submit an electronic application, follow the instructions for the RCDG funding announcement located at *http://www.grants.gov.* If you want to submit a paper application, send it to the State Office located in the State where you are headquartered. If you are headquartered in Washington, DC please contact the Grants Division, Cooperative Programs, Rural Business-Cooperative Service, at (202) 690–1374 for guidance on where to submit your application.

FOR FURTHER INFORMATION CONTACT: Grants Division, Cooperative Programs, Rural Business-Cooperative Service, United States Department of Agriculture, 1400 Independence Avenue SW., Mail Stop 3253, Room 4208—South, Washington, DC 20250–3253, (202) 690–1374.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Business-Cooperative Service.

Funding Opportunity Title: Rural Cooperative Development Grants.

Announcement Type: Initial Notice.

Catalog of Federal Domestic Assistance Number: 10.771.

Date: Application Deadline. Paper applications must be postmarked, mailed, shipped, or sent overnight no later than June 23, 2016, or it will not be considered for funding. You may also hand carry your application to one of our field offices, but it must be received by close of business on the deadline date. Electronic applications must be received by *http://www.grants.gov* no later than midnight eastern time June 20, 2016, or it will not be considered for funding.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act, the paperwork burden associated with this Notice has been approved by the Office of Management and Budget (OMB) under OMB Control Number 0570–0006.

A. Program Description

The RCDG program is authorized under section 310B(e) of the Consolidated Farm and Rural Development Act (CONACT) (7 U.S.C. 1932 (e)) as amended by the Agricultural Act of 2014 (Pub. L. 113–79). You are required to comply with the regulations for this program published at 7 CFR part 4284, subparts A and F, which are incorporated by reference in this Notice. Therefore, you should become familiar with these regulations. The primary objective of the RCDG program is to improve the economic condition of rural areas through cooperative development. Grants are awarded on a competitive basis. The maximum award amount per grant is $200,000. Grants are available for non-profit corporations or higher education institutions only. Grant funds may be used to pay for up to 75 percent of the cost of establishing and operating centers for rural cooperative development. Grant funds may be used to pay for 95 percent of the cost of establishing and operating centers for rural cooperative development, when the applicant is a 1994 Institution as defined by 7 U.S.C. 301. The 1994 Institutions are commonly known as Tribal Land Grant Institutions. Centers may have the expertise on staff or they can contract out for the expertise, to assist individuals or entities in the startup, expansion or operational improvement of rural businesses, especially cooperative or mutually-owned businesses.

Definitions

The terms you need to understand are defined and published at 7 CFR 4284.3 and 7 CFR 4284.504. In addition, the terms ''rural'' and ''rural area,'' defined at section 343(a)(13) of the CONACT (7 U.S.C. 1991(a)), are incorporated by reference, and will be used for this program instead of those terms currently published at 7 CFR 4284.3. The term ''you'' referenced throughout this Notice should be understood to mean ''you'' the applicant. Finally, there has been some confusion on the Agency's meaning of the terms ''conflict of interest'' and ''mutually-owned business,'' because they are not defined in the CONACT or in the regulations used for the program. Therefore, the terms are clarified and should be understood as follows.

Conflict of interest—A situation in which a person or entity has competing personal, professional, or financial interests that make it difficult for the person or business to act impartially. Regarding use of both grant and matching funds, Federal procurement standards prohibit transactions that involve a real or apparent conflict of interest for owners, employees, officers, agents, or their immediate family members having a financial or other interest in the outcome of the project; or that restrict open and free competition for unrestrained trade. Specifically, project funds may not be used for services or goods going to, or coming from, a person or entity with a real or apparent conflict of interest, including, but not limited to, owner(s) and their immediate family members. An example of conflict of interest occurs when the grantee's employees, board of directors, or the immediate family of either, have the appearance of a professional or personal financial interest in the recipients receiving the benefits or services of the grant.

Mutually-owned business—An organization owned and governed by members who either are its consumers, producers, employees, or suppliers.

B. Federal Award Information

Type of Award: Competitive Grant.

Fiscal Year Funds: FY 2016.

Total Funding: Approximately $5.8 million.

Maximum Award: $200,000.

Anticipated Award Date: September 30, 2016.

C. Eligibility Information

Applicants must meet all of the following eligibility requirements. Applications which fail to meet any of these requirements by the application deadline will be deemed ineligible and will not be evaluated further.

1. Eligible Applicants

You must be a nonprofit corporation or an institution of higher education to apply for this program. Public bodies and individuals cannot apply for this program. See 7 CFR 4284.507. You must also meet the following requirements:

a. An applicant is ineligible if they have been debarred or suspended or otherwise excluded from or ineligible for participation in Federal assistance programs under Executive Order 12549, ''Debarment and Suspension.'' The Agency will check the System for Award Management (SAM) to determine if the applicant has been debarred or suspended. In addition, an applicant

will be considered ineligible for a grant due to an outstanding judgment obtained by the U.S. in a Federal Court (other than U.S. Tax Court), is delinquent on the payment of Federal income taxes, or is delinquent on Federal debt. See 7 CFR 4284.6. The applicant must certify as part of the application that they do not have an outstanding judgement against them. The Agency will check the Credit Alert Interactive Voice Response System (CAIVRS) to verify this.

b. Any corporation that has been convicted of a felony criminal violation under any Federal law within the past 24 months or that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, is not eligible for financial assistance provided with funds appropriated by the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government. Applicants will be required to complete Form AD–3030, ''Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants,'' if you are a corporation.

c. Applications will be deemed ineligible if the application includes any funding restrictions identified under section D.6. a and b. Inclusion of funding restrictions outlined in section D.6.a. and b. precludes the agency from making a federal award.

d. Applications will be deemed ineligible if the application is not complete in accordance with the requirements stated in section C.3.e., and will not be reviewed.

2. Cost Sharing or Matching

Your matching funds requirement is 25 percent of the total project cost (5 percent for 1994 Institutions). See 7 CFR 4284.508. When you calculate your matching funds requirement, please round up or down to whole dollars as appropriate. An example of how to calculate your matching funds is as follows:

a. Take the amount of grant funds you are requesting and divide it by .75. This will give you your total project cost.

Example: $200,000 (grant amount)/.75 (percentage for use of grant funds) = $266,667 (total project cost)

b. Subtract the amount of grant funds you are requesting from your total project cost. This will give you your matching funds requirement.

Example: $266,667 (total project cost)—$200,000 (grant amount) = $66,667 (matching funds requirement)

c. A quick way to double check that you have the correct amount of matching funds is to take your total project cost and multiply it by .25.

Example: $266,667 (total project cost) × .25 (maximum percentage of matching funds requirement) = $66,667 (matching funds requirement)

You must verify that all matching funds are available during the grant period and provide this documentation with your application in accordance with requirements identified in section D.2.e.8. If you are awarded a grant, additional verification documentation may be required to confirm the availability of matching funds.

Other rules for matching funds that you must follow are listed below.

- They must be spent on eligible expenses during the grant period.
- They must be from eligible sources.
- They must be spent in advance or as a pro-rata portion of grant funds being spent.
- They must be provided by either the applicant or a third party in the form of cash or an in-kind contribution.
- They cannot include board/advisory council members' time.
- They cannot include other Federal grants unless provided by authorizing legislation.
- They cannot include cash or in-kind contributions donated outside the grant period.
- They cannot include over-valued, in-kind contributions.
- They cannot include any project costs that are ineligible under the RCDG program.
- They cannot include any project costs that are unallowable under the applicable grant ''Cost Principles,'' including 2 CFR part 200, subpart E, and the Federal Acquisition Regulation (for-profits) or successor regulation.
- They can include loan funds from a Federal source.
- They can include travel and incidentals for board/advisory council members if you have established written policies explaining how these costs are normally reimbursed, including rates. You must include an explanation of this policy in your application or the contributions will not be considered as eligible matching funds.
- You must be able to document and verify the number of hours worked and the value associated with any in-kind contribution being used to meet a matching funds requirement.
- In-kind contributions provided by individuals, businesses, or cooperatives which are being assisted by you cannot be provided for the direct benefit of their own projects as USDA Rural Development considers this to be a conflict of interest or the appearance of a conflict of interest.

3. Other Eligibility Requirements

a. Purpose Eligibility

Your application must propose the establishment or continuation of a cooperative development center concept. You must use project funds, including grant and matching funds for eligible purposes only (see 7 CFR 4284.508). In addition, project funds may be used for programs providing for the coordination of services and sharing of information among the centers (see 7 U.S.C 1932(e) (4) (C) (vi)).

b. Project Eligibility

All project activities must be for the benefit of a rural area.

c. Multiple Application Eligibility

Only one application can be submitted per applicant. If two applications are submitted (regardless of the applicant name) that include the same Executive Director and/or advisory boards or committees of an existing center, both applications will be determined not eligible for funding.

d. Grant Period

Your application must include a one-year grant period or it will not be considered for funding. The grant period should begin no earlier than October 1, 2016, and no later than January 1, 2017. Prior approval is needed from the Agency if you are awarded a grant and desire the grant period to begin earlier or later than previously discussed. Projects must be completed within a one-year timeframe. The Agency may approve requests to extend the grant period for up to an additional 12 months at its discretion. Further guidance on grant period extensions will be provided in the award document.

e. Completeness

Your application will not be considered for funding if it fails to meet an eligibility criterion by time of application deadline and does not provide sufficient information to determine eligibility and scoring. In particular, you must include all of the forms and proposal elements as discussed in the regulation and as clarified further in this Notice.

Incomplete applications will not be reviewed by the Agency. For more information on what is required for an application, see 7 CFR 4284.510.

f. Satisfactory Performance

If you have an existing RCDG award, you must discuss the status of your existing RCDG award at application time under the Eligibility Discussion. You must be performing satisfactorily to be considered eligible for a new award. Satisfactory performance includes being up-to-date on all financial and performance reports and being current on all tasks as approved in the work plan. The Agency will use its discretion to make this determination. In addition, if you have an existing award from the Socially-Disadvantaged Groups Grant (SDGG) program, formerly known as the Small Socially-Disadvantaged Producer Grants (SSDPG) program, you must discuss the status of your existing SSDPG award at application time under Eligibility Discussion and be performing satisfactorily to be considered for a new RCDG award.

g. Indirect Costs

Your negotiated indirect cost rate approval does not need to be included in your application, but you will be required to provide it if a grant is awarded. Approval for indirect costs that are requested in an application without an approved indirect cost rate agreement is at the discretion of the Agency.

D. Application and Submission Information

1. Address to Request Application Package

For further information, you should contact your State Office at *http://www.rd.usda.gov/contact-us/state-offices*. Program materials may also be obtained at *http://www.rd.usda.gov/programs-services/rural-cooperative-development-grant-program*. You may also obtain a copy by calling 202–690–1374.

2. Content and Form of Application Submission

You may submit your application in paper form or electronically through Grants.gov. If you submit in paper form, any forms requiring signatures must include an original signature.

a. Electronic Submission

To submit an application electronically, you must use the Grants.gov Web site at *http://www.Grants.gov*. You may not submit an application electronically in any way other than through Grants.gov.

You can locate the Grants.gov downloadable application package for this program by using a keyword, the program name, or the Catalog of Federal Domestic Assistance Number for this program.

When you enter the Grants.gov Web site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

To use Grants.gov, you must already have a DUNS number and you must also be registered and maintain registration in SAM. We strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.gov.

You must submit all of your application documents electronically through Grants.gov. Applications must include electronic signatures. Original signatures may be required if funds are awarded.

After electronically submitting an application through Grants.gov, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number.

b. Paper Submission

If you want to submit a paper application, send it to the State Office located in the State where your project will primarily take place. You can find State Office Contact information at: *http://www.rd.usda.gov/contact-us/state-offices*. An optional-use Agency application template is available online at *http://www.rd.usda.gov/programs-services/rural-cooperative-development-grant-program*.

c. Supplemental Information

Your application must contain all of the required forms and proposal elements described in 7 CFR 4284.510 and as otherwise clarified in this Notice. Specifically, your application must include: (1) The required forms as described in 7 CFR 4284.510(b) and (2) the required proposal elements as described in 7 CFR 4284.510(c). If your application is incomplete, it is ineligible to compete for funds. Applications lacking sufficient information to determine eligibility and scoring will be considered ineligible. Information submitted after the application deadline will not be accepted. You are encouraged, but not required to utilize the application template found at *http://www.rd.usda.gov/programs-services/rural-cooperative-development-grant-program*.

d. Clarifications on Forms

- Standard Form (SF) 424—Your DUNS number should be identified in the ''Organizational DUNS'' field on SF 424, ''Application for Federal Assistance.'' Since there are no specific fields for a Commercial and Government Entity (CAGE) code and expiration date, you may identify them anywhere you want to on Form SF 424. In addition, you should provide the DUNS number and the CAGE code and expiration date under the applicant eligibility discussion in your proposal narrative. If you do not include the CAGE code and expiration date and the DUNS number in your application, it will not be considered for funding.
- Form AD–3030, ''Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants,'' if you are a corporation. A corporation is any entity that has filed articles of incorporation in one of the 50 States, the District of Columbia, the Federated States of Micronesia, the Republic of Palau, and the Republic of the Marshall Islands, or the various territories of the United States including American Samoa, Guam, Midway Islands, the Commonwealth of the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands. Corporations include both for profit and non-profit entities.
- You can voluntarily fill out and submit the ''Survey on Ensuring Equal Opportunity for Applicants,'' as part of your application if you are a nonprofit organization.

e. Clarifications on Proposal Elements

1. You must include the title of the project as well as any other relevant identifying information on the Title Page.

2. You must include a Table of Contents with page numbers for each component of the application to facilitate review.

3. Your Executive Summary must include the items in 7 CFR 4284.510 (c)(3), and also discuss the percentage of work that will be performed among organizational staff, consultants, or other contractors. It should not exceed two pages.

4. Your Eligibility Discussion must not exceed two pages and cover how you meet the eligibility requirements for applicant, matching funds, other eligibility requirements and grant period. If you have an existing RCDG or the Socially-Disadvantaged Groups Grant (SDGG) program, formerly known as the Small Socially-Disadvantaged Producer Grants (SSDPG) program award or both, you must discuss the current status of those award(s) under grant period eligibility.

5. Your Proposal Narrative must not exceed 40 pages and should describe the essential aspects of the project.

i. You are only required to have one title page for the proposal.

ii. If you list the evaluation criteria on the Table of Contents and specifically and individually address each criterion in narrative form, then it is not necessary for you to include an Information Sheet. Otherwise, the Information Sheet is required under 7 CFR 4284.510(c)(ii).

iii. You should include the following under Goals of the Project:

A. A statement that substantiates that the Center will effectively serve rural areas in the United States;

B. A statement that the primary objective of the Center will be to improve the economic condition of rural areas through cooperative development;

C. A description of the contributions that the proposed activities are likely to make to the improvement of the economic conditions of the rural areas for which the Center will provide services. Expected economic impacts should be tied to tasks included in the work plan and budget; and

D. A statement that the Center, in carrying out its activities, will seek, where appropriate, the advice, participation, expertise, and assistance of representatives of business, industry, educational institutions, the Federal government, and State and local governments.

iv. The Agency has established annual performance evaluation measures to evaluate the RCDG program. You must provide estimates on the following performance evaluation measures.

- Number of groups who are not legal entities assisted.
- Number of businesses that are not cooperatives assisted.
- Number of cooperatives assisted.
- Number of businesses incorporated that are not cooperatives.
- Number of cooperatives incorporated.
- Total number of jobs created as a result of assistance.
- Total number of jobs saved as a result of assistance.
- Number of jobs created for the Center as a result of RCDG funding.
- Number of jobs saved for the Center as a result of RCDG funding.

It is permissible to have a zero in a performance element. When you calculate jobs created, estimates should be based upon actual jobs to be created by your organization as a result of the RCDG funding or actual jobs to be created by cooperative businesses or other businesses as a result of assistance from your organization. When you calculate jobs saved, estimates should be based only on actual jobs that have been lost if your organization did not receive RCDG funding or actual jobs that would have been lost without assistance from your organization.

v. You can also suggest additional performance elements for example where job creation or jobs saved may not be a relevant indicator (*e.g.* housing). These additional criteria should be specific, measurable performance elements that could be included in an award document.

vi. You must describe in the application how you will undertake to do each of the following. We would prefer if you described these undertakings within proposal evaluation criteria to reduce duplication in your application. The specific proposal evaluation criterion where you should address each undertaking is noted below.

A. Take all practicable steps to develop continuing sources of financial support for the Center, particularly from sources in the private sector (should be presented under proposal evaluation criterion j., utilizing the specific requirements of section E.1.j.);

B. Make arrangements for the Center's activities to be monitored and evaluated (should be addressed under proposal evaluation criterion number h. utilizing the specific requirements of section E.1.h.); and

C. Provide an accounting for the money received by the grantee in accordance with 7 CFR part 4284, subpart F. This should be addressed under proposal evaluation criterion number a., utilizing the specific requirements of section E.1.a.

vii. You should present the Work Plan and Budget proposal element under proposal evaluation criterion number h., utilizing the specific requirements of section E.1.h. of this Notice to reduce duplication in your application.

viii. You should present the Delivery of Cooperative development assistance proposal element under proposal evaluation criterion number b., utilizing the specific requirements of section E.1.b. of this Notice.

ix. You should present the Qualifications of Personnel proposal element under proposal evaluation criterion number i., utilizing the specific requirements of section E.1.i. of this Notice.

x. You should present the Local Support and Future Support proposal elements under proposal evaluation criterion number j., utilizing the requirements of section E.1.j. of this Notice.

xi. Your application will not be considered for funding if you do not address all of the proposal evaluation criteria. See section E.1. of this Notice for a description of the proposal evaluation criteria.

xii. Only appendices A–C will be considered when evaluating your application. You must not include resumes of staff or consultants in the application.

6. You must certify that there are no current outstanding Federal judgments against your property and that you will not use grant funds to pay for any judgment obtained by the United States. To satisfy the Certification requirement, you should include this statement in your application: ''[INSERT NAME OF APPLICANT] certifies that the United States has not obtained an unsatisfied judgment against its property and will not use grant funds to pay any judgments obtained by the United States.'' A separate signature is not required.

7. You must certify that matching funds will be available at the same time grant funds are anticipated to be spent and that expenditures of matching funds are pro-rated or spent in advance of grant funding, such that for every dollar of the total project cost, not less than the required amount of matching funds will be expended. Please note that this Certification is a separate requirement from the Verification of Matching Funds requirement. To satisfy the Certification requirement, you should include this statement in your application: ''[INSERT NAME OF APPLICANT] certifies that matching funds will be available at the same time grant funds are anticipated to be spent and that expenditures of matching funds shall be pro-rated or spent in advance of grant funding, such that for every dollar of the total project cost, at least 25 cents (5 cents for 1994 Institutions) of matching funds will be expended.'' A separate signature is not required.

8. You must provide documentation in your application to verify all of your proposed matching funds. The documentation must be included in Appendix A of your application and will not count towards the 40-page limitation. Template letters are available for each type of matching funds contribution at *http://www.rd.usda.gov/programs-services/rural-cooperative-development-grant-program*.

a. If matching funds are to be provided in cash, you must meet the following requirements.

- You: The application must include a statement verifying (1) the amount of the cash and (2) the source of the cash. You may also provide a bank statement

dated 30 days or less from the application deadline date to verify your cash match.

• Third-party: The application must include a signed letter from the third party verifying (1) how much cash will be donated and (2) that it will be available corresponding to the proposed grant period or donated on a specific date within the grant period.

b. If matching funds are to be provided by an in-kind donation, you must meet the following requirements.

• You: The application must include a signed letter from you or your authorized representative verifying (1) the nature of the goods and/or services to be donated and how they will be used, (2) when the goods and/or services will be donated (*i.e.,* corresponding to the proposed grant period or to specific dates within the grant period), and (3) the value of the goods and/or services. Please note that most applicant contributions for the RCDG program are considered applicant cash match in accordance with this Notice. If you are unsure, please contact your State Office because identifying your matching funds improperly can affect your scoring.

• Third-Party: The application must include a signed letter from the third party verifying (1) the nature of the goods and/or services to be donated and how they will be used, (2) when the goods and/or services will be donated (*i.e.,* corresponding to the proposed grant period or to specific dates within the grant period), and (3) the value of the goods and/or services.

To ensure that you are identifying and verifying your matching funds appropriately, please note the following:

• If you are paying for goods and/or services as part of the matching funds requirement, the expenditure is considered a cash match, and you must verify it as such. Universities must verify the goods and services they are providing to the project as a cash match and the verification must be approved by the appropriate approval official (*i.e.,* sponsored programs office or equivalent).

• If you have already received cash from a third-party (*i.e.,* Foundation) before the start of your proposed grant period, you must verify this as your own cash match and not as a third-party cash match. If you are receiving cash from a third-party during the grant period, then you must be verifying the cash as a third-party cash match.

• Board resolutions for a cash match must be approved at the time of application.

• You can only consider goods or services for which no expenditure is made as an in-kind contribution.

• If a non-profit or another organization contributes the services of affiliated volunteers, they must follow the third-party, in-kind donation verification requirement for each individual volunteer.

• Expected program income may not be used to fulfill your matching funds requirement at the time you submit your application. However, if you have a contract to provide services in place at the time you submit your application, you can verify the amount of the contract as a cash match.

• The valuation process you use for in-kind contributions does not need to be included in your application, but you must be able to demonstrate how the valuation was derived if you are awarded a grant. The grant award may be withdrawn or the amount of the grant reduced if you cannot demonstrate how the valuation was derived.

Successful applicants must comply with requirements identified in Section F, Federal Award Administration.

3. Dun and Bradstreet Data Universal Numbering System (DUNS) and System for Awards Management (SAM)

In order to be eligible (unless you are excepted under 2 CFR 25.110(b), (c) or (d), you are required to:

(a) Provide a valid DUNS number in your application, which can be obtained at no cost via a toll-free request line at (866) 705–5711;

(b) Register in SAM before submitting your application. You may register in SAM at no cost at *https://www.sam.gov/portal/public/SAM/;* and

(c) Continue to maintain an active SAM registration with current information at all times during which you have an active Federal award or an application or plan under consideration by a Federal awarding agency.

The Agency may not make a Federal award to you until you have complied with all applicable DUNS and SAM requirements. If you have not fully complied with requirements, the Agency may determine that the applicant is not qualified to receive a Federal award and the Agency may use this determination as a basis for making an award to another applicant.

4. Submission Dates and Times

Application Deadline Date: June 23, 2016.

Explanation of Deadlines: Complete applications must be submitted on paper or electronically according to the following deadlines:

Paper applications must be postmarked and mailed, shipped, or sent overnight no later than June 23, 2016, to be eligible for grant funding. The Agency will determine whether your application is late based on the date shown on the postmark or shipping invoice. You may also hand carry your application to one of our field offices, but it must be received by close of business on the deadline date. If the due date falls on a Saturday, Sunday, or Federal holiday, the reporting package is due the next business day. Late applications will automatically be deemed ineligible.

Electronic applications must be received by *http://www.grants.gov* no later than midnight eastern time June 20, 2016, to be eligible for grant funding. Please review the Grants.gov Web site at *http://grants.gov/applicants/organization_registration.jsp* for instructions on the process of registering your organization as soon as possible to ensure you are able to meet the electronic application deadline. Grants.gov will not accept applications submitted after the deadline.

5. Intergovernmental Review of Applications

Executive Order (E.O.) 12372, ''Intergovernmental Review of Federal Programs,'' applies to this program. This E.O. requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many States have established a Single Point of Contact (SPOC) to facilitate this consultation. For a list of States that maintain a SPOC, please see the White House Web site: *http://www.whitehouse.gov/omb/grants_spoc*. If your State has a SPOC, you may submit a copy of the application directly for review. Any comments obtained through the SPOC must be provided to your State Office for consideration as part of your application. If your State has not established a SPOC, or if you do not want to submit a copy of the application, our State Offices will submit your application to the SPOC or other appropriate agency or agencies.

6. Funding Restrictions

a. Project funds, including grant and matching funds, cannot be used for ineligible grant purposes (see 7 CFR 4284.10). Also, you shall not use project funds for the following:

• To purchase, rent, or install laboratory equipment or processing machinery;

• To pay for the operating costs of any entity receiving assistance from the Center;

• To pay costs of the project where a conflict of interest exists;

• To fund any activities prohibited by 2 CFR part 200; or

• To fund any activities considered unallowable by 2 CFR part 200, subpart E, ''Cost Principles,'' and the Federal Acquisition Regulation (for-profits) or successor regulations.

b. In addition, your application will not be considered for funding if it does any of the following:

• Focuses assistance on only one cooperative or mutually-owned business;

• Requests more than the maximum grant amount; or

• Proposes ineligible costs that equal more than 10 percent of total project costs. The ineligible costs will NOT be removed at this stage to proceed with application processing. For purposes of this determination, the grant amount requested plus the matching funds amount constitutes the total project costs.

We will consider your application for funding if it includes ineligible costs of 10 percent or less of total project costs, as long as the remaining costs are determined eligible otherwise. However, if your application is successful, those ineligible costs must be removed and replaced with eligible costs before the Agency will make the grant award, or the amount of the grant award will be reduced accordingly. If we cannot determine the percentage of ineligible costs, your application will not be considered for funding.

7. Other Submission Requirements

a. You should not submit your application in more than one format. You must choose whether to submit your application in hard copy or electronically. Applications submitted in hard copy should be mailed or hand-delivered to the State Office located in the State where you are headquartered. You can find State Office contact information at: *http://www.rd.usda.gov/contact-us/state-offices.* To submit an application electronically, you must follow the instruction for this funding announcement at *http://www.grants.gov.* A password is not required to access the Web site.

b. National Environmental Policy Act

All recipients under this Notice are subject to the requirements of 7 CFR part 1940, subpart G and any successor regulations. However, technical assistance awards under this Notice are classified as a Categorical Exclusion according to 7 CFR 1940.310(e), and do not require any additional documentation.

c. Civil Rights Compliance Requirements

All grants made under this Notice are subject to title VI of the Civil Rights Act of 1964 as required by the USDA (7 CFR part 15, subpart A) and section 504 of the Rehabilitation Act of 1973.

E. Application Review Information

The State Offices will review applications to determine if they are eligible for assistance based on requirements in 7 CFR part 4284, subparts A and F, this Notice, and other applicable Federal regulations. If determined eligible, your application will be scored by a panel of USDA employees in accordance with the point allocation specified in this Notice. A recommendation will be submitted to the Administrator to fund applications in highest ranking order. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion.

1. Scoring Criteria

Scoring criteria will follow criteria published at 7 CFR 4284.513 as supplemented below including any amendments made by the section 6013 of the Food, Conservation, and Energy Act of 2008 (Pub. L. 110–234), which is incorporated by reference in this Notice. The regulatory and statutory criteria are clarified and supplemented below. You should also include information as described in section D.2.e.5.vi. if you choose to address these items under the scoring criteria. Evaluators will base scores only on the information provided or cross-referenced by page number in each individual evaluation criterion. The maximum amount of points available is 100. Newly established or proposed Centers that do not yet have a track record on which to evaluate the following criteria should refer to the expertise and track records of staff or consultants expected to perform tasks related to the respective criteria. Proposed or newly established Centers must be organized well-enough at time of application to address its capabilities for meeting these criteria.

a. Administrative capabilities (maximum score of 10 points). A panel of USDA employees will evaluate your demonstrated track record in carrying out activities in support of development assistance to cooperatively and mutually owned businesses. At a minimum, you must discuss the following administrative capabilities:

1. Financial systems and audit controls;

2. Personnel and program administration performance measures;

3. Clear written rules of governance; and

4. Experience administering Federal grant funding no later than the last 5 years, including but not limited to past RCDGs. Please list the name of the Federal grant program(s) and the amount(s) of funding received.

You will score higher on this criterion if you can demonstrate that the Center has independent governance. For applicants that are universities or parent organizations, you should demonstrate that there is a separate board of directors for the Center.

b. Technical assistance and other services (maximum score of 10 points). A panel of USDA employees will evaluate your demonstrated expertise no later than the last 5 years in providing technical assistance and accomplishing effective outcomes in rural areas to promote and assist the development of cooperatively and mutually owned businesses. You must discuss at least:

1. Your potential for delivering effective technical assistance;

2. The types of assistance provided;

3. The expected effects of that assistance;

4. The sustainability of organizations receiving the assistance; and

5. The transferability of your cooperative development strategies and focus to other areas of the U.S.

A chart or table showing the outcomes of your demonstrated expertise based upon the performance elements listed in section D.2.e.5.iv. or as identified in your award document on previous RCDG awards. At a minimum, please provide information for FY 2012–FY 2014 awards. We prefer that you provide one chart or table separating out award years. The intention here is for you to provide actual performance numbers based upon award years even though your grant period for the award was for the next calendar or fiscal year. Please provide a narrative explanation if you have not received a RCDG award.

You will score higher on this criterion if you provide more than 3 years of outcomes and can demonstrate that the organizations you assisted within the last 5 years are sustainable. Additional outcome information should be provided on RCDG grants awarded before FY 2012. Please describe specific project(s) when addressing a–e of this paragraph.

c. Economic development (maximum score of 10 points). A panel of USDA employees will evaluate your demonstrated ability to facilitate:

1. Establishment of cooperatives or mutually owned businesses;

2. New cooperative approaches (*i.e.,* organizing cooperatives among

underserved individuals or communities; an innovative market approach; a type of cooperative currently not in your service area; a new cooperative structure; novel ways to raise member equity or community capitalization; conversion of an existing business to cooperative ownership); and

3. Retention of businesses, generation of employment opportunities or other factors, as applicable, that will otherwise improve the economic conditions of rural areas.

You will score higher on this criterion if you provide economic statistics showing the impacts of your past development projects no later than 5 years old and identify your role in the economic development outcomes.

d. Past performance in establishing legal business entities (maximum score of 10 points). A panel of USDA employees will evaluate your demonstrated past performance in establishing legal cooperative business entities and other legal business entities during January 1, 2013–December 31, 2015. Provide the name of the organization(s) established, the date of formation and your role in assisting with the incorporation(s) under this criterion. In addition, documentation verifying the establishment of legal business entities must be included in Appendix C of your application and will not count against the 40-page limit for the narrative. The documentation must include proof that organizational documents were filed with the Secretary of State's Office (*i.e.* Certificate of Incorporation or information from the State's official Web site naming the entity established and the date of establishment); or if the business entity is not required to register with the Secretary of State, a certification from the business entity that a legal business entity has been established and when. Please note that you are not required to submit articles of incorporation to receive points under this criterion. You will score higher on this criterion if you have established legal cooperative businesses.

e. Networking and regional focus (maximum score of 10 points). A panel of USDA employees will evaluate your demonstrated commitment to:

1. Networking with other cooperative development centers, and other organizations involved in rural economic development efforts, and

2. Developing multi-organization and multi-state approaches to addressing the economic development and cooperative needs of rural areas.

You will score higher on this criterion if you can demonstrate the outcomes of your multi-organizational and multi-state approaches. Please describe the project(s), partners and the outcome(s) that resulted from the approach.

f. Commitment (maximum score of 10 points). A panel of USDA employees will evaluate your commitment to providing technical assistance and other services to under-served and economically distressed areas in rural areas of the United States. You will score higher on this criterion if you define and describe the underserved and economically distressed areas within your service area, provide statistics, and identify projects within or affecting these areas, as appropriate.

g. Matching Funds (maximum score of 10 points). A panel of USDA employees will evaluate your commitment for the 25 percent (5 percent for 1994 Institutions) matching funds requirement. A chart or table should be provided to describe all matching funds being committed to the project. However, formal documentation to verify all of the matching funds must be included in Appendix A of your application. You will be scored on how you identify your matching funds.

1. If you met the 25 percent (5 percent for 1994 Institutions) matching requirement, points will be assigned as follows:

- In-kind only—1 point,
- Mix of in-kind and cash—3–4 points (maximum points will be awarded if the ratio of cash to in-kind is 30 percent and above of matching funds), or
- Cash only—5 points.

2. If you exceeded the 25 percent (5 percent for 1994 Institutions) matching requirement, points will be assigned as follows:

- In-kind only—2 points,
- Mix of in-kind and cash—6–7 points (maximum points will be awarded if the ratio of cash to in-kind is 30 percent and above of matching funds), or
- Cash only—10 points.

h. Work Plan/Budget (maximum score of 10 points). A panel of USDA employees will evaluate your work plan for detailed actions and an accompanying timetable for implementing the proposal. The budget must present a breakdown of the estimated costs associated with cooperative and business development activities as well as the operation of the Center and allocate these costs to each of the tasks to be undertaken. Matching funds as well as grant funds must be accounted for in the budget.

You must discuss at a minimum:

1. Specific tasks (whether it be by type of service or specific project) to be completed using grant and matching funds;

2. How customers will be identified;

3. Key personnel; and

4. The evaluation methods to be used to determine the success of specific tasks and overall objectives of Center operations. Please provide qualitative methods of evaluation. For example, evaluation methods should go beyond quantitative measurements of completing surveys or number of evaluations.

You will score higher on this criterion if you present a clear, logical, realistic, and efficient work plan and budget.

i. Qualifications of those Performing the Tasks (maximum score of 10 points). A panel of USDA employees will evaluate your application to determine if the personnel expected to perform key tasks have a track record of:

1. Positive solutions for complex cooperative development and/or marketing problems; or

2. A successful record of conducting accurate feasibility studies, business plans, marketing analysis, or other activities relevant to your success as determined by the tasks identified in the your work plan; and

3. Whether the personnel expected to perform the tasks are full/part-time employees of your organization or are contract personnel.

You will score higher on this criterion if you demonstrate commitment and availability of qualified personnel expected to perform the tasks.

j. Local and Future Support (maximum score of 10 points). A panel of USDA employees will evaluate your application for local and future support. Support should be discussed directly within the response to this criterion.

1. Discussion on local support should include previous and/or expected local support and plans for coordinating with other developmental organizations in the proposed service area or with state and local government institutions. You will score higher if you demonstrate strong support from potential beneficiaries and formal evidence of intent to coordinate with other developmental organizations. You may also submit a maximum of 10 letters of support or intent to coordinate with the application to verify your discussion. These letters should be included in Appendix B of your application and will not count against the 40-page limit for the narrative.

2. Discussion on future support will include your vision for funding operations in future years. You should document:

(i) New and existing funding sources that support your goals;

(ii) Alternative funding sources that reduce reliance on Federal, State, and local grants; and

(iii) The use of in-house personnel for providing services versus contracting out for that expertise. Please discuss your strategy for building in-house technical assistance capacity.

You will score higher if you can demonstrate that your future support will result in long-term sustainability of the Center.

2. Review and Selection Process

The State Offices will review applications to determine if they are eligible for assistance based on requirements in 7 CFR part 4284, subparts A and F, this Notice, and other applicable Federal regulations. If determined eligible, your application will be scored by a panel of USDA employees in accordance with the point allocation specified in this Notice. A recommendation will be submitted to the Administrator to fund applications in highest ranking order. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion. If your application is evaluated, but not funded, it will not be carried forward into the next competition.

F. Federal Award Administration Information

1. Federal Award Notices

If you are selected for funding, you will receive a signed notice of Federal award by postal mail from the State Office where your application was submitted, containing instructions on requirements necessary to proceed with execution and performance of the award.

If you are not selected for funding, you will be notified in writing via postal mail and informed of any review and appeal rights. You must comply with all applicable statutes, regulations, and notice requirements before the grant award will be approved. There will be no available funds for successful appellants once all FY 15 funds are awarded and obligated. See 7 CFR part 11 for USDA National Appeals Division procedures.

2. Administrative and National Policy Requirements

Additional requirements that apply to grantees selected for this program can be found in 7 CFR part 4284, subpart F; the Grants and Agreements regulations of the Department of Agriculture codified in 2 CFR parts 180, 400, 415, 417, 418, 421; 2 CFR parts 25 and 170; and 48 CFR 31.2, and successor regulations to these parts.

In addition, all recipients of Federal financial assistance are required to report information about first-tier subawards and executive compensation (see 2 CFR part 170). You will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282) reporting requirements (see 2 CFR 170.200(b), unless you are exempt under 2 CFR 170.110(b)).

The following additional requirements apply to grantees selected for this program:

- Agency-approved Grant Agreement.
- Letter of Conditions.
- Form RD 1940–1, ''Request for Obligation of Funds.''
- Form RD 1942–46, ''Letter of Intent to Meet Conditions.''
- Form AD–1047, ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters-Primary Covered Transactions.''
- Form AD–1048, ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions.''
- Form AD–1049, ''Certification Regarding Drug-Free Workplace Requirements (Grants).''
- Form RD 400–4, ''Assurance Agreement.''
- SF LLL, ''Disclosure of Lobbying Activities,'' if applicable.
- Form AD–3031, ''Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants.'' Must be signed by corporate applicants who receive an award under this Notice.

3. Reporting

After grant approval and through grant completion, you will be required to provide the following:

A SF–425, ''Federal Financial Report,'' and a project performance report will be required on a semiannual basis (due 30 working days after end of the semiannual period). The project performance reports shall include the following: A comparison of actual accomplishments to the objectives established for that period;

a. Reasons why established objectives were not met, if applicable;

b. Reasons for any problems, delays, or adverse conditions, if any, which have affected or will affect attainment of overall project objectives, prevent meeting time schedules or objectives, or preclude the attainment of particular objectives during established time periods. This disclosure shall be accompanied by a statement of the action taken or planned to resolve the situation; and

c. Objectives and timetable established for the next reporting period.

d. Provide a final project and financial status report within 90 days after the expiration or termination of the grant.

e. Provide outcome project performance reports and final deliverables.

G. Agency Contacts

If you have questions about this Notice, please contact the appropriate State Office at *http://www.rd.usda.gov/contact-us/state-offices.* Program guidance as well as application and matching funds templates may be obtained at *http://www.rd.usda.gov/programs-services/rural-cooperative-development-grant-program.* If you want to submit an electronic application, follow the instructions for the RCDG funding announcement located at *http://www.grants.gov.* You may also contact National Office staff: Susan Horst, RCDG Program Lead, *susan.horst@wdc.usda.gov,* or call the main line at 202–690–1374.

H. Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.)

If you wish to file an employment complaint, you must contact your agency's EEO Counselor within 45 days of the date of the alleged discriminatory act, event, or in the case of a personnel action. Additional information can be found online at *http://www.ascr.usda.gov/complaint_filing_cust.html.*

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at *http://www.ascr.usda.gov/complaint_filing_cust.html,* or at any USDA office, or call (866) 632–9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence

Avenue SW., Washington, DC 20250–9410, by fax (202) 690–7442 or email at *program.intake@usda.gov.*

Individuals who are deaf, hard of hearing or have speech disabilities and you wish to file either an EEO or program complaint please contact USDA through the Federal Relay Service at (800) 877–8339 or (800) 845–6136 (in Spanish).

Persons with disabilities, who wish to file a program complaint, please see information above on how to contact us by mail directly or by email. If you require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Dated: March 17, 2016.

Samuel H. Rikkers,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2016–06765 Filed 3–24–16; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Proposed collection; Comments requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Business-Cooperative Service's (RBS) intention to request an extension of a currently approved information collection in support of the program 7 CFR part 4279–B, '' Guaranteed Loanmaking—Business and Industry Loans.''

DATES: Comments on this notice must be received by May 24, 2016 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: Ginger Allen, Business and Industry Loan Processing Branch, Rural Business-Cooperative Service, U.S. Department of Agriculture, STOP 3224, 1400 Independence Ave. SW., Washington, DC 20250–3224. Telephone: (202) 690–0309. The TDD number is (800) 877–8339 or (202) 708–9300.

SUPPLEMENTARY INFORMATION:

Title: Guaranteed Loanmaking—Business and Industry Loans.

OMB Number: 0570–0017.

Expiration Date of Approval: August 31, 2016.

Type of Request: Extension of a currently approved information collection.

Abstract: The Business and Industry (B&I) Guaranteed Loan Program was legislated in 1972 under section 310B of the Consolidated Farm and Rural Development Act, as amended. The purpose of the program is to improve, develop, or finance businesses, industries, and employment and improve the economic and environmental climate in rural communities. This purpose is achieved through bolstering the existing private credit structure through the guaranteeing of quality loans made by lending institutions, thereby providing lasting community benefits.

Estimate of Burden: Public reporting for this collection of information is estimated to average 2 hours per response.

Respondents: Business or other for-profit; State, Local or Tribal; Lenders, accountants, attorneys.

Estimated Number of Respondents: 413.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Responses: 5,384.

Estimated Total Annual Burden on Respondents: 13,349 hours.

Copies of this information collection can be obtained from Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division at (202) 692–0040.

Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of RBS, including whether the information will have practical utility; (b) the accuracy of RBS's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division, U.S. Department of Agriculture, Rural Development, STOP 0742, 1400 Independence Ave. SW., Washington, DC 20250.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: February 25, 2016.

William C. Smith,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2016–06767 Filed 3–24–16; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Proposed collection; Comments requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Business-Cooperative Service's (RBS) intention to request an extension of a currently approved information collection in support of the program for 7 CFR part 4279–A, ''Guaranteed Loanmaking—General.

DATES: Comments on this notice must be received by May 24, 2016 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: Ginger Allen, Business and Industry Loan Processing Branch, Rural Business-Cooperative Service, U.S. Department of Agriculture, STOP 3224, 1400 Independence Avenue SW., Washington, DC 20250–3224. Telephone: (202) 690–0309. The TDD number is (800) 877–8339 or (202) 708–9300.

SUPPLEMENTARY INFORMATION:

Title: Guaranteed Loanmaking—Business and Industry Loans.

OMB Number: 0570–0018.

Expiration Date of Approval: August 31, 2016.

Type of Request: Extension of a currently approved information collection.

Abstract: The Business and Industry (B&I) Guaranteed Loan Program was legislated in 1972 under Section 310B of the Consolidated Farm and Rural Development Act, as amended. The purpose of the program is to improve, develop, or finance businesses, industries, and employment and improve the economic and environmental climate in rural communities. This purpose is achieved through bolstering the existing private

credit structure through the guaranteeing of quality loans made by lending institutions, thereby providing lasting community benefits. The collected information is necessary to assist Agency loan officers and approval officials in determining program eligibility and program monitoring.

Estimate of Burden: Public reporting for this collection of information is estimated to average 30 minutes to 12 hours per response.

Respondents: Business or other for-profit; State, Local or Tribal; Lenders, accountants, attorneys.

Estimated Number of Respondents: 225.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Responses: 462.

Estimated Total Annual Burden on Respondents: 955 hours.

Copies of this information collection can be obtained from Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division at (202) 692–0040.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of RBS, including whether the information will have practical utility; (b) the accuracy of RBS's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division, U.S. Department of Agriculture, Rural Development, STOP 0742, 1400 Independence Ave. SW., Washington, DC 20250.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: February 25, 2016.

William C. Smith,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2016–06768 Filed 3–24–16; 8:45 am]

BILLING CODE 3410–XY–P

UNITED STATES DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Nutveena Sirirojnananont, 399 Maplewood Avenue, Portmouth, NH 03801; Order Denying Export Privileges

On August 26, 2014, in the U.S. District Court for the District of New Hamsphire, Nutveena Sirirojnananont (''Sirirojnananont''), was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (''AECA''). Specifically, Sirirojnananont knowingly and willfully caused to be exported from the United States to Thailand firearms which were designated as defense articles on the United States Munitions List, without having obtained from the United States Department of State a license or written approval for the export of these defense articles. Sirirojnananont was sentenced to 10 months of imprisonment, one year of supervised release, and fined a $600 assessment.

Section 766.25 of the Export Administration Regulations (''EAR'' or ''Regulations'') [1] provides, in pertinent part, that ''[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of the Export Administration Act (''EAA''), the EAR, or any order, license or authorization issued thereunder; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. § 1701–1706); 18 U.S.C. §§ 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. § 783(b)), or section 38 of the Arms Export Control Act (22 U.S.C. § 2778).'' 15 CFR 766.25(a); *see also* Section 11(h) of the EAA, 50 U.S.C. 4610(h). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d); *see also* 50 U.S.C. 4610(h). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security's Office of Exporter Services may revoke any Bureau of Industry and Security (''BIS'') licenses previously issued in which the person had an interest in at the time of her conviction.

BIS has received notice of Sirirojnananont's conviction for violating the AECA, and has provided notice and an opportunity for Sirirojnananont to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from Sirirojnananont.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Sirirojnananont's export privileges under the Regulations for a period of 10 years from the date of Sirirojnananont's conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which Sirirojnananont had an interest at the time of her conviction.

Accordingly, it is hereby ORDERED:

First, from the date of this Order until August 26, 2024, Nutveena Sirirojnananont, with a last known address of 399 Maplewood Avenue, Portmouth, NH 03801, and when acting for or on her behalf, her successors, assigns, employees, agents or representatives (the ''Denied Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2015). The Regulations issued pursuant to the Export Administration Act (50 U.S.C. 4601–4623 (Supp. III 2015) (available at *http://uscode.house.gov*)). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2015 (80 FR 48,233 (Aug. 11, 2015)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2006 & Supp. IV 2010)).

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Sirirojnananont by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Sirirojnananont may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to the Sirirojnananont. This Order shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until August 26, 2024.

Issued this 18th day of March, 2016.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2016–06820 Filed 3–24–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–983]

Notice of Final Results of Antidumping Duty Changed Circumstances Review: Drawn Stainless Steel Sinks From the People's Republic of China

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce

SUMMARY: On February 12, 2016, the Department of Commerce (the Department) published its notice of initiation and preliminary results of a changed circumstances review of the antidumping duty order on drawn stainless steel sinks (drawn sinks) from the People's Republic of China (PRC).[1] In that notice, we preliminarily determined that Ningbo Afa Kitchen and Bath Co., Ltd. (Ningbo) is the successor-in-interest to Yuyao Afa Kitchenware Co., Ltd. (Yuyao) for purposes of determining antidumping duty cash deposits and liabilities. No interested party submitted comments in opposition to the *Initiation and Preliminary Results*. For these final results, the Department continues to find that Ningbo is the successor-in-interest to Yuyao.

DATES: Effective March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Ross Belliveau or Brian Smith, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4952 or (202) 482–1766, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 11, 2013, the Department published in the **Federal Register** an AD order on drawn sinks from the PRC.[2] On November 19, 2015, Yuyao, a producer/exporter of drawn sinks covered by this order, changed its name from Yuyao to Ningbo. On December 22, 2015, Ningbo requested that the Department conduct a changed circumstances review under section 751(b) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.216.[3] In this request, Ningbo asked the Department to determine that it is the successor-in-interest to Yuyao and, accordingly, to assign it the cash deposit rate of Yuyao.[4]

On February 12, 2016, the Department published its notice of initiation and preliminary results of this changed circumstances review, determining that Ningbo is the successor-in-interest to Yuyao.[5] In the *Initiation and Preliminary Results,* we provided all interested parties with an opportunity to comment and to request a public hearing regarding our preliminary finding that Ningbo is the successor-in-interest to Yuyao. On February 26, 2016, Ningbo submitted comments in support of our preliminary finding.[6] We received no comments in opposition to our preliminary finding and no requests for a public hearing from interested parties within the time period set forth in the *Initiation and Preliminary Results*.

Scope of the Order

The products covered by the scope of this order are drawn stainless steel sinks with single or multiple drawn bowls, with or without drain boards, whether finished or unfinished, regardless of type of finish, gauge, or grade of stainless steel. Mounting clips, fasteners, seals, and sound-deadening pads are also covered by the scope of this order if they are included within the sales price of the drawn stainless steel sinks. For purposes of this scope definition, the term ''drawn'' refers to a manufacturing process using metal forming technology to produce a smooth basin with seamless, smooth, and rounded corners. Drawn stainless steel sinks are available in various shapes and configurations and may be described in a number of ways including flush mount, top mount, or undermount (to include the attachment relative to the countertop). Stainless

[1] *See Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Drawn Stainless Steel Sinks From the People's Republic of China,* 81 FR 7504 (February 12, 2016) (*Initiation and Preliminary Results*).

[2] *See Drawn Stainless Steel Sinks from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 78 FR 21592 (April 11, 2013).

[3] *See* Letter from Ningbo, entitled ''Drawn Stainless Steel Sinks from the People's Republic of China: Request for Changed Circumstances Review by Yuyao Afa Kitchenware Co., Ltd. and Ningbo Afa Kitchen and Bath Co., Ltd.,'' dated December 22, 2015.

[4] *Id.*

[5] *See Initiation and Preliminary Results.*

[6] *See* Letter from Ningbo, entitled ''Drawn Stainless Steel Sinks from the People's Republic of China: Comments on Changed Circumstances Review by Yuyao Afa Kitchenware Co., Ltd. and Ningbo Afa Kitchen and Bath Co., Ltd.,'' dated February 26, 2016.

steel sinks with multiple drawn bowls that are joined through a welding operation to form one unit are covered by the scope of the order. Drawn stainless steel sinks are covered by the scope of the order whether or not they are sold in conjunction with non-subject accessories such as faucets (whether attached or unattached), strainers, strainer sets, rinsing baskets, bottom grids, or other accessories.

Excluded from the scope of the order are stainless steel sinks with fabricated bowls. Fabricated bowls do not have seamless corners, but rather are made by notching and bending the stainless steel, and then welding and finishing the vertical corners to form the bowls. Stainless steel sinks with fabricated bowls may sometimes be referred to as ''zero radius'' or ''near zero radius'' sinks.

The products covered by this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under statistical reporting number 7324.10.0000 and 7324.10.0010. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive.

Final Results of Changed Circumstances Review

For the reasons stated in the *Initiation and Preliminary Results,* and because we received no comments from interested parties to the contrary, the Department continues to find that Ningbo is the successor-in-interest to Yuyao. As a result of this determination, we find that Ningbo should receive the cash deposit rate previously assigned to Yuyao in the most recently completed review of the antidumping duty order on drawn sinks from the PRC.[7] Consequently, the Department will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced or exported by Ningbo and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at 4.29 percent, which is the current antidumping duty cash deposit rate for Yuyao.[8] This cash deposit requirement shall remain in effect until further notice.

We are issuing this determination and publishing these final results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Act and 19 CFR 351.216 and 351.221(c)(3).

Dated: March 21, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–06847 Filed 3–24–16; 8:45 am]

BILLING CODE 3510–DS–P

[7] *See Drawn Stainless Steel Sinks From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review; 2012–2014,* 80 FR 69644 (November 10, 2015) (*AR1 Final Results*).

[8] Yuyao received a 4.29 percent dumping margin in the 2012–2014 administrative review of the AD order on drawn sinks from the PRC. *See AR1 Final Results* at 69645. We note that Yuyao is also a respondent in the current 2014–2015 administrative review of this antidumping duty order. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 80 FR 30041 (May 26, 2015). Because we determined that Ningbo is the successor-in-interest to Yuyao, we will assign Ningbo an updated cash deposit rate based on the final results of that administrative review.

DEPARTMENT OF COMMERCE

International Trade Administration

United States Manufacturing Council: Meeting of the United States Manufacturing Council

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Manufacturing Council (Council) will hold an open meeting on Tuesday, April 12, 2016. The Council was established in April 2004 to advise the Secretary of Commerce on matters relating to the U.S. manufacturing industry. The purpose of the meeting is for Council members to review and deliberate on recommendations developed by the Workforce Development subcommittee looking at high school educational approach enhancements for consideration by the Manufacturing Council. The agenda may change to accommodate Council business. The final agenda will be posted on the Department of Commerce Web site for the Council at *http://trade.gov/manufacturingcouncil,* at least one week in advance of the meeting.

DATES: Tuesday, April 12, 2016, 9:00 a.m.–12:00 p.m. The deadline for members of the public to register, including requests to make comments during the meetings and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EDT on April 4, 2016.

ADDRESSES: The meeting will be held at 1211 Euclid Avenue, Cleveland, Ohio. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to: U.S. Manufacturing Council, U.S. Department of Commerce, Room 4043, 1401 Constitution Avenue NW., Washington, DC 20230, *archana.sahgal@trade.gov.* Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Archana Sahgal, the United States Manufacturing Council, Room 4043, 1401 Constitution Avenue NW., Washington, DC 20230, telephone: 202–482–4501, email: *archana.sahgal@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Council advises the Secretary of Commerce on matters relating to the U.S. manufacturing industry.

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. All guests are required to register in advance by the deadline identified under the DATES caption. Seating is limited and will be on a first come, first served basis. Requests for sign language interpretation or other auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may be impossible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. on Monday, April 4, 2016, for inclusion in the meeting records and for circulation to the members of the Manufacturing Council. Speakers additionally are requested to bring at least 25 copies of their oral comments for distribution to the members of the Manufacturing Council and to the public at the meeting. In addition, any member of the public may submit pertinent written comments concerning the Council's affairs at any time before or after the meeting. Comments may be submitted to Archana Sahgal at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on April 4, 2016, to

ensure transmission to the Council prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered during the meeting. Copies of Council meeting minutes will be available within 90 days of the meeting.

Dated: March 21, 2016.

Archana Sahgal,

Executive Secretary, United States Manufacturing Council.

[FR Doc. 2016–06853 Filed 3–24–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Small Business Innovation Research (SBIR) Request for Public Comments

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Request for public comments and ideas on NOAA SBIR subtopics which would satisfy unmet industry needs.

SUMMARY: Notice is hereby given that the U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA), Small Business Innovation Research (SBIR) Program Office is requesting public comments to better understand the scientific community and small business concerns associated with the environmental industry, as well as improve our SBIR solicitation process.

Of NOAA's four major topics, which was derived from NOAA's Research and Development (R&D) goals, what problem statements or subtopic ideas can you suggest where the project outcome enables commercial products/services which would satisfy current or near term unmet industry needs. Please remember all submissions must be directly relevant to NOAA's mission. NOAA's four major mission topics are as follows:

a. Climate Adaptation and Mitigation

b. Weather-Ready Nation

c. Healthy Oceans

d. Resilient Coastal Communities and Economies

Please categorize submissions based on the four topics above and include as many problem statements or subtopic ideas as you see fit per topic. Also, please provide a brief description of the potential commercialized products/services for each idea submitted.

DATES: Comments and ideas must be received on or before April 29, 2016.

ADDRESSES: Send all comments via email to *NOAA.SBIR@noaa.gov.* Subject Line shall contain ''NOAA SBIR Request for Public Comments—**Federal Register**.''

FOR FURTHER INFORMATION CONTACT: Vince Garcia, NOAA SBIR Program Manager, at: *vincent.garcia@noaa.gov.*

SUPPLEMENTARY INFORMATION: The NOAA Small Business Innovation Research (SBIR) Program Office is exploring options in streamlining and improving existing agency SBIR Phase I subtopic selection processes. The SBIR Program Office seeks to better understand unmet industry needs, which directly relate to NOAA's mission. Historically, subtopics are suggested by NOAA federally-employed scientists and engineers and are selected for publication in the annual SBIR Phase I solicitation by NOAA Line Office leadership.

Respondents shall not be obligated to provide the services described herein, if applicable, and it is understood by the United States Government that any cost estimates provided as a result of this request are ''best'' estimates only. All information submitted in response to this request for public comments is voluntary; the United States Government will not pay for information requested nor will it compensate any respondent for any cost incurred in developing information provided to the United States Government.

Dated: March 15, 2016.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–06555 Filed 3–24–16; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

Science Advisory Board (SAB)

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: The Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Time and Date: The meeting will be held Thursday April 28 from 9:45 a.m. EDT to 5:45 p.m. EDT and on Friday April 29, from 9:00 a.m. EDT to 1:00 p.m. EDT. These times and the agenda topics described below are subject to change. Please refer to the Web page *http://www.sab.noaa.gov/Meetings/meetings.html* for the most up-to-date meeting times and agenda.

Place: The meeting will be held at Sheraton Silver Spring Magnolia Ballroom, 8777 Georgia Avenue, Silver Spring, Maryland. Please check the SAB Web site *http://www.sab.noaa.gov/Meetings/meetings.html* for directions to the meeting location.

Status: The meeting will be open to public participation with a 15-minute public comment period on April 28 from 5:30–5:45 p.m. EDT (check Web site to confirm time). The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of two (2) minutes. Individuals or groups planning to make a verbal presentation should contact the SAB Acting Executive Director by April 21, 2016 to schedule their presentation. Written comments should be received in the SAB Executive Director's Office by April 21, 2016, to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after April 21, 2016, will be distributed to the SAB, but may not be reviewed prior to the meeting date. Seating at the meeting will be available on a first-come, first-served basis.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for special accommodations may be directed no later than 12:00 p.m. on April 21, 2016, to Dr. Elizabeth Turner, Acting SAB Executive Director, Room 146, Gregg Hall, 35 Colovos Road, Durham, NH 03824; Email: *Elizabeth.Turner@noaa.gov.*

Matters To Be Considered: The meeting will include the following topics: (1) Report on Ecosystem Services Valuation from the Ecosystem Sciences and Management Working Group; (2) Updates from the NOAA Administrator, Chief Scientist and the Chief Economist; (3)SAB Strategy Discussion and

Implications for NOAA; and (4) Discussion of Working Group Issues and Working Group Concept of Operations.

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth Turner, Acting Executive Director, Science Advisory Board, NOAA, Room 146 Gregg Hall, 35 Colovos Road, Durham, NH 03824. Email: *Elizabeth.Turner@noaa.gov;* or visit the NOAA SAB Web site at *http://www.sab.noaa.gov.*

Dated: March 15, 2016.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–06554 Filed 3–24–16; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE527

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Pre-Assessment Webinar for South Atlantic Red Snapper and Gray Triggerfish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 41 Post-Review Workshop Webinar.

SUMMARY: The SEDAR 41 assessments of the South Atlantic stocks of *red snapper* and *gray triggerfish* will consist of a series of workshop and webinars: Data Workshops; an Assessment Workshop and Webinars; and a Review Workshop, see **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR 41 Post-Review Workshop Webinar will be held on Friday, April 8, 2016, from 1 p.m. to 3 p.m.

ADDRESSES: The Webinar is open to members of the public. Those interested in participating should contact Julia Byrd at SEDAR (see **FOR FURTHER INFORMATION CONTACT** below) to request an invitation providing Webinar access information. Please request Webinar invitations at least 24 hours in advance of each Webinar.

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405. *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION:

Agenda

The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion for the Post-Review Workshop Webinar are as follows:

1. Participants will discuss any remaining assessment issues and recommendations from the Review Workshop in order to finalize the Review Workshop summary reports.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see **ADDRESSES**) at least ten working days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 21, 2016.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–06755 Filed 3–24–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Southeast Region Permit Family of Forms.

OMB Control Number: 0648–0205.

Form Number(s): None.

Type of Request: Regular (revision of a currently approved information collection).

Number of Respondents: 13,909.

Average Hours per Response: Vessel and dealer permit applications, 29 minutes each; wreckfish permit applications, live rock permit applications and operator card applications, 21 minutes each.

Burden Hours: 7,023.

Needs and Uses: This request is for a revision to the existing reporting requirements. The SERO Permits Office (Southeast Permits Office) administers Federal fishing permits in the Gulf of Mexico (Gulf), South Atlantic, and Caribbean Sea under the authority of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801. The Southeast Permits Office proposes to revise two parts of the collection-of-information approved under OMB Control Number 0648–0205.

The Southeast Permits Office proposes to collect additional information on five applications for economic analysis and for purposes of notifying respondents. These data include race, sex, and business type and ownership information, as well as email addresses and the option to provide cellular contact information for digital notifications. The revision will also include a small business certification section, so NMFS can determine if the respondent is a small or large business according to standards established by the Small Business Administration. These proposed revisions will not change the current cost burden but will increase the annual time burden for respondents.

Currently, NMFS requires fishermen (respondents) to display one adhesive decal on their vessel indicating that they have a Federal fishing permit in at least one of two Gulf fisheries; the applicable permits are the Charter Vessel/Headboat Permit for Gulf Reef Fish, the Charter Vessel/Headboat Permit for Gulf Coastal Migratory Pelagic fish, and their respective Historical Captain endorsements. NMFS proposes to revise OMB Control Number 0648–0205 to split the single decal covering both fisheries into two decals, with one decal administered with each specific fishery permit or endorsement. In addition, this revision also addresses a new fee of $10 per decal to cover administrative costs, as required by NOAA Finance Handbook, Exhibit 9–1. The Federal Permit Application for Vessels Fishing in the Exclusive Economic Zone would also be revised to reflect the new fee. The decal is currently issued at no cost to permit applicants. These decals allow individuals and law enforcement officials to easily identify vessels that have Federal permits.

Affected Public: Business or other for-profit organizations.

Frequency: Annually and on occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: March 22, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–06803 Filed 3–24–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO–P–2016–0006]

Patent Quality Metrics for Fiscal Year 2017 and Request for Comments on Improving Patent Quality Measurement

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO) is revising its patent quality metrics to better identify quality-related issues and more clearly communicate its quality measurements to the public. The new patent quality metrics are part of the USPTO's Enhanced Patent Quality Initiative (EPQI), which was launched in 2015 to engage patent stakeholders in enhancing patent quality. As part of the Enhanced Patent Quality Initiative, the prior patent quality metrics have been reassessed, and new patent quality metrics are now being designed for adoption for fiscal year 2017. The new patent quality metrics for use in fiscal year 2017 are planned to focus on the correctness and clarity of Office actions and will be applied through a newly unified review process using a standardized review form that will permit data from a significantly larger number of finished product quality reviews conducted at the agency to be aggregated and mined for information. The USPTO will also mine data on transactions during patent prosecution (*e.g.,* the types of actions taken by the applicant and the USPTO) to assess examination processes and identify potential quality issues requiring further study. The review process will apply the new quality metrics and standardized form to increase the accuracy, consistency, transparency, clarity, and simplicity of USPTO quality review procedures. The USPTO is seeking comment from its stakeholders on further improvements to the changes proposed herein.

DATES: *Comment Deadline Date:* To be ensured of consideration in the development of the next iteration of metrics, written comments must be received on or before May 24, 2016.

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: *QualityMetrics2017@uspto.gov.* Comments may also be submitted by postal mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313–1450, marked to the attention of Michael Cygan, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy.

Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message over the Internet because sharing comments with the public is more easily accomplished. Electronic comments are preferred to be submitted in plain text, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

Timely filed comments will be available for public inspection at the Office of the Commissioner for Patents, currently located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia 22314. Comments also will be available for viewing via the Office's Internet Web site (*http://www.uspto.gov/patent/laws-and-regulations/comments-public/comments-improving-patent-quality-measurement*). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments. It would be helpful to the USPTO if comments included information about: (1) The name and affiliation of the individual responding; and (2) an indication of whether the comments represent views of the respondent's organization or are the respondent's personal views.

FOR FURTHER INFORMATION CONTACT: Michael T. Cygan, Senior Legal Advisor, at (571) 272–7700. Inquiries regarding this notice may be directed to the Office of Patent Legal Administration, by telephone at (571) 272–7701, or by electronic mail at *PatentPractice@uspto.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Prior to fiscal year 2005, the USPTO quality metric was solely directed to the correctness of the final output of the examination process that would result in a patent: An allowed application. During fiscal years 2005 through 2009, the USPTO expanded its review efforts, employing two official metrics of examination quality: (1) The correctness of the examiner's determination of allowance of an application; and (2) the quality of the actions taken during the

course of examination. In fiscal year 2010, the first metric was modified to include final Office actions, and the second metric was modified to focus on the quality of non-final Office actions during prosecution. All quality analysis was performed by random selection of actions for review by a dedicated Office of Patent Quality Assurance (OPQA) team of reviewers, which reviewed each selected action to determine whether all required claim rejections were properly made in compliance with the patent statutes.

In 2011, based on stakeholder input, the USPTO adopted a new ''Composite Quality Metric'' for fiscal years 2011–2015 to track performance of those aspects that affect quality and provide a single comprehensive metric representing the overall state of patent examination quality. The Composite Quality Metric was composed of seven total factors: (1) The final disposition review, (2) the in-process review, (3) the first action on the merits (FAOM) search review, (4) the complete FAOM review, (5) the external quality survey, (6) the internal quality survey, and (7) an aggregation of five factors from the USPTO's Quality Index Report (QIR). The first four factors continued the USPTO's focus on the statutory compliance of work product; *i.e.,* the correctness of the Office actions. The first four factors were derived from the results of reviews of randomly selected Office actions that were conducted by OPQA. These reviews continued the USPTO's focus on the statutory compliance of work product; *i.e.,* the correctness of the Office actions, with only a basic assessment of whether the examiner had sufficiently set forth his or her position for any claim rejections. The next two factors were derived from surveys that assessed both internal and external stakeholder views on USPTO quality. The final factor was based on the USPTO's QIR, which measures the degree to which actions in the prosecution of patent applications reveal trends indicative of quality concerns and uses a statistical analysis of occurrences of certain types of events (*e.g.,* reopening after final Office actions, consecutive non-final Office actions, consecutive restriction requirements) based on data available through the USPTO's Patent Application Locating and Monitoring (PALM) system. Performance in the overall Composite Quality Metric and in each of the component metric factors has been published on the USPTO dashboard Web site on a quarterly basis. The information from the Composite Quality Metric has been used to identify trends and areas of concern and to target those areas in need of increased training and/or resources.

On February 5, 2015, the USPTO launched the Enhanced Patent Quality Initiative to improve the quality of patents issued by the USPTO. This initiative began with a request for public comments on a set of six proposals outlined in a **Federal Register** Notice. See *Request for Comments on Enhancing Patent Quality,* 80 FR 6475 (Feb. 5, 2015). The USPTO also held a two-day ''Quality Summit'' on March 25 and 26, 2015, at the USPTO headquarters in Alexandria, Virginia, to discuss the quality concerns of patent stakeholders and to receive feedback on the USPTO's proposals. Following the Quality Summit, the USPTO has continued its engagement with the public through numerous roadshows, events, and stakeholder meetings to further refine the steps that may be taken to improve quality.

The Enhanced Patent Quality Initiative targets three pillars of patent quality: (1) Excellence in work products; (2) excellence in measuring patent quality; and (3) excellence in customer service. In furtherance of the second pillar of patent quality, the USPTO is focusing on improving the internal metrics used to evaluate patent examination quality and on improving the communication of its patent examination quality measurements to the public. Through this initiative, the USPTO has received numerous comments on establishing appropriate quality metrics. The USPTO has considered all of the comments received through the Summit, the **Federal Register** Notice, and numerous quality outreach events. Based on the information received to date, the USPTO has identified key aspects of quality measurement essential to developing more effective quality metrics.

First, the clarity of the examiner's determinations and the rationale underlying the decisions made in Office actions is an important part of overall patent examination quality and should be emphasized in reviews of USPTO work product. Second, individual metrics that clearly reflect individual aspects of USPTO work product would better communicate patent quality than a single quality composite number that combines scores from unrelated sources such as surveys, procedural efficiency statistics, and substantive patentability compliance reviews. Third, improving the granularity of work product quality measurement to monitor compliance with each statutory provision and enable meaningful data at the work group and art unit level is highly desirable for providing targeted training resulting in greater consistency. Fourth, monitoring the process of examination, *i.e.,* the type and number of actions taken during prosecution as reflected in the QIR, remains a high priority that is best used to spot unusual trends or occurrences that deserve further attention. Lastly, capturing a larger number of finished product quality reviews conducted at the agency and using a standardized review form will lead to a significantly greater number of data points, which will allow for greater consistency in the review of application quality within the Patents Organization. More information on the public comments received on the metrics, and how those are being used to identify improvements to the metrics, is available at *http://www.uspto.gov/patent/initiatives/quality-metrics.* In view of these guideposts, a new set of metrics is now being proposed to incorporate these and other improvements to the collection of data and reporting of metrics.

II. Improving Measurement of Patent Examination Quality

As the next step in advancing the second pillar of the Enhanced Patent Quality Initiative, the proposed fiscal year 2017 patent quality metrics refocus the USPTO's measurement of the quality of the work products produced from first Office action through final disposition. The proposed metrics continue to assess the correctness of an examiner's determinations in a given Office action with increased attention on assessing whether the examiner clearly set forth his or her reasoning in a given Office action. In addition, the Office will continue to review the transactions taken during patent prosecution through the QIR, but this information will be used to identify the need for further investigation rather than being measured against a goal. Additionally, the USPTO is changing its reporting of the quality metrics to provide simpler and clearer communication of results to the public.

A. Measurement of Statutory Compliance and Clarity in Work Products

The patent quality metrics of work product proposed here for fiscal year 2017 provide a tighter focus on measuring two foundational characteristics of patent examination: Statutory compliance and clarity of decision making in Office actions. These proposed patent quality metrics continue to measure correctness of actions in terms of their compliance

with each of the statutory requirements for issuance of a patent. To this end, a sampling of Office actions will continue to be reviewed both for improperly made rejections and for failure to make rejections where required by statute. The substantive review items will also include other items, for example, the propriety of the examiner's search, any interpretation of claim language under 35 U.S.C 112(f), any determination that an action is made final, any restriction or election of species requirement.

Furthermore, the new metrics greatly enhance the review of the clarity of the components of Office actions by including new clarity review items specifically designed for each of the substantive patentability determinations made in Office actions. For example, when reviewing an Office action containing an obviousness rejection under 35 U.S.C. 103, the review items consider not only whether the obviousness rejection was proper, but also whether the statement of the rejection mapped the elements identified in the prior art to the claim limitations, and whether the statement of the rejection explained the reasons for the rejection in a clear manner. The new clarity review items will also include, for example, items directed to the sufficiency of the recordation of any interview and the propriety of any reasons for allowance of an application.

For fiscal year 2017, the USPTO is proposing to capture the correctness and clarity review items with a single standardized review form as a repository for all of the review items, replacing the review-specific forms used in the 2011–2015 Composite Quality Metric. The review questions on such a standardized form, colloquially referred to as the ''Master Review Form,'' is planned to be used by all USPTO reviewers for finished product quality reviews of actions at every stage of prosecution. This Master Review Form will contain the above-described criteria for recording correctness for each of the substantive patentability requirements and for recording the clarity of each of those decisions and the supporting rationales set forth in the Office action under review. The full list of correctness and clarity items in the draft proposed version of the Master Review Form is available for viewing at *http://www.uspto.gov/patentquality.* The USPTO welcomes and appreciates feedback on the elements of this form through this notice, and will use the input to help finalize the Master Review Form that will be deployed throughout the USPTO in fiscal year 2017.

This draft proposed ''Master Review Form'' was developed as part of the Clarity and Correctness Data Capture program, which is part of the USPTO's Enhanced Patent Quality Initiative. The Clarity and Correctness Data Capture Program has been instituted to better capture the data produced through the different types of reviews within the Patents Organization. Historically, reviews have been performed not only by the quality assurance team, but also by other Technology Center personnel, with each reviewing area setting its own reviewing criteria. Moreover, the only work product reviews recorded for identification of trends were those undertaken by the Office of Patent Quality Assurance. The Master Review Form is designed to provide standardized reviewing criteria for quality reviews of finished work product. Through application of standardized reviewing criteria, the USPTO can better leverage the results from the many levels of review conducted at the agency. The improvements to the data capture process will enable meaningful data analysis at a more granular level than previously possible, permitting valid inferences to be drawn at the workgroup and art unit levels. Through this process, the USPTO and the stakeholders in the patent system will be able to gain a greater understanding of the state of patent prosecution and to work better together towards its improvement.

B. Measurement of Transactions During Patent Prosecution

A further aspect of the new patent quality metrics will be the leveraging of the data representing the thousands of transactions made by the USPTO during prosecution to reveal information on the quality of the patent prosecution process itself. Transactions during prosecution, such as restrictions, first Office actions, and allowances, are monitored through the USPTO's PALM system. The USPTO monitors many of these transactions through its QIR. Since 2011, the USPTO has included some of these transactions, such as the number of occurrences of consecutive non-final rejections, as part of its reported quality data. For the proposed 2017 quality metrics, transactional data from the QIR will be used to identify information that can be used to prevent reopening of prosecution, reduce rework, and improve the consistency of decision making throughout the USPTO. Key indicators of the efficiency of prosecution will be instances of reopening of prosecution and repeated non-final Office actions, as well as other instances of rework (*e.g.,* consecutive final Office actions, consecutive restrictions). These indicators do not, by themselves, provide a numerical measure of quality. Rather, these indicators will reveal trends and outlier behavior that will draw attention to potential quality concerns.

C. Clearer Reporting of the Metrics

In presenting the results of the quality data, the USPTO will seek to further improve the usefulness and transparency of our quality reporting and to communicate the results in a clear and simple manner. The 2011–2015 Composite Quality Metric, which combined seven different quality variables into a single composite number, will be discontinued. The Quality Index Report will be used to identify potential areas of concern, rather than as providing a single, reportable number. While internal and external surveys will still be performed, the results will not be part of the quality metric, but instead will serve as independent checks on the quality metrics.

D. Refinement of Proposed Quality Metrics in FY 2016

Fiscal year 2016 will represent a transitional period for the quality metrics, emphasizing the fine-tuning of the fiscal year 2017 patent quality metrics. The USPTO will test and refine its proposed Master Review Form. This Master Review Form will contain new items, such as additional clarity review items, that will require a period of data collection to create numerical baselines for these items. The Master Review Form will initially be used in targeted reviews to determine the effectiveness of each individual clarity and correctness review item. The transactional data from the QIR will also be reviewed during 2016 to optimize the data analysis therein. Stakeholder comments on the Master Review Form in response to this notice will also form an important part of the process of optimizing the components of the patent quality metrics. During this transitional period, the information gleaned during fiscal year 2016 will be used to produce a finalized set of quality metrics for fiscal year 2017 that will represent the next phase of quality measurement, analysis, tracking, and reporting at the USPTO.

III. Feedback Sought on Improving Metrics of Patent Examination Quality

The USPTO seeks input and comments from the public through this notice and through public outreach on the following:

(1) Is the USPTO moving in the right direction by choosing to focus on two

core metrics: A work product metric representing correctness of actions, and a clarity metric that more thoroughly explores the sufficiency of the examiner's reasoning in an Office action, thus moving away from the prior goal-based quality ''score'' that reflected not only quality of work product but also results of surveys, used to discover both internal and external stakeholder opinions, and QIR process indicators? Which of the proposed clarity and correctness review items in the proposed standardized ''Master Review Form,'' available at *http://www.uspto.gov/patentquality,* should be used as the key drivers of patent examination quality metrics?

(2) How can patent metrics best provide objective, rather than subjective, measurements of quality-related features in clarity and correctness reviews?

In addition to the three questions posed above, the USPTO welcomes comments on any and all areas of quality measurement. Suggestions for rephrased or additional quality metrics review items, especially clarity indicators, are welcomed. The USPTO will consider all submitted comments as it develops the next iteration of quality metrics.

For the most current information on this and other patent quality initiatives, please visit the Enhanced Patent Quality Initiative micro site at *http://www.uspto.gov/patentquality.*

Dated: March 22, 2016.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2016–06851 Filed 3–24–16; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes products from the Procurement List that were previously furnished by a nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: *Effective:* April 24, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 2/19/2016 (81 FR 8486), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

NSN(s)—Product Name(s):

7530–00–160–8475—Index Sheet Set, Alphabetical, 8 ½″ x 11″, Buff

7530–00–160–8477—Index Sheet Set, Alphabetical, 11″ x 8 ½″, Buff

Mandatory Source of Supply: Life'sWork of Western PA, Pittsburgh, PA

Contracting Activity: General Services Administration, New York, NY

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016–06827 Filed 3–24–16; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products to the Procurement List that will be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities and, deletes services previously furnished by such agencies.

Comments Must be Received on Or Before: 4/24/2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products listed below from the nonprofit agency employing persons who are blind or have other severe disabilities.

The following products are proposed for addition to the Procurement List for production by the nonprofit agency listed:

NSN(s)—Product Name(s)

7220–00–NSH–0022—Mat, Floor, Chair, 45″ x 53″ x 0.110″, w/20″ x 12″ Lip
7220–00–NSH–0023—Mat, Floor, Chair, 45″ x 53″ x 0.110″, w/25″ x 12″ Lip
7220–00–NSH–0024—Mat, Floor, Chair, 46″ x 60″ x 0.110″, w/25″ x 12″ Lip
7220–00–NSH–0025—Mat, Floor, Chair, 46″ x 60″ x 0.110″, Without Lip
7220–00–NSH–0026—Mat, Floor, Chair, 60″ x 60″ x 0.110″, Without Lip
7220–00–NSH–0030—Mat, Floor, Chair, 36″ x 48″ x 0.150″, w/20″ x 12″ Lip
7220–00–NSH–0031—Mat, Floor, Chair, 45″ x 53″ x 0.150″, w/25″ x 12″ Lip
7220–00–NSH–0032—Mat, Floor, Chair, 45″ x 53″ x 0.150″, w/20″ x 12″ Lip
7220–00–NSH–0033—Mat, Floor, Chair, 45″ x 53″ x .220″, w/20″ x 12″ Lip

7220–00–NSH–0035—Mat, Floor, Chair, 46″ x 60″ x .150″, Without Lip
7220–00–NSH–0036—Mat, Floor, Chair, 46″ x 60″ x .150″, w/25″ x 12″ Lip
7220–00–NSH–0038—Mat, Floor, Chair, 46″ x 60″ x .220″, w/25″ x 12″ Lip
7220–00–NSH–0039—Mat, Floor, Chair, 46″ x 60″ x .220″, Without Lip
7220–00–NSH–0040—Mat, Floor, Chair, 60″ x 60″ x .150″, Without Lip
Mandatory Source(s) of Supply: Northeastern Michigan Rehabilitation and Opportunity Center, Alpena, MI
Mandatory for: Total Government Requirement
Contracting Activity: General Services Administration, New York, NY
Distribution: A-List

Deletions

The following services are proposed for deletion from the Procurement List:

Services

Service Type: Switchboard Service
Service Mandatory For: Minot Air Force Base, Minot AFB, ND
Mandatory Source of Supply: MVW Services, Inc., Minot, ND
Contracting Activity: Dept of the Air Force, FA4528 5 CONS LGCP, Minot AFB, ND
Service Type: Library Service
Service Mandatory For: Minot Air Force Base, Minot AFB, ND
Mandatory Source of Supply: MVW Services, Inc., Minot, ND
Contracting Activity: Dept of the Air Force, FA7014 AFDW PK, Andrews AFB, MD
Service Type: Mess Attendant Service
Service Mandatory For: 192d FW VA Air National Guard, Sandston, VA
Mandatory Source of Supply: Richmond Area Association for Retarded Citizens, Richmond, VA
Contracting Activity: Dept of the Air Force, FA7014 AFDW PK, Andrews AFB, MD
Service Type: Switchboard Operation Service
Service Mandatory For: Ellsworth Air Force Base, Ellsworth AFB, SD
Mandatory Source of Supply: BH Services, Inc., Ellsworth AFB, SD
Contracting Activity: Dept of the Air Force, FA4690 28 CONS LGC, Ellsworth AFB, SD

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016–06826 Filed 3–24–16; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes products from the Procurement List that were previously furnished by a nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: Effective April 24, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 2/19/2016 (81 FR 8486), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

NSN(s)—Product Name(s):
7530–00–160–8475—Index Sheet Set, Alphabetical, 8 ½″ x 11″, Buff
7530–00–160–8477—Index Sheet Set, Alphabetical, 11″ x 8 ½″, Buff
Mandatory Source of Supply: Life'sWork of Western PA, Pittsburgh, PA
Contracting Activity: General Services Administration, New York, NY

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016–06825 Filed 3–24–16; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2016–OS–0028]

Proposed Collection; Comment Request

AGENCY: Defense Finance and Accounting Service (DFAS), DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Finance and Accounting Service announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by May 24, 2016.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information. Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this

proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Finance and Accounting Service; Office of Financial Operations; Retired and Annuitant Pay Quality Product Assurance Division ATTN: Chuck Moss, Cleveland, OH 44199–2001, or call at (216) 204–4426.

SUPPLEMENTARY INFORMATION: *Title; Associated Form; and OMB Number:* Survivor Benefit Plan (SBP)—Automatic Coverage Fact Sheet; DD Form 2656–8; OMB Control Number 0730–TBD.

Needs and Uses: The information collection requirement is necessary to identify and determine the marital status of the retiree in order to correctly establish the retired pay account.

Affected Public: Individuals or households.

Annual Burden Hours: 60.

Number of Respondents: 240.

Responses per Respondent: 1.

Annual Responses: 240.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

If no SBP election is made at retirement time this form is mailed to the retiree. Automatic spouse coverage is established and the completion of this form provides Retired Pay with information about the spouse. In some instances, the retiree is unmarried and the coverage will be changed to reflect that.

Dated: March 21, 2016.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2016–06719 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2016–OS–0027]

Proposed Collection; Comment Request

AGENCY: Defense Finance and Accounting Service (DFAS), DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Finance and Accounting Service announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by May 24, 2016.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information. Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Finance and Accounting Service; Office of Financial Operations; Retired and Annuitant Pay Quality Product Assurance Division ATTN: Chuck Moss, Cleveland, OH 44199–2001, or call at (216) 204–4426.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Request for Withholding State Tax; DD Form 2868; OMB Control Number 0730–TBD.

Needs and Uses: The information collection requirement is necessary to start state tax withholding from a retiree's pay account or to change the amount currently withheld. The retiree's SSN is a required entry as it is necessary to positively identify the retiree in order to send the correct payroll tax withholding information to the appropriate state taxing authority as directed by the retiree.

Affected Public: Individuals or households.

Annual Burden Hours: 50.

Number of Respondents: 200.

Responses per Respondent: 1.

Annual Responses: 200.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

The form is completed whenever a retiree determines that it is necessary for them to begin or change state tax withholding from their retired pay account.

Dated: March 21, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–06716 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

One-Time Deauthorization of Water Resources Projects

AGENCY: Army Corps of Engineers, DoD.

ACTION: Notice of Final Deauthorization Report.

SUMMARY: The U.S. Army Corps of Engineers is publishing a Final Deauthorization Report of water resources development projects and separable elements that have been identified for deauthorization in accordance with section 6001(d) of the Water Resources Reform and Development Act of 2014, Public Law 113–121, 128 STAT. 1346–1347 (WRRDA 2014). The Assistant Secretary of the Army for Civil Works transmitted the Final Deauthorization Report to Congress on February 26, 2016. An electronic copy of the complete report is available at: *http://www.usace.army.mil/Portals/2/docs/civilworks/budget/final_deauth_report_23feb2016.pdf.*

FOR FURTHER INFORMATION CONTACT OR TO PROVIDE COMMENTS: Mr. Joseph W. Aldridge, Headquarters, U.S. Army Corps of Engineers, Attention: CECW–IP, Washington, DC 20314–1000. Tel. (202) 761–4130 or *joseph.w.aldridge@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Final Deauthorization Report required by § 6001(d).

Section 6001(d) provides that the Secretary shall develop a Final Deauthorization Report. This report includes a list of each water resources

development project, or separable element of a project, described in Section 6001(c) and the other provisions of Section 6001(d), as well as an appendix (Appendix A) that lists any project, or separable element of a project, included as part of the Interim Deauthorization List but not included in the Final Deauthorization Report and the reasons why they are not included in the report. Appendix B of the Final Deauthorization Report (available on the U.S. Army Corps of Engineers Web site referenced below) contains copies of the comments received during the public comment period. The Final Deauthorization Report with Appendix A follows below in Table 1. An electronic copy of the Final Deauthorization Report with appendices can be found at: *http://www.usace.army.mil/Portals/2/docs/civilworks/budget/final_deauth_report_23feb2016.pdf.*

The Interim Deauthorization List was developed in accordance with Section 6001(c) of WRRDA 2014 and was published for public comment in the **Federal Register** on October 7, 2015. Per Section 6001(d), not later than 120 days following the 90-day public comment period of the Interim Deauthorization List, that ended on January 4, 2016, the Assistant Secretary of the Army for Civil Works (ASA(CW)) will transmit the Final Deauthorization Report to the Environment & Public Works Committee of the Senate and the Transportation and Infrastructure Committee of the House of Representatives. Additionally, the ASA(CW) will publish the Final Deauthorization Report in the **Federal Register**. The ASA(CW) transmitted the Final Deauthorization Report to the Committees on February 26, 2016.

Section 6001(d)(2)(A) of WRRDA 2014 requires that the Secretary shall include on the Final Deauthorization Report, projects and separable elements of projects that have, in the aggregate, an estimated Federal cost to complete that is at least $18 billion. The ASA(CW) has strived to meet the requirements of Section 6001, but was not able to identify projects that totaled $18 billion based upon the criteria provided in Section 6001. The projects and elements on the Final Deauthorization Report will be deauthorized automatically after 180 days following the date that the ASA(CW) submits the Final Deauthorization List to the Committees, unless the Congress passes a joint resolution disapproving the Final Deauthorization Report or the non-Federal interest for the project or separable element of a project provides sufficient funds to complete the construction of the project or separable element. The amount shown as the Federal Balance to complete is a working estimate generally based on the authorization and as such any non-Federal interests considering providing sufficient funds to complete a project or separable element should contact the appropriate District Commander to discuss the process necessary to develop a final cost to complete a project or separable element.

The Final Deauthorization Report identifies water resources development projects, or separable elements of a project, that meet the following criteria. Projects and separable elements eligible for deauthorization are those uncompleted construction projects and separable elements meeting all of the following criteria: (1) They were authorized for construction before November 8, 2007, or their most recent modification of the construction authorization predates November 8, 2007; (2) their construction has not been initiated, or, if construction has been initiated, there have been no obligations of Federal or non-Federal funds for construction in the current fiscal year or any of the past 6 fiscal years; and, (3) there has been no funding for a post-authorization study in the current fiscal year or any of the past 6 fiscal years. As specifically provided in section 6001(f)(1)(B) of WRRDA 2014, water resources development projects include environmental infrastructure assistance projects and programs of the U.S. Army Corps of Engineers. In accordance with section 103(f) of the Water Resources Development Act of 1986, separable elements is defined as ''a portion of a project—

(1) which is physically separable from other portions of the project; and

(2) which—

(A) achieves hydrologic effects, or

(B) produces physical or economic benefits, which are separately identifiable from those produced by other portions of the project.''

The following elements of an authorized water resources development project also qualify as separable elements: an element for which there is an executed design agreement or project partnership agreement specific to that element; an element that has received funding specified for that element; an element that was authorized separately from or as an amendment to the authorization for the remainder of the water resources development project, that was separately identified in the authorization for the water resources development project, or for which a statute specifies an authorized cost, estimated cost, or amount authorized to be appropriated; an element that has been placed in service or for which the Government or the non-Federal partner has assumed operation and maintenance; an element that has been deauthorized; or the remaining portion of the water resources development project apart from other separable elements.

Authority: This notice is required by § 6001(d) of the Water Resources Reform and Development Act of 2014, Public Law 113–121, 128 STAT 1346–1347.

Jo-Ellen Darcy,

Assistant Secretary of the Army (Civil Works).

TABLE 1 (FINAL DEAUTHORIZATION REPORT)

State	Project/Element name	Public law of authorization or latest amendment	Section of public law	Latest fiscal year of Federal or non-Federal obligations for construction	Federal balance to complete (subject to section 902 where applicable) ($)
AL	ALABAMA-COOSA RIVER AND TRIBUTARIES, AL (COOSA RIVER BETWEEN MONTGOMERY AND GADSDEN).	99–662	813	1986	3,781,921,691
AL	DUCK RIVER, AL	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	5,000,000
AR	UNION COUNTY, AR	106–554	108d	2008	51,247,100
	L'ANGUILLE RIVER BASIN, AR	99–662	103	2004	19,466,768
	ARKANSAS RIVER LEVEES, AR	101–640	110(a1)	NO OBLIGATION FOR CONSTRUCTION.	591,605
	BEAVER DAM, AR (TROUT PRODUCTION CENTER).	94–587	105	NO OBLIGATION FOR CONSTRUCTION.	5,990,000

TABLE 1 (FINAL DEAUTHORIZATION REPORT)—Continued

State	Project/Element name	Public law of authorization or latest amendment	Section of public law	Latest fiscal year of Federal or non-Federal obligations for construction	Federal balance to complete (subject to section 902 where applicable) ($)
	BEAVER LAKE, BENTON/WASH, AR	104–303	523	2002	5,000,000
CA	CALAVERAS COUNTY, CA	104–303	526	NO OBLIGATION FOR CONSTRUCTION.	1,500,000
	CLEAR LAKE BASIN, CA	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	COLUSA TROUGH DRAINAGE CANAL, SACRAMENTO RIVER AND TRIBUTARIES, CA.	99–662	830	NO OBLIGATION FOR CONSTRUCTION.	18,900,846
	PINE FLAT DAM, CA	106–541	101b(7)	NO OBLIGATION FOR CONSTRUCTION.	41,502,918
	CHINO HILLS, CA	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	EASTERN MUNICIPAL WATER DISTRICT, CA.	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	GOLETA & VICINITY, CA	102–580	102b	1984	1,233,626
	LOS ANGELES HARBOR/TERMINAL ISLAND, CA.	106–554	108d	NO OBLIGATION FOR CONSTRUCTION.	6,500,000
	LOWER MISSION CREEK, CA	100–676	3a	NO OBLIGATION FOR CONSTRUCTION.	14,625,971
	SAN DIEGO AREA WATER REUSE DEMOSTRATION FACILITIES, CA.	102–580	217c(2)	NO OBLIGATION FOR CONSTRUCTION.	5,000,000
	SAN DIEGO COUNTY, CA (CORONADO TRANSBAY WASTEWATER PIPELINE).	106–554	108d	NO OBLIGATION FOR CONSTRUCTION.	10,000,000
	SOUTHERN CALIFORNIA COMPREHENSIVE WATER REUSE SYSTEM, CA.	102–580	217c(1)	NO OBLIGATION FOR CONSTRUCTION.	5,000,000
CT	BRIDGEPORT COMBINED SEWER OVERFLOW PTOJECT, CT.	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	10,000,000
CT, ME, MA, NH, RI & VT.	NEW ENGLAND WATER RESOURCES AND ECOSYSTEM RESTORATION, CT, ME, MA, NH, RI & VT.	106–541	507	NO OBLIGATION FOR CONSTRUCTION.	0
DC & MD	WASHINGTON, DC AND MARYLAND, DC & MD.	106–554	108d	1998	14,807,000
FL	COMPREHENSIVE EVERGLADES RESTORATION PLAN, FL (LAKE BELT IN-GROUND RESERVOIR TECHNOLOGY).	106–541	601b2bii	2005	17,000,000
	COMPREHENSIVE EVERGLADES RESTORATION PLAN, FL (NORTH NEW RIVER IMPROVEMENTS).	106–541	601b2cix	NO OBLIGATION FOR CONSTRUCTION.	67,150,000
	COMPREHENSIVE EVERGLADES RESTORATION PLAN, FL (RAISE AND BRIDGE EAST PORTION OF TAMIAMI TRAIL AND FILL MIAMI CANAL WITHIN WATER) (CONSEVATION AREA 3).	106–541	601b2cviii	NO OBLIGATION FOR CONSTRUCTION.	21,500,000
	COMPREHENSIVE EVERGLADES RESTORATION PLAN, FL (TAYLOR CREEK/NUBBIN SLOUGH STORAGE AND TREATMENT AREA).	106–541	601b2cvii	NO OBLIGATION FOR CONSTRUCTION.	67,800,000
	COMPREHENSIVE EVERGLADES RESTORATION PLAN, FL (WASTEWATER REUSE TECHNOLOGY).	106–541	601b2biv	2005	20,500,000
	HUDSON RIVER, FL	81–516	101	NO OBLIGATION FOR CONSTRUCTION.	3,650,000
	KEY BISCAYNE, FL	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	LITTLE TALBOT ISLAND, FL	106–53	101(b)(7)	2000	6,786,030
	SOUTH TAMPA, FL	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	TAMPA HARBOR, ALAFIA RIVER, FL	106–554	107	2006	64,771,847
	TAMPA HARBOR, FL ((PORT SUTTON TURNING BASIN) WIDENING TO AN ADDITIONAL 105 FEET TO THE FENDER LINE ALONG PENDOLA POINT).	99–662	858	NO OBLIGATION FOR CONSTRUCTION.	8,434,881

TABLE 1 (FINAL DEAUTHORIZATION REPORT)—Continued

State	Project/Element name	Public law of authorization or latest amendment	Section of public law	Latest fiscal year of Federal or non-Federal obligations for construction	Federal balance to complete (subject to section 902 where applicable) ($)
HI	WAIKIKI EROSION CONTROL, HI	89–298	301	NO OBLIGATION FOR CONSTRUCTION.	16,584,000
ID	SNAKE RIVER INTERPRETIVE CENTER, CLARKSTON, WA.	108–137	124	2004	3,750,044
IL	AURORA, IL	106–554	108d	NO OBLIGATION FOR CONSTRUCTION.	8,000,000
	DES PLAINES RIVER, IL (NORTH FORK MILL CREEK DAM MODIFICATION).	106–53	101b(10)	NO OBLIGATION FOR CONSTRUCTION.	5,795,400
IN	FORT WAYNE, IN	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,529,324
	INDIANAPOLIS, IN	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
KY	BEAVER CREEK BASIN, KY	89–298	204	NO OBLIGATION FOR CONSTRUCTION.	20,873,500
KY & TN	REELFOOT LAKE, TN & KY	106–53	101b(11)	NO OBLIGATION FOR CONSTRUCTION.	33,072,769
LA	PEARL RIVER, SLIDELL, SAINT TAMMANY PARISH, LA.	99–662	401b	2002	29,311,000
	BAYOU COCODRIE AND TRIBUTARIES, LA.	93–251	87	1987	345,472,000
	GULF INTRACOASTAL WATERWAY, LA & TX (LA–TX SECTION—UNCONSTRUCTED FEATURES).	87–874	101	NO OBLIGATION FOR CONSTRUCTION.	201,422,000
	KENNER, LA	106–554	108	NO OBLIGATION FOR CONSTRUCTION.	5,000,000
	ST. CHARLES, ST. BERNARD, AND PLAQUEMINES PARISHES, LA.	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	ST. JOHN THE BAPTIST AND ST. JAMES PARISHES, LA.	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	TANGIPAHOA, TCHEFUNCTE, AND TICKFAW RIVERS, LA.	99–662	401	NO OBLIGATION FOR CONSTRUCTION.	21,723,000
MA	MUDDY RIVER, BROOKLINE AND BOSTON, MA (AQUATIC ECOSYSTEM RESTORATION FEATURES).	106–541	522	NO OBLIGATION FOR CONSTRUCTION.	24,050,000
MI	ALPENA HARBOR, MI (25-FOOT CHANNEL).	104–303	363d	NO OBLIGATION FOR CONSTRUCTION.	4,063,120
	BAY CITY, MI	101–640	105	NO OBLIGATION FOR CONSTRUCTION.	8,466,275
	BENTON HARBOR, ST JOSEPH WASTEWATER TREATMENT PLANT, ST JOSEPH, MI.	106–554	108d	NO OBLIGATION FOR CONSTRUCTION.	1,500,000
	CHARLEVOIX, MI (REVETMENT CONNECTION).	106–53	373	NO OBLIGATION FOR CONSTRUCTION.	52,500
	ONTONAGON HARBOR, ONTONAGON COUNTY MI.	104–303	363e	NO OBLIGATION FOR CONSTRUCTION.	37,134,623
	SAGINAW RIVER AND TRIBUTARIES, MI (CASS RIVER AT VASSAR).	106–53	364(3)	NO OBLIGATION FOR CONSTRUCTION.	13,909,394
	SAGINAW RIVER AND TRIBUTARIES, MI (CURTIS ROAD BRIDGE).	99–662	845	NO OBLIGATION FOR CONSTRUCTION.	720,653
	SAGINAW RIVER AND TRIBUTARIES, MI (FLINT RIVER AT FLINT).	104–303	329	NO OBLIGATION FOR CONSTRUCTION.	571,781
	SAGINAW RIVER AND TRIBUTARIES, MI (SHIAWASSEE FLATS).	106–53	364(4)	NO OBLIGATION FOR CONSTRUCTION.	106,825,583
MI, MN & WI	GREAT LAKES CONNECTING CHANNELS & HARBORS, MN, MI & WI.	101–640	101a15	NO OBLIGATION FOR CONSTRUCTION.	17,938,174
MN	DULUTH, MN (ALTERNATIVE TECHNOLOGY PROJECT).	104–303	541a/b	NO OBLIGATION FOR CONSTRUCTION.	1,000,000
	LAKE SUPERIOR CENTER, MN	104–303	542	NO OBLIGATION FOR CONSTRUCTION.	10,000,000
	MISSISSIPPI PLACE, MN	106–53	577	2006	2,968,178
MN & WI	DULUTH-SUPERIOR CHANNEL EXTENSION, MN & WI.	99–662	201a	1995	14,064,481

TABLE 1 (FINAL DEAUTHORIZATION REPORT)—Continued

State	Project/Element name	Public law of authorization or latest amendment	Section of public law	Latest fiscal year of Federal or non-Federal obligations for construction	Federal balance to complete (subject to section 902 where applicable) ($)
MO	KANSAS CITY, MO	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	15,000,000
MO & IL	ST LOUIS HARBOR, MO & IL	99–662	601a	NO OBLIGATION FOR CONSTRUCTION.	43,253,100
MS	YAZOO BASIN, TRIBUTARIES, MS (UNCONSTRUCTED FEATURES).	89–298	204	2007	233,490,728
	YAZOO RIVER, MS (SHEPARDSTOWN BRIDGE).	99–662	822	NO OBLIGATION FOR CONSTRUCTION.	2,011,094
MS & LA	MISSISSIPPI AND LOUISIANA ESTUARINE AREAS, MS & LA.	100–676	3(a)8	2003	70,668,540
NC	LUMBERTON, NC	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	1,700,000
	UNION COUNTY, NC	106–554	108a	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
NC & SC	SUGAR CREEK BASIN, NC & SC	99–662	401a	NO OBLIGATION FOR CONSTRUCTION.	54,523,100
NH	NASHUA, NH (COMBINED SEWER OVERFLOW).	106–53	502(b)	NO OBLIGATION FOR CONSTRUCTION.	19,853,000
	ROCHESTER, NH	104–303	504(e)(4)	NO OBLIGATION FOR CONSTRUCTION.	10,897,120
NJ	ELIZABETH, NJ	106–53	502(f)	NO OBLIGATION FOR CONSTRUCTION.	20,000,000
	NORTH HUDSON, NJ	106–53	502(f)	NO OBLIGATION FOR CONSTRUCTION.	20,000,000
	PATTERSON AND PASSAIC COUNTY, NJ.	106–554	108c	NO OBLIGATION FOR CONSTRUCTION.	30,000,000
	STATE OF NEW JERSEY AND NEW JERSEY WASTEWATER TREATMENT TRUST, NJ.	102–580	219c(10)	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	TOWN OF NEWTON, NJ	106–554	108d	NO OBLIGATION FOR CONSTRUCTION.	7,000,000
NV	LAS VEGAS WASH AND TRIBUTARIES, NV.	102–580	101(13)	NO OBLIGATION FOR CONSTRUCTION.	3,360,938
	LAS VEGAS, NV	109–103	115	NO OBLIGATION FOR CONSTRUCTION.	20,000,000
	ERIE COUNTY, BUFFALO AMHERST, NY.	102–580	221	NO OBLIGATION FOR CONSTRUCTION.	7,000,000
NY	ERIE COUNTY, NY (SLUDGE DISPOSAL).	102–580	219c(12)	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	ERIE COUNTY, NY (WATER QUALITY TUNNEL).	102–580	219c(11)	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	LEWISTON STORMWATER, NY	102–580	222	NO OBLIGATION FOR CONSTRUCTION.	200,000
	LIVERPOOL, NY	106–554	108d	NO OBLIGATION FOR CONSTRUCTION.	2,000,000
	INNER HARBOR PROJECT, NEW YORK, NY.	106–53	502(f)	NO OBLIGATION FOR CONSTRUCTION.	15,000,000
	LOWER HUDSON RIVER & TRIBUTARIES, NY.	106–53	212e	NO OBLIGATION FOR CONSTRUCTION.	30,000,000
	OUTER HARBOR PROJECT, NEW YORK, NY.	106–53	502(f)	NO OBLIGATION FOR CONSTRUCTION.	15,000,000
NY/NJ	NEW YORK HARBOR COLLECTION AND REMOVAL OF DRIFT, NY & NJ.	101–640	102	2005	201,549,768
OH	OTTAWA RIVER HARBOR, OH	101–640	107a(7)	2006	13,218,200
	HOCKING RIVER, LOGAN, OH	99–662	401a	NO OBLIGATION FOR CONSTRUCTION.	16,282,709
	MIAMI RIVER BASIN, PLEASANT RUN, VICINITY FAIRFIELD, OH.	99–662	401(a)	NO OBLIGATION FOR CONSTRUCTION.	18,041,480
OK	FORT GIBSON LAKE, OK (POWER UNITS 5 & 6).	99–662	601a	NO OBLIGATION FOR CONSTRUCTION.	45,485,000
OR	ASTORIA, OR	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	5,000,000
	HOOD RIVER, OR	106–554	108a(36)	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	MEDFORD, OR	106–554	108a(37)	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	PORTLAND, OR	106–554	108a(38)	NO OBLIGATION FOR CONSTRUCTION.	1,543,324

TABLE 1 (FINAL DEAUTHORIZATION REPORT)—Continued

State	Project/Element name	Public law of authorization or latest amendment	Section of public law	Latest fiscal year of Federal or non-Federal obligations for construction	Federal balance to complete (subject to section 902 where applicable) ($)
PA	COUDERSPORT, PA	106–554	108	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	FINDLAY TOWNSHIP, PA	106–53	502	NO OBLIGATION FOR CONSTRUCTION.	11,000,000
	GREENSBORO AND GLASSWORKS, PA.	102–580	219c(15)	NO OBLIGATION FOR CONSTRUCTION.	1,543,324
	JEFFERSON TOWNSHIP, GREENE COUNTY, PA.	106–53	502	NO OBLIGATION FOR CONSTRUCTION.	1,000,000
	NORTH FAYETTE TOWNSHIP, ALLEGHENY COUNTY, PA.	106–53	502	NO OBLIGATION FOR CONSTRUCTION.	500,000
	ROBINSON TOWNSHIP, PA	106–53	502	NO OBLIGATION FOR CONSTRUCTION.	1,200,000
	SPRINGDALE BOROUGH, PA	106–53	502	NO OBLIGATION FOR CONSTRUCTION.	500,000
	TITUSVILLE, PA	106–554	108	NO OBLIGATION FOR CONSTRUCTION.	7,300,000
	WASHINGTON, GREENE, WESTMORELAND, AND FAYETTE COUNTIES, PA.	106–554	108	NO OBLIGATION FOR CONSTRUCTION.	8,000,000
	BRADFORD AND SULLIVAN COUNTIES, PA.	106–53	548	NO OBLIGATION FOR CONSTRUCTION.	13,000,000
	DAUPHIN COUNTY, PA	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	2,000,000
	DILLSBURG BOROUGH AUTHORITY, PA.	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	2,000,000
	HAMPDEN TOWNSHIP, PA	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	3,000,000
	MOUNT JOY TOWNSHIP AND CONEWAGO TOWNSHIP, PA.	106–554	108d	NO OBLIGATION FOR CONSTRUCTION.	8,300,000
	PATTON TOWNSHIP, PA	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	1,400,000
	UPPER ALLEN TOWNSHIP, PA	106–53	502b	NO OBLIGATION FOR CONSTRUCTION.	3,400,000
	DELAWARE RIVER BASIN—WABASH CREEK, BOROUGH OF TAMAQUA, PA.	93–251	2	1993	13,194,000
	PHILADELPHIA, PA (FRANKFORD DAM).	104–303	564e	NO OBLIGATION FOR CONSTRUCTION.	900,000
	PHILADELPHIA, PA (PENNYPACK PARK).	104–303	564d	NO OBLIGATION FOR CONSTRUCTION.	15,000,000
	PHILADELPHIA, PA (WATER WORKS RESTORATION).	104–303	564a	NO OBLIGATION FOR CONSTRUCTION.	1,000,000
	PHOENIXVILLE BOROUGH, CHESTER COUNTY, PA.	106–554	108d	NO OBLIGATION FOR CONSTRUCTION.	2,400,000
	TOWAMENCIN TOWNSHIP, PA	106–53	502b	2005	1,462,000
PR	GUANAJIBO RIVER, PR	106–53	101	NO OBLIGATION FOR CONSTRUCTION.	3,495,941
	RIO NIGUA AT SALINAS, PR	106–53	101	NO OBLIGATION FOR CONSTRUCTION.	12,145,000
RI	CRANSTON, RI	101–640	54	NO OBLIGATION FOR CONSTRUCTION.	6,000,000
	DREDGING OF SALT PONDS IN THE STATE OF RHODE ISLAND, RI.	106–53	578	NO OBLIGATION FOR CONSTRUCTION.	1,100,000
SC	CHARLESTON, SC	108–137	127	NO OBLIGATION FOR CONSTRUCTION.	10,000,000
TN	MEMPHIS HARBOR, MEMPHIS, TN	106–53	364	NO OBLIGATION FOR CONSTRUCTION.	110,044,000
	NONCONNAH CREEK, TN & MS (EXTENSION).	106–541	334	2004	36,188,000
TX	NAVASOTA RIVER BASIN, TX (MILLICAN LAKE, TX).	90–483	203	1983	778,421,000
	TRINITY RIVER AND TRIBUTARIES, TX (LIBERTY LOCAL PROTECTION PROJECT).	108–447	116	1981	19,985,000
	TRINITY RIVER AND TRIBUTARIES, TX (NAVIGATION CHANNEL ABOVE LIBERTY).	108–447	116	1981	5,412,060,000
	TRINITY RIVER AND TRIBUTARIES, TX (WEST FORK FLOODWAY).	108–447	116	1981	119,408,000

TABLE 1 (FINAL DEAUTHORIZATION REPORT)—Continued

State	Project/Element name	Public law of authorization or latest amendment	Section of public law	Latest fiscal year of Federal or non-Federal obligations for construction	Federal balance to complete (subject to section 902 where applicable) ($)
	BUFFALO BAYOU AND TRIBUTARIES, TX (HALLS BAYOU).	101–640	101(21)	NO OBLIGATION FOR CONSTRUCTION.	112,536,000
	LOWER RIO GRANDE BASIN, TEXAS (SOUTH MAIN CHANNEL), TX.	99–662	401(a)	2005	207,183,000
TX & OK	RED RIVER WATERWAY (BANK STABILIZATION FEATURES).	90–483	101	2004	685,324,228
UT	CACHE COUNTY, UT	106–53	502(b)	NO OBLIGATION FOR CONSTRUCTION.	5,000,000
UT	UPPER JORDAN RIVER, UT	106–53	357	2004	11,087,268
VA	LEVISA AND TUG FORKS AND UPPER CUMBERLAND RIVER VA, WV, KY (HAYSI LAKE, VA).	104–303	353	1989	185,915,319
	NORFOLK HARBOR ANCHORAGES, VA.	101–640	107(a)(13)	NO OBLIGATION FOR CONSTRUCTION.	63,130,000
	WALLOPS ISLAND, VA	106–53	567	NO OBLIGATION FOR CONSTRUCTION.	8,000,000
WA	STILLAGUMAISH RIVER BASIN, WA	106–541	101b(27)	NO OBLIGATION FOR CONSTRUCTION.	26,047,966
WV	CABIN CREEK LPP, WV	99–662	601a	NO OBLIGATION FOR CONSTRUCTION.	10,409,900
	ISLAND CREEK BASIN, VICINITY OF LOGAN, WV (NON-STRUCTURAL FEATURES).	99–662	401a	NO OBLIGATION FOR CONSTRUCTION.	107,707,600
	WEST VIRGINIA PORT DEVELOPMENT, WV.	106–53	557(3)	NO OBLIGATION FOR CONSTRUCTION.	24,144,000
	WEIRTON PORT, WV	106–53	557(2)	NO OBLIGATION FOR CONSTRUCTION.	15,274,778
				TOTAL	14,255,612,373

Final Deauthorization Report WRRDA 2014, Section 6001(d)(3)(B)

Appendix A—Projects Removed From the Interim Deauthorization List

State	Project/Element name	Reason project removed from interim deauthorization list
Louisiana	Amite River and Tributaries	Technical Correction: The Amite River and Tributaries project is identified in later authorizations as the Comite River Diversion project, which is under construction.
Connecticut	Hartford Environmental Infrastructure	Technical Correction: Project Previously Deauthorized (**Federal Register** 74.126).
Connecticut	New Haven Environmental Infrastructure	Technical Correction: Project Previously Deauthorized (**Federal Register** 74.126).
Maine	Fall River and New Bedford Environmental Infrastructure.	Technical Correction: Project Previously Deauthorized (**Federal Register** 74.126).

[FR Doc. 2016–06695 Filed 3–24–16; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0034]

Agency Information Collection Activities; Comment Request; Study of the Title III Native American and Alaska Native Children in School (NAM) Program

AGENCY: Office of Planning, Evaluation and Policy Development (OPEPD), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before May 24, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0034. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Joanne Bogart, 202–205–7855.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Study of the Title III Native American and Alaska Native Children in School (NAM) Program.

OMB Control Number: 1875—New.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, or Tribal Governments.

Total Estimated Number of Annual Responses: 509.

Total Estimated Number of Annual Burden Hours: 510.

Abstract: The NAM Program seeks to improve academic outcomes in English for Native American and Alaska Native (NA/AN) students, providing funding for programs that support language instruction educational programs, including NA/AN language and culture revitalization. The goal of this study is to describe how 22 current grantees have use the NAM Program to support NA/AN students. Results will help the Department structure future funding rounds and better support current and future grantees.

Dated: March 22, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–06823 Filed 3–24–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Application for New Awards; Native American and Alaska Native Children in School Program

AGENCY: Office of English Language Acquisition, Department of Education.

ACTION: Notice.

Overview Information:

Native American and Alaska Native Children in School Program Notice inviting applications for new awards for fiscal year (FY) 2016.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.365C.

DATES: Applications Available: March 25, 2016.

Deadline for Notice of Intent to Apply: April 14, 2016.

Deadline for Transmittal of Applications: May 24, 2016.

Deadline for Intergovernmental Review: July 25, 2016.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program

The purpose of the Native American and Alaska Native Children in School (NAM) program is to award grants to eligible entities to develop and enhance capacity to provide effective instruction and support to Native American students, including Native Hawaiian and Native American Pacific Islander, who are identified as English learners (ELs). The goal of this program is to support the teaching, learning, and studying of Native American languages while also increasing the English language proficiency of students served to meet challenging State academic content and achievement standards.

Background

Through previous competitions, the NAM program has funded a range of grantees that are currently implementing 25 projects across the country. As the educational needs of Native Americans and Alaska Natives continue to grow, there is also a need to increase knowledge of what practices work to effectively improve learning outcomes for Native American and Alaska Native ELs.

Congress, in the Native American Languages Act of 1990, recognized the fundamental importance of preserving Native American languages. Congress states that it is the policy of the United States to:

> Preserve, protect, and promote the rights and freedom of Native Americans to use, practice, and develop Native American languages.

25 U.S.C. 2903(1)

In addition, it is the policy of the United States to encourage and support the use of Native American languages as a medium of instruction in order to encourage and support—

> (A) Native American language survival,
> (B) educational opportunity,
> (C) increased student success and performance,
> (D) increased student awareness and knowledge of their culture and history, and
> (E) increased student and community pride.

25 U.S.C. 2903 (3)

This Federal policy is supported by growing recognition of the importance

of native language preservation in facilitating educational success for Native students. In a 2007 study by Teachers of English to Students of Other Languages (TESOL), the majority of Native youth surveyed stated that they value their native language, viewed it as integral to their sense of self, wanted to learn it, and viewed it as a means of facilitating their success in school and life.[1] Collaborative efforts between educators, families, and communities, the study suggests, may be especially promising ways to ensure that all Native students have the critical opportunity to learn their native languages.

Not only is native language instruction critical for student engagement and fostering a rich sense of self, but research has shown that students who are bilingual have certain cognitive and social benefits that their monolingual peers may lack.[2] Additionally, for students who are classified as ELs, well-implemented language instruction educational programs (as defined in this notice), including dual language approaches, may result in ELs performing equal to or better than their peers in English-only language instruction programs. These approaches have shown promise in increasing language acquisition in English and native languages, and may also promote greater achievement in the academic content areas, including English language arts and mathematics.[3]

Therefore, to facilitate high-quality language instruction and academic success for Native American students who are classified as ELs, this competition includes an absolute priority for projects that will support the preservation and revitalization of Native American languages while also increasing the English language proficiency of the children served under the project.

For this competition, the Department also seeks to support projects designed to improve early learning and development outcomes for Native American and Alaskan Native students across one or more of the essential domains of school readiness for children from birth through third grade and throughout the early elementary school years. Accordingly, this notice includes a competitive preference priority related to improving early learning and development outcomes.

In addition, the Department is interested in projects designed to improve parental, family, and community engagement. Literature suggests that educators who involve families in their students' education can strengthen their instructional effectiveness with ELs.[4] [5] Accordingly, this notice includes an invitational priority related to improving parent, family, and community engagement.

Finally, to grow the evidence available on effective ways to support Native American and Alaska Native ELs, we include a selection criterion under which applications will be evaluated on the extent to which their proposed project designs are supported by strong theory, as defined in this notice. In addition, we include a selection criterion that encourages applicants to design evaluations of their projects that would provide them with continuous, formative feedback on their progress toward their project goals.

Priorities: This notice includes one absolute priority, one competitive preference priority, and one invitational priority. The absolute priority is from section 3128 of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (NCLB) (20 U.S.C. 7801). The competitive preference priority is from the Department's notice of final supplemental priorities and definitions for discretionary grant programs (Supplemental Priorities), published in the **Federal Register** on December 10, 2014 (79 FR 73425).

Absolute Priority: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Projects that support the teaching, learning, and studying of Native American languages while also increasing the English language proficiency of the children served.

Competitive Preference Priority: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award up to an additional five points to an application, depending on how well the application meets this priority.

This priority is:

Improving Early Learning and Development Outcomes (0 to 5 points).

Projects that are designed to improve early learning and development outcomes across one or more of the essential domains of school readiness for children from birth through third grade (or for any age group within this range) through a focus on one or both of the following:

(a) Increasing access to high-quality early learning and development programs and comprehensive services, particularly for children with high needs.

(b) Improving the coordination and alignment among early learning and development systems and between such systems and elementary education systems, including coordination and alignment in engaging and supporting families and improving transitions for children along the birth-through-third-grade continuum, in accordance with applicable privacy laws.

Invitational Priority: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Parent, Family, and Community Engagement.

Projects that will support meaningful parent, family, and community engagement (as defined in this notice) to improve student achievement.

Applicants are encouraged to design a comprehensive approach to leveraging sustained partnerships (as defined in this notice) with community-based organizations, institutions of higher education (IHEs), and other entities.

Definitions: The following definitions are from 34 CFR 77.1, 34 CFR 200.6, the Supplemental Priorities, and sections 3201 and 8101 of the ESEA, as amended by the Every Student Succeeds Act (ESSA) (20 U.S.C. 7011 and 7801), and apply to the priorities, selection criteria, and performance measures in this notice. The source of each definition is noted in parentheses following the text of the definition.

[1] Romero-Little, M.E., McCarty, T.L., Warhol, L., and Zepeda, O. (2007). Language policies in practice: Preliminary findings from a large-scale study of Native American language shift. TESOL Quarterly 41:3, 607–618.

[2] Valentino, R.A., and Reardon, S.F. (2015). Effectiveness of four instructional programs designed to serve English language learners: Variation by ethnicity and initial English proficiency. Educational Evaluation and Policy Analysis, doi: 10.3102/0162373715573310.

[3] Lindholm-Leary, K.J. (2001). Dual-language education (Vol. 28). Multilingual Matters.

[4] Chen, C., Kyle, D.W., and McIntyre, M. (2008). Helping teachers work effectively with English language learners and their families. The School Community Journal, 18 (1), 7–20.

[5] Waterman, R., and Harry, B. (2008). *Building Collaboration Between Schools and Parents of English Language Learners: Transcending Barriers, Creating Opportunities.* Tempe, AZ: National Center for Culturally Responsive Educational Systems.

Ambitious means promoting continued, meaningful improvement for program participants or for other individuals or entities affected by the grant, or representing a significant advancement in the field of education research, practices, or methodologies. When used to describe a performance target, whether a performance target is ambitious depends upon the context of the relevant performance measure and the baseline for that measure. (34 CFR 77.1)

Baseline means the starting point from which performance is measured and targets are set. (34 CFR 77.1)

Children with high needs means children from birth through kindergarten entry who are from low-income families or otherwise in need of special assistance and support, including children who have disabilities or developmental delays; who are English learners; who reside on ''Indian lands'' as that term is defined by section 8013(7) of the ESEA, as amended by NCLB; who are migrant, homeless, or in foster care; and who are other children as identified by the State. (34 CFR 77.1)

Community engagement means the systematic inclusion of community organizations as partners with State educational agencies (SEAs), local educational agencies (LEAs), or other educational institutions, or their school or program staff to accomplish activities that may include developing a shared community vision, establishing a shared accountability agreement, participating in shared data-collection and analysis, or establishing community networks that are focused on shared community-level outcomes. These organizations may include faith- and community-based organizations, IHEs (including minority-serving institutions eligible to receive aid under title III or title V of the Higher Education Act of 1965 (HEA)), businesses and industries, labor organizations, State and local government entities, or Federal entities other than the Department. (Supplemental Priorities)

English learner, when used with respect to an individual, means an individual—

(A) Who is aged 3 through 21;

(B) Who is enrolled or preparing to enroll in an elementary school or secondary school;

(C)(i) Who was not born in the United States or whose native language is a language other than English;

(ii)(I) Who is a Native American or Alaska Native, or a Native resident of the outlying areas; and

(II) Who comes from an environment where a language other than English has had a significant impact on the individual's level of English language proficiency; or

(iii) Who is migratory, whose native language is a language other than English, and who comes from an environment where a language other than English is dominant; and

(D) Whose difficulties in speaking, reading, writing, or understanding the English language may be sufficient to deny the individual—

(i) The ability to meet the State's challenging State academic standards;

(ii) The ability to successfully achieve in classrooms where the language of instruction is English; or

(iii) The opportunity to participate fully in society. (Section 8101 of the ESEA, as amended by ESSA)

Essential domains of school readiness means the domains of language and literacy development, cognition and general knowledge (including early mathematics and early scientific development), approaches toward learning (including the utilization of the arts), physical well-being and motor development (including adaptive skills), and social and emotional development. (Supplemental Priorities)

Language instruction educational program means an instruction course—

(A) In which an English learner is placed for the purpose of developing and attaining English proficiency, while meeting challenging State academic achievement standards; and

(B) That may make instructional use of both English and a child's native language to enable the child to develop and attain English proficiency, and may include the participation of English proficient children if such course is designed to enable all participating children to become proficient in English and a second language. (Section 3201 of the ESEA, as amended by ESSA)

Logic model (also referred to as theory of action) means a well-specified conceptual framework that identifies key components of the proposed process, product, strategy, or practice (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the relationships among the key components and outcomes, theoretically and operationally. (34 CFR 77.1)

Note: Applicants may use resources such as the Pacific Education Laboratory's Education Logic Model Application (*http://relpacific.mcrel.org/resources/elm-app*) to help design their logic models.

Native Hawaiian or Native American Pacific Islander native language educational organization means a nonprofit organization with—

(A) A majority of its governing board and employees consisting of fluent speakers of the traditional Native American languages used in the organization's educational programs; and

(B) Not less than five years successful experience in providing educational services in traditional Native American languages. (Section 3201 of the ESEA, as amended by ESSA)

Parent and family engagement means the systematic inclusion of parents and families, working in partnership with SEAs, State lead agencies (under Part C of the Individuals with Disabilities Education Act or the State's Race to the Top-Early Learning Challenge grant), LEAs, or other educational institutions, or their staff, in their child's education, which may include strengthening the ability of (A) parents and families to support their child's education; and (B) school or program staff to work with parents and families. (Supplemental Priorities)

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project. (34 CFR 77.1)

Strong theory means a rationale for the proposed process, product, strategy, or practice that includes a logic model. (34 CFR 77.1)

Student achievement means—

For grades and subjects in which assessments are required under section 1111(b)(3) of the ESEA, as amended by NCLB: (1) A student's score on such assessments; and, as appropriate (2) other measures of student learning, such as those described in the subsequent paragraph, provided that they are rigorous and comparable across schools within an LEA.

For grades and subjects in which assessments are not required under section 1111(b)(3) of the ESEA, as amended by NCLB: (1) Alternative measures of student learning and performance, such as student results on pre-tests, end-of-course tests, and objective performance-based assessments; (2) student learning objectives; (3) student performance on English language proficiency assessments; and (4) other measures of student achievement that are rigorous and comparable across schools within an LEA. (Supplemental Priorities)

Sustained partnership means a relationship that has demonstrably adequate resources and other support to continue beyond the funding period and that consist of community organizations as partners with an LEA and one or more of its schools. These organizations may include faith- and community-

based organizations, IHEs (including minority-serving institutions eligible to receive aid under title III or title V of the HEA), businesses and industries, labor organizations, State and local government entities, or Federal entities other than the Department. (Supplemental Priorities)

Program Authority: 20 U.S.C. 6822.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Government-wide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended in 2 CFR part 3474. (d) The Supplemental Priorities.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $3,223,778.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2017 or later years from the list of unfunded applications from this competition.

Estimated Range of Awards: $275,000–325,000 per year.

Estimated Average Size of Awards: $300,000.

Estimated Number of Awards: 10.

Note: The Department is not bound by any estimates in this notice.

Project Period: 60 months.

III. Eligibility Information

1. *Eligible Applicants:* The following entities, when they operate elementary, secondary, or postsecondary schools primarily for Native American children (including Alaska Native children), are eligible applicants under this program:

(a) Indian tribes.

(b) Tribally sanctioned educational authorities.

(c) Native Hawaiian or Native American Pacific Islander native language educational organizations.

(d) Elementary schools or secondary schools that are operated or funded by the Department of the Interior's Bureau of Indian Affairs, or a consortium of these schools.

(e) Elementary schools or secondary schools operated under a contract with or grant from the Bureau of Indian Affairs in consortium with another such school or a tribal or community organization.

(f) Elementary schools or secondary schools operated by the Bureau of Indian Affairs and an IHE, in consortium with an elementary school or secondary school operated under a contract with or a grant from the Bureau of Indian Affairs or a tribal or community organization.

Note: Eligible applicants applying as a consortium should read and follow the regulations in 34 CFR 75.127 through 75.129.

Under section 3112(c) of the ESEA, as amended by NCLB, EL students served under NAM grants must not be included in the child count submitted by a school district under section 3114(a) for purposes of receiving funding under the English Language Acquisition State Grants program.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Equitable Participation by Public and Private School Students and Educational Personnel in a Title III Program:* An entity that receives a grant under the NAM program must provide for the equitable participation of private school children and their teachers or other educational personnel. To ensure that grant program activities address the needs of private school children, the applicant must engage in timely and meaningful consultation with appropriate private school officials during the design and development of the program. This consultation must take place before the applicant makes any decision that affects the opportunities for participation by eligible private school children, teachers, and other educational personnel. Administrative direction and control over grant funds must remain with the grantee. (See section 9501 of the ESEA, as amended by NCLB Participation by Private School Children and Teachers.)

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA 84.365C.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person listed under *Accessible Format* in section VIII of this notice.

2. a. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition. Deadline for Notice of Intent to Apply: April 14, 2016.

We will be able to develop a more efficient process for reviewing grant applications if we know the approximate number of applicants that intend to apply for funding under this competition. Therefore, we strongly encourage each potential applicant to notify us of the applicant's intent to submit an application by emailing *NAM2016@ed.gov* with the subject line ''Intent to Apply'' and include in the content of the email the following information: (1) The applicant organization's name and address, and (2) whether the applicant is addressing the competitive preference priority or the invitational priority. Applicants that do not provide notice of their intent to apply may still submit an application. Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. Applicants must limit the application narrative to no more than 35 pages. Applicants are also strongly encouraged not to include lengthy appendices that contain information that they were unable to include within the page limits for the narrative.

Applicants must use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles,

charts, tables, headings, footnotes, quotations, references, and captions.

• Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The page limit for the application does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, certification of eligibility, or letters of support of project partners if applied as a consortium. However, the page limit does apply to all of the application narrative section of the application.

We will reject your application if you exceed the page limit.

b. *Submission of Proprietary Information:*

Given the types of projects that may be proposed in applications for the NAM program, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Consistent with the process followed in the prior NAM competitions, we may post the project narrative section of funded NAM applications on the Department's Web site so you may wish to request confidentiality of business information. Identifying proprietary information in the submitted application will help facilitate this public disclosure process.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Deadline for Notice of Intent to Apply: April 14, 2016. Informational Meetings: We intend to hold Webinars to provide technical assistance to interested applicants. Detailed information regarding these meetings will be provided on the NAM Web site at*http://www2.ed.gov/about/offices/list/oela/index.html.*

Deadline for Transmittal of Applications: May 24, 2016.

Applications for grants under this competition must be submitted electronically using the Grants.gov application site. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: July 25, 2016.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, Grants.gov.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:*

Applications for grants for the NAM program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the NAM program, CFDA number 84.365C, must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this

site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the NAM program at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.365, not 84.365C).

Please note the following:

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through Grants.gov, please refer to the Grants.gov Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the project narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. This notification indicates receipt by Grants.gov only, not receipt by the Department. Grants.gov will also notify you automatically by email if your application met all the Grants.gov validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by Grants.gov, the Department will retrieve your application from Grants.gov and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by Grants.gov, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that the problem

affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to:

Patrice Swann, U.S. Department of Education, 400 Maryland Avenue SW., Room 5C144, Washington, DC 20202–6510. FAX: (202) 260–5496.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.365C),
LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.365C),
550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from section 75.210 of EDGAR. The maximum score for all of these criteria is 100 points (not including competitive preference priority points). The maximum score for each criterion is indicated in parentheses.

(a) *Quality of the project design.* (up to 45 points)

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(2) The extent to which the design for implementing and evaluating the proposed project will result in information to guide possible replications of project activities or strategies including information about the effectiveness of the approach or strategies employed by the project.

(3) The extent to which the proposed project is supported by strong theory (as defined in this notice).

(b) *Quality of project personnel.* (up to 10 points)

The Secretary considers the quality of the personnel who will carry out the proposed project. In determining the quality of project personnel, the Secretary considers the following factors:

(1) The extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(2) The qualifications, including relevant training and experience, of key project personnel.

(c) *Quality of the management plan.* (up to 25 points)

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(2) The extent to which the time commitments of the project director and the principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(d) *Quality of the project evaluation.* (up to 20 points)

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(2) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

2. *Review and Selection Process:* The Department will screen applications that are submitted for NAM grants in accordance with the requirements in this notice and determine which applications meet the eligibility and other requirements. Peer reviewers will review all eligible applications for NAM grants that are submitted by the established deadline on the four selection criteria.

Applicants should note, however, that we may screen for eligibility at multiple points during the competition process, including before and after peer review; applicants that are determined to be ineligible will not receive a grant award regardless of peer reviewer scores or comments. If we determine that a NAM grant application does not meet a NAM requirement, the application will not be considered for funding.

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www2.ed.gov/fund/grant/apply/appforms/appforms.html*.

(c) The Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* Under the Government Performance and Results Act (GPRA), Federal departments and agencies must clearly describe the goals and objectives of programs, identify resources and actions needed to accomplish goals and objectives, develop a means of measuring progress made, and regularly report on achievement. One important source of program information on successes and lessons learned is the project evaluation conducted under individual grants.

(a) *Measures.* The Department has developed the following GPRA performance measures for evaluating the overall effectiveness of the NAM program:

Measure 1: The number and percentage of ELs served by the program who score proficient or above on the State reading assessment.

Measure 2: The number and percentage of ELs served by the program who are making progress in learning English as measured by the State-approved English language proficiency assessment.

Measure 3: The number and percentage of ELs served by the program who are attaining proficiency in English as measured by the State-approved English language proficiency assessment.

Note: Data from local assessments are acceptable for evaluation under a performance measure only in cases in which a grantee is in a State that is undergoing an assessment transition.

Measure 4: The number and percentage of students served by the program who are enrolled in Native American language instruction programs.

Measure 5: The number and percentage of students making progress in learning a Native American language, as determined by each grantee, including through measures such as performance tasks, portfolios, and pre- and post-tests.

Measure 6: The number and percentage of students who are attaining proficiency in a Native American language as determined by each grantee, including through measures such as performance tasks, portfolios, and pre- and post-tests.

Measure 7: For programs that received competitive preference points, the number and percentage of preschool children ages three and four enrolled in the program.

Measure 8: For programs that received competitive preference points, the number and percentage of preschool children ages three and four who are screened for developmental or cognitive delays.

Measure 9: For programs that received competitive preference points, the number and percentage of coordination contacts between elementary schools and early learning programs to improve coordination and transition of children from preschool to kindergarten.

(b) *Baseline data.* Applicants must provide baseline data for each of the GPRA performance measures listed in paragraph (a) and include why each proposed baseline (as defined in this notice) is valid; or, if the applicant has determined that there are no established baseline data for a particular performance measure, explain why there is no established baseline and explain how and when, during the project period, the applicant will establish a valid baseline for the performance measure.

(c) *Performance measure targets.* In addition, the applicant must propose in its application annual targets for the measures listed in paragraph (a). Applications must also include the following information as directed under 34 CFR 75.110(b) and (c):

(1) Why each proposed performance target (as defined in this notice) is ambitious (as defined in this notice) yet achievable compared to the baseline for the performance measure.

(2) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data.

(3) The applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

Note: If the applicant does not have experience with collection and reporting of performance data through other projects or research, the applicant should provide other evidence of capacity to successfully carry out data collection and reporting for its proposed project.

(d) *Performance Reports.* All grantees must submit an annual performance report and final performance report with information that is responsive to these performance measures. The Department will consider this data in making annual continuation awards.

(e) *Department Evaluations.* Consistent with 34 CFR 75.591, grantees funded under this program must comply with the requirements of any evaluation of the program conducted by the Department or an evaluator selected by the Department.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Francisco Javier Lopez, U.S. Department of Education, 400 Maryland Avenue SW., Room 5E112, Washington, DC 20202. Telephone: (202) 401–4300. FAX: (202) 205–1229 or by email at *NAM2016@ed.gov.*

If you use a TDD or a TTY, call the Federal Relay Service, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: March 22, 2016.

Libia S. Gil,

Assistant Deputy Secretary and Director for the Office of English Language Acquisition.

[FR Doc. 2016–06838 Filed 3–24–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Committee on Foreign Medical Education and Accreditation

AGENCY: Office of Postsecondary Education, National Committee on Foreign Medical Education and Accreditation, U.S. Department of Education.

ACTION: Announcement of a Committee meeting.

SUMMARY: The purpose of this notice is to announce the upcoming meeting of the National Committee on Foreign Medical Education and Accreditation (NCFMEA). Parts of this meeting will be open to the public, and the public is invited to attend those portions.

Meeting Date and Place: The meeting will be held on April 21–22, 2016, from 9:00 a.m. until approximately 5:00 p.m. both days, at the Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314. The Committee will meet in Executive Session on April 22, 2016. The entire April 22nd session will be devoted to training sessions for the Committee; and, therefore, is closed to the public.

FOR FURTHER INFORMATION CONTACT: Jennifer Hong, Executive Director for the NCFMEA, U.S. Department of Education, 400 Maryland Avenue SW., Room 6W250, Washington, DC 20202; telephone: 202–453–7805, or email: *Jennifer.Hong@ed.gov*

SUPPLEMENTARY INFORMATION:

Statutory Authority and Function: The NCFMEA was established by the Secretary of Education under § 102 of the Higher Education Act of 1965, as amended. The NCFMEA's responsibilities are to:

- Evaluate the standards of accreditation applied to foreign medical schools and,
- Determine the comparability of those standards to standards for accreditation applied to United States medical schools. A determination of comparability of accreditation standards by the NCFMEA is an eligibility requirement for foreign medical schools to participate in the William D. Ford Federal Direct Student Loan Program, 20 U.S.C. 1087a *et seq.*

Meeting Agenda: The NCFMEA will review the standards of accreditation applied to medical schools to determine

whether those standards are comparable to the standards of accreditation applied to medical schools in the United States. The NCFMEA will also review previously requested reports from accrediting entities that accredit medical schools. Discussion of the standards of accreditation will be held in sessions open to the public. Discussions resulting in specific determinations of comparability are closed to the public until proper notification of the NCFMEA's decision is provided to the country and accrediting entity by the Department.

The countries which are scheduled to be discussed are: Australia, Grenada, Pakistan, St. Kitts and Nevis, and the Dominican Republic. The meeting agenda, as well as the staff analyses pertaining to the meeting, will be posted on the Department of Education's Web site prior to the meeting at *http://www2.ed.gov/about/bdscomm/list/ncfmea.html.*

Reasonable Accommodations: The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice by April 1, 2016, although we will attempt to meet a request received after that date.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: § 102 of the Higher Education Act of 1965, as amended.

Lynn B. Mahaffie,

Deputy Assistant Secretary for Planning, Policy and Innovation, delegated the duties of Assistant Secretary for Postsecondary Education.

[FR Doc. 2016–06837 Filed 3–24–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings # 1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–89–000.

Applicants: FirstLight Hydro Generating Company, FirstLight Power Resources Management, LLC.

Description: Application for section 203 Authorization of FirstLight Hydro Generating Company and FirstLight Power Resources Management, LLC.

Filed Date: 3/17/16.

Accession Number: 20160317–5182.

Comments Due: 5 p.m. ET 4/7/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4625–002; ER10–2861–001; ER13–2169–001; ER10–2862–002; ER11–3634–002; ER13–1504–002; ER10–2866–001; ER10–2867–002.

Applicants: Colton Power L.P., Fountain Valley Power, LLC, Goal Line L.P., Harbor Cogeneration Company, LLC, KES Kingsburg, L.P., SWG Arapahoe, LLC, SWG Colorado, LLC, Valencia Power, LLC.

Description: Notice of Change in Status of the Southwest Generation Operating Company, LLC public utility subsidiaries.

Filed Date: 3/17/16.

Accession Number: 20160317–5207.

Comments Due: 5 p.m. ET 4/7/16.

Docket Numbers: ER12–2511–007.

Applicants: C.P. Crane LLC.

Description: Notice of Change in Status of C.P. Crane LLC.

Filed Date: 3/17/16

Accession Number: 20160317–5187.

Comments Due: 5 p.m. ET 4/7/16.

Docket Numbers: ER15–953–000.

Applicants: Arkansas Electric Cooperative Corp.

Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b): Refund Report to be effective N/A.

Filed Date: 3/18/16.

Accession Number: 20160318–5089.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–647–001.

Applicants: Otter Tail Power Company.

Description: Compliance filing: Compliance Filing Regarding Service Agreement with CPEC Under the CASOT to be effective 1/1/2016.

Filed Date: 3/18/16.

Accession Number: 20160318–5101.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–715–001.

Applicants: DanMar Transmission, LLC.

Description: Tariff Amendment: Response to Request for Additional Information to be effective 3/13/2016.

Filed Date: 3/18/16.

Accession Number: 20160318–5051.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–1222–000.

Applicants: EnergyConnect, Inc.

Description: Tariff Cancellation: EnergyConnect, Inc. Cancellation to be effective 3/18/2016.

Filed Date: 3/17/16.

Accession Number: 20160317–5177.

Comments Due: 5 p.m. ET 4/7/16.

Docket Numbers: ER16–1223–000.

Applicants: Pacific Gas and Electric Company.

Description: Section 205(d) Rate Filing: Amendment to the San Joaquin Cogen GSFA (SA 130) to be effective 6/1/2016.

Filed Date: 3/18/16.

Accession Number: 20160318–5000.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–1224–000.

Applicants: FirstEnergy Solutions Corp.

Description: Request of FirstEnergy Solutions Corp. for Authorization to Make Wholesale Power Sales to Affiliated Utility, The Potomac Edison Company (2–1–16).

Filed Date: 3/17/16.

Accession Number: 20160317–5181.

Comments Due: 5 p.m. ET 4/7/16.

Docket Numbers: ER16–1225–000.

Applicants: Niagara Mohawk Power Corporation.

Description: Notice of Cancellation of Interconnection Agreement Service Agreement No. 919 of Niagara Mohawk Power Corporation.

Filed Date: 3/17/16.

Accession Number: 20160317–5200.

Comments Due: 5 p.m. ET 4/7/16.

Docket Numbers: ER16–1226–000.

Applicants: New Covert Generating Company, LLC.

Description: Section 205(d) Rate Filing: Reactive Tariff to be effective 6/1/2016.

Filed Date: 3/18/16.

Accession Number: 20160318–5028.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–1227–000.

Applicants: Southern California Edison Company.

Description: Section 205(d) Rate Filing: SGIA with North Lancaster Ranch LLC to be effective 3/19/2016.

Filed Date: 3/18/16.

Accession Number: 20160318–5044.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–1228–000.
Applicants: Virginia Electric and Power Company, PJM Interconnection, L.L.C.
Description: Section 205(d) Rate Filing: Virginia Electric and Power Company submits Mutual Operating Agreement No. 2032 to be effective 5/31/2016.
Filed Date: 3/18/16.
Accession Number: 20160318–5071.
Comments Due: 5 p.m. ET 4/8/16.
Docket Numbers: ER16–1229–000.
Applicants: PJM Interconnection, L.L.C., Trans-Allegheny Interstate Line Company.
Description: Section 205(d) Rate Filing: TrAILCo submits Original Service Agreement No. 4368 to be effective 3/19/2016.
Filed Date: 3/18/16.
Accession Number: 20160318–5073.
Comments Due: 5 p.m. ET 4/8/16.
Docket Numbers: ER16–1230–000.
Applicants: New York Independent System Operator, Inc., New York State Electric & Gas Corporation.
Description: Section 205(d) Rate Filing: Executed IA among NYISO, NYSEG and TrAILCO SA No. 2257 to be effective 3/19/2016.
Filed Date: 3/18/16.
Accession Number: 20160318–5084.
Comments Due: 5 p.m. ET 4/8/16.
Docket Numbers: ER16–1231–000.
Applicants: PacifiCorp.
Description: Section 205(d) Rate Filing: OATT Revised Attachment H–1 (Rev Depreciation Rates 2016) to be effective 6/1/2016.
Filed Date: 3/18/16.
Accession Number: 20160318–5099.
Comments Due: 5 p.m. ET 4/8/16.
Docket Numbers: ER16–1232–000.
Applicants: PJM Interconnection, L.L.C.
Description: Section 205(d) Rate Filing: Revisions to OATT Schedule 12 Appdx A- RTEP Approved by the PJM Board Feb 2016 to be effective 6/16/2016.
Filed Date: 3/18/16.
Accession Number: 20160318–5100.
Comments Due: 5 p.m. ET 4/8/16.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF16–556–000.
Applicants: Adelphi University.
Description: Form 556 of Adelphi University.
Filed Date: 3/17/16.
Accession Number: 20160317–5105.
Comments Due: None Applicable.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 18, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06778 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–81–000.
Applicants: Enterprise Solar, LLC, Escalante Solar I, LLC, Escalante Solar II, LLC, Escalante Solar III, LLC, Granite Mountain Solar East, LLC, Granite Mountain Solar West, LLC, Iron Springs Solar, LLC.
Description: Supplement to February 25, 2016 Application for Authorization Under Section 203 of the Federal Power Act and Request for Shortened Comment Period of Enterprise Solar, LLC, et al.
Filed Date: 3/18/16.
Accession Number: 20160318–5060.
Comments Due: 5 p.m. ET 3/28/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–40–001.
Applicants: Nevada Power Company.
Description: Compliance filing: OATT Supplement to Attachment O moving NVE Database to NPC Database to be effective 11/1/2014.
Filed Date: 3/18/16.
Accession Number: 20160318–5119.
Comments Due: 5 p.m. ET 4/8/16.
Docket Numbers: ER16–1233–000.
Applicants: PJM Interconnection, L.L.C.
Description: Section 205(d) Rate Filing: Original Service Agreement No. 4423; Queue Position #AA1–145 to be effective 2/18/2016.
Filed Date: 3/18/16.
Accession Number: 20160318–5115.
Comments Due: 5 p.m. ET 4/8/16.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF16–561–000.
Applicants: UE–00209NJ.
Description: Form 556 of UE–00209NJ.
Filed Date: 3/18/16.
Accession Number: 20160318–5111.
Comments Due: None Applicable.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 18, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06771 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–48–000]

NextEra Energy Power Marketing, LLC Northeast Energy Associates, a Limited Partnership v. ISO New England Inc.; Notice of Complaint

Take notice that on March 18, 2016, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824e and 825e (2012), and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2015), NextEra Energy Power Marketing, LLC and Northeast Energy Associates, a Limited Partnership (collectively, Complainants) filed a complaint against ISO New England Inc. (Respondent) alleging that Respondent violated its

Transmission, Markets and Services Tariff in preventing the Significant Increase at NEA's Bellingham Energy Center (Bellingham) from being added to Bellingham's summer Qualified Capacity in the tenth Forward Capacity Auction that was held on February 8, 2016, all as more fully explained in the complaint.

Complainants certify that copies of the complaint were serve on contacts for Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on April 7, 2016.

Dated: March 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06775 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–100–000]

Pike County Light & Power Company; Notice of Application

Take notice that on March 10, 2016, Pike County Light & Power Company (PCL&P), 402 Broad Street, Milford, Pennsylvania 18337, filed an application pursuant to section 7(f) of the Natural Gas Act (NGA) for a service area determination. PCL&P also requests: (1) A finding that PCL&P continues to qualify as a local distribution company (LDC) for purposes of section 311 of the Natural Gas Policy Act of 1978 (NGPA); and (2) a waiver of the Commission's accounting and reporting requirements and other regulatory requirements ordinarily applicable to natural gas companies under the NGA and NGPA, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Specifically, PCL&P requests a service area determination to allow it to continue to own and operate a 6-inch-diameter gas distribution pipeline at the Pennsylvania/New York border to receive natural gas in New York from the facilities of Orange and Rockland Utilities, Inc. (O&R), an LDC providing utility service in New York, and re-deliver the gas to PCL&P customers in Pennsylvania. PCL&P's application is related to O&R's application for a limited jurisdiction blanket certificate of public convenience and necessity filed in Docket No. CP16–101–000 on March 10, 2016.

Any questions regarding this application should be directed to John L. Carley, Assistant General Counsel, Orange and Rockland Utilities, Inc., Room 1815–S, 4 Irving Place, New York, New York 10003, (212) 460–2097 (telephone), or by email at *carleyj@coned.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be

placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''filing'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit original and 5 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: April 11, 2016.

Dated: March 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06773 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR16–28–000.

Applicants: Bay Gas Storage Company, Ltd.

Description: Tariff filing per 284.123/.224: 2016 Annual Adjustment of Company Use Percentage to be effective 3/1/2016; Filing Type: 790.

Filed Date: 2/24/16.

Accession Number: 201602245071.

Comments/Protests Due: 5 p.m. ET 3/24/16.

Docket Numbers: PR14–55–000.

Applicants: Arkansas Oklahoma Gas Corporation.

Description: Annual Report under PR14–55.

Filed Date: 2/25/16.

Accession Number: 201602255170.

Comments/Protests Due: 5 p.m. ET 3/28/16.

Docket Numbers: PR14–23–002.

Applicants: Kansas Gas Service, A Division of ONE Gas, Inc.

Description: Tariff filing per 284.123/.224: KGS, Revision to Requirements for Transportation Service to be effective 4/1/2016; Filing Type: 790.

Filed Date: 3/16/16.

Accession Number: 201603165106.

Comments/Protests Due: 5 p.m. ET 3/28/16.

Docket Numbers: RP15–1022–000.

Applicants: Alliance Pipeline L.P.

Description: Report Filing: 2016–03 Sheet 92.

Filed Date: 3/10/16.

Accession Number: 20160310–5126.

Comments Due: 5 p.m. ET 3/22/16.

Docket Numbers: RP16–719–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Section 4(d) Rate Filing: Negotiated Rates—Con Ed Release to Buy Energy to be effective 3/11/2016.

Filed Date: 3/10/16.

Accession Number: 20160310–5122.

Comments Due: 5 p.m. ET 3/22/16.

Docket Numbers: RP16–720–000.

Applicants: Gulf South Pipeline Company, LP.

Description: Section 4(d) Rate Filing: Remove expired agreements from Tariff (3/11/2016) to be effective 4/1/2016.

Filed Date: 3/11/16.

Accession Number: 20160311–5009.

Comments Due: 5 p.m. ET 3/23/16.

Docket Numbers: RP16–721–000.

Applicants: CenterPoint Energy Services, Inc.,Continuum Energy Services, L.L.C.

Description: Petition for Commission Approval of Request for Temporary Waivers of Capacity Release Regulations and Actions Necessary to Permit the Transfer of Gas Supply, Sale and Transportation Contracts ofCenterPoint Energy Services, Inc., et al.

Filed Date: 3/11/16.

Accession Number: 20160311–5238.

Comments Due: 5 p.m. ET 3/24/16.

Docket Numbers: RP16–722–000.

Applicants: Texas Eastern Transmission, LP.

Description: Section 4(d) Rate Filing: Cleanup Filing to Remove Customer Names from Statements of Rates to be effective 4/14/2016.

Filed Date: 3/14/16.

Accession Number: 20160314–5088.

Comments Due: 5 p.m. ET 3/28/16.

Docket Numbers: RP16–723–000.

Applicants: Enable Gas Transmission, LLC.

Description: Section 4(d) Rate Filing: Negotiated Rate Filing- March 2016 LER 1005896 to be effective 3/14/2016.

Filed Date: 3/14/16.

Accession Number: 20160314–5138.

Comments Due: 5 p.m. ET 3/28/16.

Docket Numbers: RP16–724–000.

Applicants: Rager Mountain Storage Company LLC.

Description: Section 4(d) Rate Filing: Form of Service Agreement Modifications to be effective 4/15/2016.

Filed Date: 3/15/16.

Accession Number: 20160315–5096.

Comments Due: 5 p.m. ET 3/28/16.

Docket Numbers: RP16–725–000.

Applicants: Natural Gas Pipeline Company of America.

Description: Section 4(d) Rate Filing: Occidental Energy Marketing to be effective 4/1/2016.

Filed Date: 3/15/16.

Accession Number: 20160315–5120.

Comments Due: 5 p.m. ET 3/28/16.

Docket Numbers: RP16–726–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Section 4(d) Rate Filing: Negotiated Rates—BBPC, d/b/a Great Eastern Energy—791351 to be effective 4/1/2016.

Filed Date: 3/16/16.

Accession Number: 20160316–5099.

Comments Due: 5 p.m. ET 3/28/16.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP15–1322–003.

Applicants: Sabine Pipe Line LLC.

Description: Compliance filing Sabine Motion to Place Rates into Effect 3–16–16 to be effective 4/1/2016.

Filed Date: 3/16/16.

Accession Number: 20160316–5103.

Comments Due: 5 p.m. ET 3/28/16.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 17, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06805 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP16–98–000; PF15–29–000]

Dominion Carolina Gas Transmission, LLC; Notice of Application

Take notice that on March 9, 2016, Dominion Carolina Gas Transmission, LLC (Dominion Carolina), filed an application pursuant to section 7(c) of the Natural Gas Act and Part 157 of the Commission's Regulations for a certificate of public convenience and necessity to construct, install, own, operate, and maintain certain facilities located in Aiken, Charleston, Dillon, Dorchester, Greenwood, Laurens, Newberry, and Spartanburg Counties, South Carolina (Transco to Charleston Project). Dominion Carolina will provide firm transportation service of 80,000 dekatherms per day (Dth/day) to meet increasing demand for natural gas for local commercial, industrial, and power generation customers. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@gerc.gov* or call toll-free, (866) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to Richard D. Jessee, Gas Transmission Certificates Program Manager, Dominion Carolina Gas Transmission, LLC, 220 Operations Way, Cayce, SC 29033. Telephone (803) 726–3738 and email: *Richard.Jessee@dom.com*.

Dominion Carolina proposes to construct approximately 55 miles of 12-inch diameter natural gas transmission pipeline in Spartanburg, Laurens, New Berry, and Greenwood Counties, SC (Moore to Chappells Pipeline) and approximately 5 miles of 4-inch diameter natural gas transmission pipeline in Dillion County, SC (Dillion Pipeline). Dominion Carolina also proposes to install: Two 1,400-horsepower (hp) compressor units at existing Moore Compressor Station located in Spartanburg County, SC; three 1,200 hp compressor units at new Dorchester Compressor Station located Dorchester County, SC; and appurtenances. In addition, Dominion Carolina proposes to convert one existing 1,200 hp compressor unit from standby to use the unit for service, at existing Southern Compressor Station located in Aiken County, SC. Dominion Carolina has executed binding precedent agreements with its customers for the project's capacity of 80,000 Dth/day. Dominion Carolina proposes to charge a negotiated incremental rate for firm transportation service using the proposed project. The cost of the project is $119.3 million. Dominion Carolina proposes an in-service date of November 1, 2017.

On September 2, 2015, the Commission staff granted Dominion Carolina's request to use the National Environmental Policy Act (NEPA) Pre-Filing Process and assigned Docket No. PF15–29–000 to staff activities involving the proposed facilities. Now, as of the filing of this application on March 9, 2016, the NEPA Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP16–98–000, as noted in the caption of this Notice.

Pursuant to Section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 5 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Motions to intervene, protests and comments may be filed electronically via the internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Comment Date: 5:00 p.m. Eastern Time on April 11, 2016.

Dated: March 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06772 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: CP16–101–000.
Applicants: Orange and Rockland Utilities, Inc.
Description: Application for Limited Jurisdiction Blanket Certificate and Request for Expedited Action of Orange and Rockland Utilities, Inc.
Filed Date: 3/10/16.
Accession Number: 20160310–5104.
Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: RP16–727–000.
Applicants: Eastern Shore Natural Gas Company.
Description: § 4(d) Rate Filing: Filling of Negotiated Rate Agreement to be effective 3/18/2016.
Filed Date: 3/17/16.
Accession Number: 20160317–5073.
Comments Due: 5 p.m. ET 3/29/16.

Docket Numbers: RP16–728–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: Penalty Revenue Crediting Report of Midcontinent Express Pipeline LLC.
Filed Date: 3/17/16.
Accession Number: 20160317–5202.
Comments Due: 5 p.m. ET 3/29/16.

Docket Numbers: RP16–729–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: § 4(d) Rate Filing: GT&C Section 49—Available Firm Capacity Posting Procedure to be effective 4/18/2016.
Filed Date: 3/18/16.
Accession Number: 20160318–5129.
Comments Due: 5 p.m. ET 3/30/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06806 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meeting related to the transmission planning activities of the Southeastern Regional Transmission Planning (SERTP) Process.

The SERTP Process First Quarter Meeting.

March 24, 2016 10:00 a.m.–1:00 p.m. (Central Time)

The above-referenced meeting will be via web conference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *www.southeasternrtp.com.*

The discussions at the meeting described above may address matters at issue in the following proceedings:

Docket Nos. ER13–1928, et al., *Duke Energy Carolinas, LLC, et al.*

Docket Nos. ER13–1923, et al., *Midcontinent Independent System Operator, Inc., et al.*

Docket No. EL15–32, *North Carolina Waste Awareness and Reduction Network, Inc.* v. *Duke Energy Carolinas and Duke Energy Progress*

For more information, contact Valerie Martin, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (202) 502–6139 or *Valerie.Martin@ferc.gov.*

Dated: March 18, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06774 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC16–5–000]

Commission Information Collection Activities (FERC–714 and FERC–730); Comment Request

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Comment request.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1)(D), the Federal Energy Regulatory Commission (Commission or FERC) is submitting its information collections FERC–714 (Annual Electric Balancing Authority Area and Planning Area Report) and FERC–730 (Report of Transmission Investment Activity) to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission previously issued a Notice in the **Federal Register** (80 FR 80355, 12/24/2015) requesting public comments. The Commission received no comments on the FERC–714 or FERC–730 and is making this notation in its submittal to OMB.

DATES: Comments on the collections of information are due by April 25, 2016.

ADDRESSES: Comments filed with OMB, identified by the OMB Control No. 1902–0140 (FERC–714) and 1902–0239 (FERC–730) should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may also be reached via telephone at 202–395–0710.

A copy of the comments should also be sent to the Commission, in Docket No. IC16–5–000, by either of the following methods:

- *eFiling at Commission's Web site*: *http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier*: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* by telephone at (202) 502–8663, and by fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Type of Request: Three-year extension of the information collection requirements for all collections described below with no changes to the current reporting requirements. Please note that each collection is distinct from the next.

Comments: Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the Commission including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FERC–714 [Annual Electric Balancing Authority Area and Planning Area Report] [1]

OMB Control No.: 1902–0140.

Abstract: The Commission uses the FERC–714 data to analyze power system operations. These analyses estimate the effect of changes in power system operations resulting from the installation of a new generating unit or plant, transmission facilities, energy transfers between systems, and/or new points of interconnections. The FERC–714 data assists in providing a broad picture of interconnected balancing authority area operations including comprehensive information of balancing authority area generation, actual and scheduled inter-balancing authority area power transfers, and net energy for load, summer and winter generation peaks and system lambda. The Commission also uses the data to prepare status reports on the electric utility industry including a review of inter-balancing authority area bulk power trade information.

The Commission uses the collected data from planning areas to monitor forecasted demands by electric utilities with fundamental demand responsibilities and to develop hourly demand characteristics.

Type of Respondent: Electric utility balancing authorities and planning areas in the United States.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden and cost[2] (rounded) for the information collection as follows:

FERC–714 (Annual Electric Balancing Authority Area and Planning Area Report)

Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response [3]	Total annual burden hours & total annual cost	Cost per respondent ($)
(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
177	1	177	87 $5,973	15,399 $1,057,295	$5,973

FERC–730 [Report of Transmission Investment Activity]

OMB Control No.: 1902–0239.

Abstract: Pursuant to Section 219 [4] of the Federal Power Act, the Commission issued FERC Order No. 679,[5] Promoting Transmission Investment Through Pricing Reform. In Order No. 679 FERC amended its regulations in 18 CFR 35.35 to establish incentive-based (including performance-based) rate treatments for the transmission of electric energy in interstate commerce by public utilities. The Commission intended the order to benefit consumers by ensuring reliability and to reduce the cost of delivered power by reducing transmission congestion. Order No. 679 also adopted an annual reporting requirement (FERC–730) for utilities that receive incentive rate treatment for specific transmission projects. The FERC–730 provides annual data on transmission capital expenditures as well as project status detail. The Commission requires that filers specify which projects are currently receiving incentives in the project detail table and that they group together those facilities receiving the same incentive. Specifically, in accordance with the statute, public utilities with incentive rates must file:

- Actual transmission investment for the most recent calendar year, and projected, incremental investments for the next five calendar years (in dollar terms); and
- a project by project listing that specifies for each project the most up to date, expected completion date, percentage completion as of the date of filing, and reasons for delays for all current and projected investments over the next five calendar years. Projects with projected costs less than $20 million are excluded from this listing.

To ensure that Commission rules are successfully meeting the objectives of Section 219, the Commission collects

[1] The renewal request in this IC docket is for the current FERC–714, with no change to the reporting requirements. The FERC–714 is also part of the Forms Refresh effort (started in Docket No. AD15–11), which is a separate activity.

[2] The hourly cost (wages plus benefits), is based on the Bureau of Labor Statistics May 2014 National Industry-Specific Occupational Employment and Wage Estimates (at *http://www.bls.gov/oes/current/naics2_22.htm*). The average hourly cost (wages plus benefits) of $68.66/hour is the average of the following:

- Management (Code 11–0000), $78.04/hr.
- Computer and mathematical (Code 15–0000), $58.25/hr.
- Electrical Engineers (Code 17–2071), $66.45/hr.
- Economist (Code 19–3011), $73.04/hr.
- Computer and Information Systems Managers (Code 11–3021), $94.55/hr.
- Accountants and Auditors (Code 13–2011), $51.11/hr.
- Transportation, Storage, and Distribution Managers (Code 11–3071), $73.65/hr.
- Power Distributors and Dispatchers (Code 51–8012), $54.16/hr.

[3] The estimates for cost per response are derived using the following formula: Average Burden Hours per Response * $72.00 per Hour = Average Cost per Response. The hourly cost figure comes from the FERC average salary plus benefits ($149,489/year). Commission staff believes the FERC average salary plus benefits to be representative wage (plus benefits) for industry respondents.

[4] Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 594, 315 and 1283 (2005).

[5] RM06–4–000 (issued 7/20/2006), published at 71 FR 43294.

industry data, projections and related information that detail the level of investment. FERC–730 information regarding projected investments as well as information about completed projects allows the Commission to monitor the success of the transmission pricing reforms and to determine the status of critical projects and reasons for delay.

Type of Respondent: Public utilities that have been granted incentives based rate treatment for specific transmission projects under the provisions of 18 CFR 35.35(h) must file the FERC–730.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden for the information collection as:

FERC–730 (REPORT OF TRANSMISSION INVESTMENT ACTIVITY)

Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response [3]	Total annual burden hours & total annual cost	Cost per respondent ($)
(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
63	1	63	30 $2,160	1,890 $136,080	$2,160

Dated: March 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06777 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC16–3–000]

Commission Information Collection Activities; (FERC–556, FERC–606, and FERC–607); Comment Request

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Comment request.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1)(D), the Federal Energy Regulatory Commission (Commission or FERC) is submitting its information collections FERC–556 (Certification of Qualifying Facility Status for a Small Power Production or Cogeneration Facility), FERC–606 (Notification of Request for Federal Authorization and Requests for Further Information), and FERC–607 (Report on Decision or Action on Request for Federal Authorization) to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission previously issued a Notice in the **Federal Register** (80 FR 74101, 11/27/2015) requesting public comments. The Commission received no comments on the FERC–556, FERC–606, or FERC–607 and is making this notation in its submittal to OMB.

DATES: Comments on the collections of information are due by April 25, 2016.

ADDRESSES: Comments filed with OMB, identified by the OMB Control Nos. 1902–0075 (FERC–556) and 1902–0241 (FERC–606 and FERC–607) should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may also be reached via telephone at 202–395–0710.

A copy of the comments should also be sent to the Commission, in Docket No. IC16–3–000, by either of the following methods:

- *eFiling at Commission's Web site: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* by telephone at (202) 502–8663, and by fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Type of Request: Three-year extension of the information collection requirements for all collections described below with no changes to the current reporting requirements. Please note that each collection is distinct from the next.

Comments: Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FERC–556, Certification of Qualifying Facility Status for a Small Power Production or Cogeneration Facility

OMB Control No.: 1902–0075.

Abstract: Form No. 556 is required to implement sections 201 and 210 of the Public Utility Regulatory Policies Act of 1978 [1] (PURPA). FERC is authorized, under those sections, to encourage cogeneration and small power production and to prescribe such rules as necessary in order to carry out the statutory directives.

A primary statutory objective is efficient use of energy resources and facilities by electric utilities. One means of achieving this goal is to encourage production of electric power by cogeneration facilities which make use of reject heat associated with commercial or industrial processes, and by small power production facilities which use other wastes and renewable resources. PURPA encourages the development of small power production facilities and cogeneration facilities that meet certain technical and corporate

[1] 16 U.S.C. 796, 824a–3.

criteria through establishment of various regulatory benefits. Facilities that meet these criteria are called Qualifying Facilities (QFs).

FERC's regulations in 18 CFR part 292, as relevant here, specify: (a) The certification procedures which must be followed by owners or operators of small power production and cogeneration facilities; (b) the criteria which must be met; (c) the information which must be submitted to FERC in order to obtain qualifying status; and (d) the PURPA benefits which are available to QFs to encourage small power production and cogeneration.

18 CFR part 292 also exempts QFs from certain corporate, accounting, reporting, and rate regulation requirements of the Federal Power Act,[2] certain state laws and the Public Utility Holding Company Act of 2005.[3]

Type of Respondent: Facilities that are self-certifying their status as a cogenerator or small power producer or that are submitting an application for FERC certification of their status as a cogenerator or small power producer.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden for the information collection as:

FERC–556—Certification of Qualifying Facility Status for a Small Power Production or Cogeneration Facility

Facility type	Filing type	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours and cost per response [4] (4)	Total annual burden hours and total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
Cogeneration Facility >1 MW [5]	Self-certification	54	1.25	67.5	1.5 hrs; $108	101.25 hrs; $7,290	$135
Cogeneration Facility >1 MW	Application for FERC certification.	1	1.25	1.25	50 hrs; $3,600	62.5 hrs; $4,500	4,500
Small Power Production Facility >1 MW.	Self-certification	1,787	1.25	2,234	1.5 hrs; $108	3,351hrs; $241,272	135
Small Power Production Facility >1 MW.	Application for FERC certification.	0	1.25	0	50 hrs; $3,600	0 hrs; $0	0
Cogeneration and Small Power Production Facility ≤1 MW (Self-Certification) [6].	Self-certification	312	1.25	390	1.5 hrs; $108 [7]	585 hrs; $42,120	135
Total		2,154		2,693		4,100 hrs; $295,182	

FERC–606, Notification of Request for Federal Authorization and Requests for Further Information; FERC–607, Report on Decision or Action on Request for Federal Authorization

OMB Control No.: 1902–0241.

Abstract: FERC–606 requires agencies and officials responsible for issuing, conditioning, or denying requests for federal authorizations necessary for a proposed natural gas project to report to the Commission regarding the status of an authorization request. This reporting requirement is intended to allow agencies to assist the Commission to make better informed decisions in establishing due dates for agencies' decisions.

FERC–607 requires agencies or officials to submit to the Commission a copy of a decision or action on a request for federal authorization and an accompanying index to the documents and materials relied on in reaching a conclusion.

The information collections can neither be discontinued nor collected less frequently because of statutory requirements. The consequences of not collecting this information are that the Commission would be unable to fulfill its statutory mandate under the Energy Policy Act of 2005 to:

- Establish a schedule for agencies to review requests for federal authorizations required for a project, and
- Compile a record of each agency's decision, together with the record of the Commission's decision, to serve as a consolidated record for the purpose of appeal or review, including judicial review.

Type of Respondent: Agencies with federal authorization responsibilities.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden and cost [8] (rounded) for the information collection as follows:

FERC–606—(Notification of Request for Federal Authorization and Requests for Further Information), and FERC–607 (Report on Decision or Action on Request for Federal Authorization)

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours and cost per response (4)	Total annual burden hours and total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
FERC–606	6	1	6	4 hrs; $288	24 hrs; $1,728	$288

[2] 16 U.S.C. 791, *et seq.*

[3] 42 U.S.C. 16, 451–63.

[4] The burden costs are based on an FERC's 2015 average annual wage (and benefits) figure for a full-time employee of $149,489 ($72/hour). The Commission staff believes that industry is similarly situated in terms of staff costs and skill sets.

[5] MW = megawatt.

[6] Not required to file.

[7] The ''Cost per Response'' for the Cogeneration and Small Power Production Facility ≤ 1MW (Self-Certification) respondent category was incorrectly presented as $3,600 in the 60-day notice for the FERC–556 information collection (Docket No. IC16–3; 80 FR 74101, 11/27/2015). The figure is corrected to $108 in this notice.

[8] The cost is based on FERC's average cost (salary plus benefits) of $72/hour for 2015. The Commission staff believes that the level and skill set (as a reporting agency official, *e.g.,* Environmental Program Manager or Reviewer) is comparable to FERC staff.

FERC–606—(NOTIFICATION OF REQUEST FOR FEDERAL AUTHORIZATION AND REQUESTS FOR FURTHER INFORMATION), AND FERC–607 (REPORT ON DECISION OR ACTION ON REQUEST FOR FEDERAL AUTHORIZATION)—Continued

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours and cost per response (4)	Total annual burden hours and total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
FERC–607	1	1	1	1 hr.; $72	1 hr.; $72	72
Total	7				25 hrs; $1,800	

Dated: March 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06776 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–13–002.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing: Compliance Filing in ER16–13—Revisions to Att AE re Annual ARR Allocation to be effective 1/28/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5085.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–628–001.

Applicants: Florida Power & Light Company.

Description: Tariff Amendment: Florida Power & Light Response to Deficiency Letter to be effective 5/21/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5150.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1234–000.

Applicants: New York State Electric & Gas Corporation.

Description: Tariff Cancellation: Cancellation of Services Agreement with FirstEnergy Service Company to be effective 3/19/2016.

Filed Date: 3/18/16.

Accession Number: 20160318–5154.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–1235–000.

Applicants: UNS Electric, Inc.

Description: Section 205(d) Rate Filing: Parker-Bagdad Interconnection Agreement to be effective 3/17/2016.

Filed Date: 3/18/16.

Accession Number: 20160318–5157.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–1236–000.

Applicants: Northern States Power Company, a Wisconsin corporation.

Description: Tariff Cancellation: 20160318_Cancellation to be effective 3/31/2016.

Filed Date: 3/18/16.

Accession Number: 20160318–5159.

Comments Due: 5 p.m. ET 4/8/16.

Docket Numbers: ER16–1237–000.

Applicants: Birdsboro Power LLC.

Description: Petition of Birdsboro Power LLC for Limited Waiver of PJM Open Access Transmission Tariff Competitive Entry Exemption Deadline and Request for Expedited Action.

Filed Date: 3/18/16.

Accession Number: 20160318–5175.

Comments Due: 5 p.m. ET 3/28/16.

Docket Numbers: ER16–1238–000.

Applicants: Avangrid Arizona Renewables, LLC.

Description: Section 205(d) Rate Filing: Avangrid Name change normal filing to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5068.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1239–000.

Applicants: Avangrid Renewables, LLC.

Description: Section 205(d) Rate Filing: Avangrid Renewables Name change normal to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5069.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1240–000.

Applicants: Alabama Electric Marketing, LLC.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5105.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1241–000.

Applicants: California Electric Marketing, LLC.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5106.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1242–000.

Applicants: Kiowa Power Partners, LLC.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5108.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1243–000.

Applicants: New Mexico Electric Marketing, LLC.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5110.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1244–000.

Applicants: Tenaska Frontier Partners, Ltd.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5112.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1245–000.

Applicants: Tenaska Gateway Partners, Ltd.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5113.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1246–000.

Applicants: Tenaska Power Management, LLC.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5115.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1247–000.

Applicants: Texas Electric Marketing, LLC.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5117.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1248–000.

Applicants: Tenaska Power Services Co.

Description: Section 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/22/2016.

Filed Date: 3/21/16.

Accession Number: 20160321–5171.

Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER16–1249–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Amendment to ISA No. 2631, Queue No. V2–019 to be effective 7/28/2010.

Filed Date: 3/21/16.

Accession Number: 20160321–5189.

Comments Due: 5 p.m. ET 4/11/16.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF16–546–000.

Applicants: UE–00212NJ.

Description: Form 556 of UE–00212NJ.

Filed Date: 3/16/16.

Accession Number: 20160316–5065.

Comments Due: None Applicable.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–06779 Filed 3–24–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9944–23–OLEM]

FY2016 Supplemental Funding for Brownfields Revolving Loan Fund (RLF) Grantees

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of the Availability of Funds.

SUMMARY: The Environmental Protection Agency (EPA) plans to make available approximately $8 million to provide supplemental funds to Revolving Loan Fund (RLF) capitalization grants previously awarded competitively under section 104(k)(3) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). Brownfields Cleanup Revolving Loan Fund pilots awarded under section 104(d)(1) of CERCLA that have not transitioned to section 104(k)(3) grants are not eligible to apply for these funds. EPA will consider awarding supplemental funding only to RLF grantees who have demonstrated an ability to deliver programmatic results by making at least one loan or subgrant. The award of these funds is based on the criteria described at CERCLA 104(k)(4)(A)(ii).

The Agency is now accepting requests for supplemental funding from RLF grantees. Requests for funding must be submitted to the appropriate EPA Regional Brownfields Coordinator (listed below) by April 25, 2016. Funding requests for hazardous substances and/or petroleum funding will be accepted. Specific information on submitting a request for RLF supplemental funding is described below and additional information may be obtained by contacting the EPA Regional Brownfields Coordinator.

DATES: This action is effective March 25, 2016.

ADDRESSES: A request for supplemental funding must be in the form of a letter addressed to the appropriate Regional Brownfields Coordinator (see listing below) with a copy to Debi Morey, *morey.debi@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Debi Morey, U.S. EPA, (202) 566–2735 or the appropriate Brownfields Regional Coordinator.

SUPPLEMENTARY INFORMATION:

Background

The Small Business Liability Relief and Brownfields Revitalization Act added section 104(k) to CERCLA to authorize federal financial assistance for brownfields revitalization, including grants for assessment, cleanup and job training. Section 104(k) includes a provision for EPA to, among other things, award grants to eligible entities to capitalize Revolving Loan Funds and to provide loans and subgrants for brownfields cleanup. Section 104(k)(4)(A)(ii) authorizes EPA to make additional grant funds available to RLF grantees for any year after the year for which the initial grant is made (noncompetitive RLF supplemental funding) taking into consideration:

(I) The number of sites and number of communities that are addressed by the revolving loan fund;

(II) the demand for funding by eligible entities that have not previously received a grant under this subsection;

(III) the demonstrated ability of the eligible entity to use the revolving loan fund to enhance remediation and provide funds on a continuing basis; and

(IV) such other similar factors as the [Agency] considers appropriate to carry out this subsection.

Eligibility

In order to be considered for supplemental funding, grantees must demonstrate that they have expended existing funds and that they have a clear plan for quickly expending requested additional funds. Grantees must demonstrate that they have made at least one loan or subgrant prior to applying for this supplemental funding and have significantly depleted existing available funds. For FY2016, EPA defines ''significantly depleted funds'' as any grant where $400,000 or less remains uncommitted. Additionally, the RLF recipient must have demonstrated a need for supplemental funding based on, among other factors, the number of sites that will be addressed; demonstrated the ability to make loans and subgrants for cleanups that can be started and completed expeditiously (*i.e.,* ''shovel-ready'' projects) and will lead to redevelopment; demonstrated the existence of additional leveraged funds to complete the project in a timely manner and move quickly from cleanup to redevelopment, including the use of tax incentives such as new market tax credits, direct funding or other resources to advance the project to completion; demonstrated the ability to administer and revolve the capitalization funding in the RLF grant; demonstrated an ability to use the RLF grant to address funding gaps for cleanup; and demonstrated that they have provided a community benefit from past and potential loan(s) and/or subgrant(s). Special consideration may

be given to those communities affected by plant closures or other economic disruptions; can demonstrate projects that have a clear prospect of aiding the in-sourcing of manufacturing capacity and keeping and/or adding jobs, or otherwise creating jobs, in the affected area; or will benefit a community that has been identified as part of EPA's Cross Agency Strategy on Working to Make a Visible Difference in Communities. EPA encourages innovative approaches to maximizing revolving and leveraging with other funds, including use of grants funds as a loan loss guarantee, combining with other government or private sector lending resources. Applicants for supplemental funding must contact the appropriate Regional Brownfields Coordinator below to obtain information on the format for supplemental funding applications for their region. When requesting supplemental funding, applicants must specify whether they are seeking funding for sites contaminated by hazardous substances or petroleum. Applicants may request both types of funding.

REGIONAL CONTACTS

Region	States	Address/phone Number/email
EPA Region 1: Frank Gardner, *Gardner.Frank@epa.gov*.	CT, ME, MA, NH, RI, VT.	5 Post Office Square, Boston, MA 02109–3912, Phone (617) 918–1278 Fax (617) 918–1291.
EPA Region 2: Lya Theodoratos, *Theodoratos.Lya@epa.gov*.	NJ, NY, PR, VI	290 Broadway, 18th Floor, New York, NY 10007, Phone (212) 637–3260 Fax (212) 637–3083.
EPA Region 3: Tom Stolle, *Stolle.Tom@epa.gov*.	DE, DC, MD, PA, VA, WV.	1650 Arch Street, Mail Code 3HS51, Philadelphia, Pennsylvania 19103, Phone (215) 814–3129 Fax (215) 814–5518.
EPA Region 4: David Egetter, *Egetter.David@epa.gov*.	AL, FL, GA, KY, MS, NC, SC, TN.	Atlanta Federal Center, 61 Forsyth Street, S.W., 10TH FL, Atlanta, GA 30303–8960, Phone (404) 562–8250 Fax (404) 562–8761.
EPA Region 5: Keary Cragan, *Cragan.Keary@epa.gov*.	IL, IN, MI, MN, OH, WI.	77 West Jackson Boulevard, Mail Code SE–4J, Chicago, Illinois 60604–3507, Phone (312) 353–5669 Fax (312) 886–7190.
EPA Region 6: Mary Kemp, *Kemp.Mary@epa.gov*.	AR, LA, NM, OK, TX.	1445 Ross Avenue, Suite 1200 (6SF–PB), Dallas, Texas 75202–2733, Phone (214) 665–8358 Fax (214) 665–6660.
EPA Region 7: Susan Klein, *Klein.Susan@epa.gov*.	IA, KS, MO, NE	11201 Renner Blvd, Lenexa, Kansas 66219, Phone (913) 551–7786 Fax (913) 551–8688.
EPA Region 8: Dan Heffernan, *Heffernan.Daniel@epa.gov*.	CO,MT, ND, SD, UT, WY.	1595 Wynkoop Street (EPR–B), Denver, CO 80202–1129, Phone (303) 312–7074 Fax (303) 312–6065.
EPA Region 9: Noemi Emeric-Ford, *Emeric-Ford.Noemi@epa.gov*.	AZ, CA, HI, NV, AS, GU.	75 Hawthorne Street, WST–8, San Francisco, CA 94105, Phone (213) 244–1821 Fax (415) 972–3364.
EPA Region 10: Susan Morales, *Morales.Susan@epa.gov*.	AK, ID, OR, WA	1200 Sixth Avenue, Suite 900, Mailstop: ECL–112 Seattle, WA 98101, Phone (206) 553–7299 Fax (206) 553–0124.

Dated: March 17, 2016.

David R. Lloyd,

Director, Office of Brownfields and Land Revitalization, Office of Land and Emergency Management.

[FR Doc. 2016–06854 Filed 3–24–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPA–2007–0042; FRL—9944–24–OLEM]

Proposed Information Collection Request; Comment Request; The National Oil and Hazardous Substance Pollution Contingency Plan Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''The National Oil and Hazardous Substance Pollution Contingency Plan Regulation, Subpart J (40 CFR 300.900)'' (EPA ICR No. 1664.11, OMB Control No. 2050–0141) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through October 31, 2016. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before May 24, 2016.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OPA–2007–0042 online using *www.regulations.gov* (our preferred method), by email to *Docket.rcra@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Leigh DeHaven, Office of Emergency Management, Regulations Implementation Division (5104A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–1974; fax number: email address: *DeHaven.Leigh@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the

burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This Information Collection Request (ICR) renewal supports activities to implement the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), Subpart J (40 CFR 300.900, ''Use of Dispersants and Other Chemicals'').

The use of bioremediation agents, dispersants, surface washing agents, surface collecting agents and miscellaneous oil spill control agents in response to oil spills in U.S. waters or adjoining shorelines is governed by Subpart J of the NCP regulation (40 CFR 300.900). Subpart J requirements include criteria for listing oil spill mitigating agents on the NCP Product Schedule, hereafter referred to as the Schedule. EPA's regulation, which is codified at 40 CFR 300.00, requires that EPA prepare a schedule of ''dispersants, other chemicals, and other spill mitigating devices and substances, if any, that may be used in carrying out the NCP.'' The Schedule is required by section 311(d)(2)(G) of the Clean Water Act (CWA), as amended by the Oil Pollution Act of 1990. The Schedule is used by Federal On-Scene Coordinators (FOSCs), Regional Response Teams (RRTs), and Area Planners to identify spill mitigating agents in preparation for and response to oil spills.

Under Subpart J, respondents who want to add a product to the Schedule must submit technical product data to the U.S. Environmental Protection Agency (EPA or Agency) as stipulated in 40 CFR 300.915. Specifically, Subpart J requires the manufacturer to conduct specific toxicity and effectiveness tests and submit the corresponding technical product data along with other detailed information to the EPA Office of Emergency Management, Office of Land and Emergency Management. For example, a dispersant must exceed the 50-percent (±5 percent) efficacy threshold in order to be listed on the Schedule. EPA places oil spill mitigating agents on the Schedule if all the required data are submitted and the product satisfies all requirements and meets or exceeds testing thresholds. The Product Schedule is available to FOSCs, RRTs, and Area Committees for determining the most appropriate products to use in various spill scenarios.

Products currently listed on the Schedule are divided into five basic categories: Dispersants, surface washing agents, surface collecting agents, bioremediation agents, and miscellaneous oil spill control agents. As of March 2016, 118 products are listed on the Schedule. It is estimated that 11 products per year will be submitted to EPA for listing on the Schedule. Over the three-year period covered by this ICR, an estimated 33 products may be listed. Additionally, EPA estimates that approximately 10 manufacturers will submit information to obtain sorbent certifications. The annual public reporting burden will be 315 hours. The total annual cost (including labor and non-labor) to manufacturers under Subpart J is estimated to be $89,590.

At 40 CFR 300.920(c), respondents are allowed to assert that certain information in the technical product data submissions is confidential business information. EPA will handle such claims pursuant to the provisions in 40 CFR part 2, subpart B. Such information must be submitted separately from non-confidential information, clearly identified, and clearly marked ''Confidential Business Information.'' If the applicant fails to make such a claim at the time of submittal, EPA may make the information available to the public without further notice.

Form Numbers: None.

Respondents/affected entities: Respondents include, but are not limited to, manufacturers of bioremediation agents, dispersants, surface collecting agents, surface washing agents, miscellaneous oil spill control agents, and other chemical agents and biological additives used as countermeasures against oil spills. Affected private industries can be expected to fall within the following industrial classifications:

- Manufacturers of industrial inorganic chemicals (SIC 281/NAICS 325188),
- Manufacturers of industrial organic chemicals (SIC 286/NAICS 325199), and
- Manufacturers of miscellaneous chemical products (SIC 289/NAICS 325988).

Respondent's obligation to respond: An oil spill mitigating agent does not have to be listed on the Product Schedule unless a manufacturer wants the product to be applied as part of an emergency response to an oil spill. If so, then certain mandatory product testing and information is required to be considered for listing on the Schedule. (The Schedule is required by section 311(d)(2)(G) of the Clean Water Act (CWA), as amended by the Oil Pollution Act of 1990).

Estimated number of respondents: Eleven per year. There are 100 manufacturers and 118 products (27 bioremediation agents, 19 dispersants, 15 miscellaneous oil spill control agents, and 55 surface washing agents, 2 surface collecting agents) currently listed on the January, 2016 Schedule. EPA estimates that manufacturers will apply to list 11 products on the Schedule each year, including 2 bioremediation agents, 3 dispersants, 2 miscellaneous oil spill control agents, 1 surface collecting agent, and 3 surface washing agents. Over a three-year period, EPA anticipates that manufacturers will apply to list a total of 6 bioremediation agents, 9 dispersants, 6 miscellaneous oil spill control agents, 3 surface collecting agent, and 9 surface washing agents on the Schedule.

Frequency of response: Each manufacturer responds one time per product submittal.

Total estimated burden: 315 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $72,450 (per year)

Changes in Estimates: There is a minor increase in burden hours and cost. All regulatory requirements are the same as in the 2010 and 2013 ICRs.

Dated: March 21, 2016.

Reggie Cheatham,

Director, Office of Emergency Management.

[FR Doc. 2016–06855 Filed 3–24–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9026–2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www2.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs)

Filed 03/14/2016 Through 03/18/2016,

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-nepa-public/action/eis/search*

EIS No. 20160063, Draft, BR, NM, Rio Grande Project, Continued Implementation of the 2008 Operating Agreement, Comment Period Ends: 05/09/2016, Contact: Rhea Graham 505–462–3560.

EIS No. 20160064, Draft, USACE, WA, Puyallup River Basin, Flood Risk Management General Investigation, Comment Period Ends: 05/09/2016, Contact: Scott Long 206–764–6697.

EIS No. 20160065, Final, WAPA, CA, San Luis Transmission Project, Review Period Ends: 04/25/2016, Contact: Donald Lash 916–353–4048.

Amended Notices

EIS No. 20160017, Draft, USFS, AK, Shoreline II Outfitter/Guide (formerly Shoreline II Outfitter and Guide Management Plan), Comment Period Ends: 04/25/2016, Contact: Carey Case 907–772–3871. Revision to FR Notice Published 01/29/2016, Extending Comment Period from 03/14/2016 to 04/25/2016.

EIS No. 20160021, Draft, USACE, NY, Mamaroneck and Sheldrake Rivers Flood Risk Management Village of Mamaroneck General Reevaluation, Comment Period Ends: 03/14/2016, Contact: Matthew Voisine 917–790–8718. Revision to FR Notice Published 01/29/2016, Extending Comment Period from 03/14/2016 to 03/30/2016.

EIS No. 20160037, Draft, USFS, WA, Colville National Forest Plan Revision, Comment Period Ends: 07/05/2016, Contact: Amy Dillon 509–684–7211. Revision to FR Notice Published 02/19/2016, Extending Comment Period from 05/19/2016 to 07/05/2016.

Dated: March 22, 2016.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–06817 Filed 3–24–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Privacy Act System of Records

AGENCY: Federal Communications Commission (FCC, Commission, or the Agency).

ACTION: Notice; one altered Privacy Act system of records; eight new routine uses.

SUMMARY: Pursuant to subsection (e)(4) of the *Privacy Act of 1974,* as amended (''Privacy Act''), 5 U.S.C. 552a, the FCC proposes to change the name and alter one system of records, FCC/OMD–7, ''FCC Transit Benefit and Parking Permit Programs'' (formerly FCC/OMD–7, ''FCC Employee Transit Benefit and Parking Permit Programs''). The FCC will alter the security classification; the system location; the categories of individuals; the categories of records; the authority for maintenance of the system; the purposes for which the information is maintained; five routine uses (1), (2), (4), (5), and (6) (and add eight new routine uses (8–15); the policies and practices for the storage, retrivability, accessibility, safeguards, and retention and disposal of the records in the system; the system manager(s) and address; the notification, record access, and contesting record procedures; the record source categories; and make other administrative edits and revisions as necessary to update the information and comply with the requirements of the Privacy Act of 1974, as amended (5 U.S.C. 552a), and the regulations and requirements of the Office of Management and Budget (OMB) and the National Archives and Records Administration (NARA).

DATES: In accordance with subsections (e)(4) and (e)(11) of the Privacy Act, any interested person may submit written comments concerning the alteration of this system of records on or before April 25, 2016. The Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB), which has oversight responsibility under the Privacy Act to review the system of records, and Congress may submit comments on or before May 4, 2016. The proposed new system of records will become effective on May 4, 2016 unless the FCC receives comments that require a contrary determination. The Commission will publish a document in the **Federal Register** notifying the public if any changes are necessary. As required by 5 U.S.C. 552a(r) of the Privacy Act, the FCC is submitting reports on this proposed altered system to OMB and Congress.

ADDRESSES: Address comments to Leslie F. Smith, Privacy Manager, Information Technology (IT), Room 1–C216, Federal Communications Commission (FCC), 445 12th Street SW., Washington, DC 20554, (202) 418–0217, or via the Internet at *Leslie.Smith@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: Contact Leslie F. Smith, Privacy Manager, Information Technology (IT), 1–C216, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554, (202) 418–0217 or via the Internet at *Leslie.Smith@fcc.gov*.

SUPPLEMENTARY INFORMATION: As required by the *Privacy Act of 1974,* as amended, 5 U.S.C. 552a(e)(4) and (e)(11), this document sets forth notice of the alteration of one system of records maintained by the FCC, the revision of six routine uses: (1), (2), (4), (5), and (6), and the addition of eight new routine uses ((8)–(15)). The FCC previously gave complete notice of the system of records (FCC/OMD–7, ''FCC Employee Transit Benefit and Parking Permit Programs'') covered under this Notice by publication in the **Federal Register** on April 5, 2006 (71 FR 17234, 17252). This notice is a summary of the more detailed information about the proposed altered system of records, which may be obtained or viewed pursuant to the contact and location information given above in the **ADDRESSES** section. The purposes for altering FCC/OMD–7, ''FCC Transit Benefit and Parking Permit Programs'' (formerly FCC/OMD–7, ''FCC Employee Transit Benefit and Parking Programs'') are to revise: The system name to reflect the expansion of the categories of individuals who are covered by this system; the security classification; the system location; the categories of individuals; the categories of records; the authority for maintenance of the system; the purposes for which the information is maintained; routine uses (1), (2), (4), (5), and (6), and add eight new routine uses ((8)–(15)); the policies and practices for the storage, retrievability, accessibility, safeguards, and retention and disposal of the records in the system; the system manager(s) and address; the notification, record access, and contesting record procedures; the record source categories; and make other administrative edits and revisions as necessary to update the information and comply with the requirements of the Privacy Act, as amended (5 U.S.C. 552a), and the regulations and requirements of OMD and NARA.

The FCC will achieve these purposes by altering this system of records with these changes:

Revision of language regarding the Security Classification, for clarity and to note that the FCC has in place a process to provide an appropriate security classification for this system, such that: The FCC's CIO team will provide a security classification to this system based on NIST FIPS–199 standards.

Revision of the language regarding the System Location, to note the changes to the system's address: Administrative Services Center (ASC), Office of the Managing Director (OMD), Federal Communications Commission (FCC), 445 12th Street SW., Washington, DC 20554. Information related to those employees who participate in the Smartrip portion of the benefits program is also stored in a database administered by the Washington Metropolitan Area Transit Authority (WMATA), headquartered at 600 Fifth Street NW., Washington, DC 20001.

Revision of the language regarding the Categories of Individuals Covered by the System, for clarity and to note the expansion of the categories of individuals covered by this system to include FCC employees and their spouses, paid interns/co-op students, FCC contractors, and non-FCC Federal employees, such that: The categories of individuals in this system include those individuals who voluntarily apply for and/or participate in one of the FCC Transit Benefit and Parking Permit Programs, which include, but are not limited to:

1. FCC employees who have applied for and received monthly transit fare subsidies;

2. FCC employees and contractors who hold monthly FCC garage parking permits;

3. FCC employees, employee spouses, paid interns and co-op students, contractors, and non-FCC Federal agency employees who are members of carpools and vanpools that park in the FCC parking garage;

4. FCC employees who have applied for and received handicap status for FCC garage parking assignments as a ''reasonable accommodation''; and

5. FCC employees who participate in ridesharing, including the Capital Bikeshare Program.

Revision of the language in the Categories of Records in the System, for clarity and to note the expansion in and various changes made to the categories of records covered by this system, including the list of FCC forms and the information requested in each form, as follows:

The FCC uses the records in this system to administer the Transit Benefit and Parking Permit Programs. These records include, but are not limited to, the information that is required to be submitted on the following forms and any related documentation that pertains to transit benefit subsidies, parking permits, ride-sharing, bike-sharing, and other, related transit and commuting programs available to FCC employees, contractors, and other individuals, which are sponsored and/or hosted by the FCC:

1. Form A–27, ''FCC Pre-Tax Parking Benefit Form,'' including, but not limited to: Employee Information: FCC employee's name; effective date; pay period; parking location; and monthly/daily fee; Benefit: Carpool/vanpool), metro parking, commercial lot, privately-owned lot, parking garage, or parking meter; and requested amount; whether the application is new, a cancellation, or a change; and effective date; and Certification: Employee signature; date; and attachments;

2. Form A–30, ''FCC Parking Application,'' including, but not limited to: Applicant's name, FCC bureau/office/division; address (required for carpool); FCC badge number; FCC telephone number; FCC employee/contractor/paid intern/co-op student; vehicle year, make, model, state, and license plate; handicap perm (yes/no); FCC title (executives only); transit benefit participant (yes/no); van pool/car pool riders (FCC and Non-FCC employees): Name, address, bureau/office or agency, telephone number, FCC ID number, and signature; applicant's signature and date; and attachments, *e.g.,* handicap certification, etc.;

3. Form A–75, ''FCC Headquarters Employee Transit Benefit Application,'' including, but not limited to:

A. Applicant Information: Applicant's name, home address, bureau/office, office room number, telephone number, FCC badge number, and WMATA Smartrip Card serial number;

B. Employment Status: Full time, part time, paid intern/co-op student; and bargaining/non-bargaining unit status;

C. Mode(s) of Transportation (costs): Metro (rail only) and station name; metro (rail and bus) and station name; Metro (bus only); one-way transit user; commuter bus; commuter rail; and/or vanpool;

D. Telework: Approved telework agreement (yes/no); and telework days (Monday–Friday);

E. Employee certification: Employee signature and date; and

F. Transit benefit office action: Approved (yes and amount/no), disapproved (reason), signature and data; and attachments;

4. Form A–75–A, ''FCC Employee Transit Benefit Change Request Form,'' including, but not limited to:

A. Applicant Information: Applicant's name, home address, bureau/office, office room number, office telephone number, and FCC badge number;

B. Employment Status: Full time, part time, paid intern, or co-op student;

C. Change(s) Requested:

1. Mode(s) of transportation: Metro rail, metro bus, commuter rail, commuter bus, one-way transit user, vanpool, other, and transit provider name;

2. Monthly commuting cost: Old and new;

3. Badge number: Old and new;

4. Address change: Home address;

5. Name change: From/to; and

6. Smartrip Card serial number: Old and new; and

D. Employee Certification: Signature; date; and attachments.

Revision to the Authority for Maintenance of the System, to add several rule sections and delete several rule sections so that the statutory authorities more closely align with the system's current requirements, such that the authorities now include, as follows:

5 U.S.C. 301; 5 U.S.C. 5701–5733; 5 U.S.C. 7905; 26 U.S.C. 132(f); 40 U.S.C. 101 and 121; 44 U.S.C. 2104; 41 CFR 101–20.104–2, 102–74.205–210 (Ridesharing), and 102–74.265–310 (Parking Facilities); Executive Order 9397, as amended by Executive Order 13478; Executive Order 13150; Pub. L. 103–172; and the *Federal Property and Administrative Services Act of 1949,* as amended.

Revision of the language regarding the Purposes for which the information in this system is maintained, for clarity, and to expand the system's purposes, to include cross-checking information and matching activity to eliminate fraud and a security check on participants to safeguard against possible criminal or terrorist activity, as follows:

The FCC will use information in this system, including the PII, to administer the Transit Benefit and Parking Permit Programs. This information enables the FCC to facilitate the timely processing of requests for parking permits, transit benefit subsidies, ride-sharing and bike-sharing programs and similar commuting arrangements, and other, related program, policies, and activities, which include, but are not limited to:

1. Managing the FCC's transit benefits program that provides transportation subsidies for public transit, including but not limited to WMATA Metro train and bus fares; Commuter rail services—Maryland Area Rail Commuters (MARC) and Virginia Railway Express (VRE) fares; Commuter bus services—DASH fares, etc.; One-way transit users; Vanpool fares; and other parking and

transit subsidies to Federal employees as allowed under 5 U.S.C. 7905, 5 U.S.C. 301, and Executive Order 13150 employee's request to participate in the transit subsidy or FCC garage parking program;

2. Managing the FCC's employee parking, executive parking, handicapped parking, and ridesharing programs (vanpools/carpools) for FCC employees, contractors, and non-FCC agency employees;

3. Conducting audits, reviews, oversight, and/or investigations of the transit benefits, parking, ridesharing programs (vanpools and carpools) to ensure their accuracy and integrity of the Transit Benefits and Parking Program, which includes but is not limited to cross-checking the Commission's data on parking assignees and transit benefit recipients to ensure that they are not participating in both programs, unless authorized; and, when appropriate, matching this information with the lists of other Federal agencies to ensure that the Commission's participants are not registered for a drive-alone, carpool, or other parking assignments with any other Federal agency, and to identify and locate former employees;

4. Administering, qualifying, and/or certifying the beneficiaries of the Transit Benefits and Parking Program, which includes but is not limited to ensure the eligibility of transit subsidy participants and to prevent misuse of the funds involved;

5. Preparing and administering listings and reports for use by the FCC and the other Federal, state, and local agencies charged with management and oversight of and/or contribution to the Transit Benefits and Parking Program subsidies, etc.; and

6. Ensuring that those non-FCC individuals who are participating in the ride-sharing and bike-sharing programs do not pose a security threat to FCC Headquarter garage facilities.

Revision of the language in Routine Use (1) ''Financial Obligations as required by the National Finance Center *et al.''* to add ''pre-tax benefit(s)'' as another category of information concerning a record from this system that may be disclosed:

When the National Finance Center (the FCC's designated payroll office), the Department of the Treasury Debt Management Services, and/or a current employer to effect a salary, IRS tax refund, pre-tax benefit(s), or administrative offset to satisfy an indebtedness; and to Federal agencies to identify and locate former employees for the purposes of collecting such indebtedness, including through administrative, salary, or tax refund offsets. Identifying and locating former employees, and the subsequent referral to such agencies for offset purposes, may be accomplished through authorized computer matching programs. Disclosures will be made only when all procedural steps established by the Debt Collection Act of 1982 and the Debt Collection Improvement Act of 1996 or the Computer Matching and Privacy Protection Act of 1988, as appropriate, have been taken;

Revision of the language in Routine Use (2) ''Program Partner'' to expand the categories of transit information to include other applicable public transportations (in addition to WMATA), to note that these benefits are for FCC employees, and that the benefits relate to public transportation fare (*e.g.,* Smartrip program) as these relate to records from this system that may be disclosed:

To WMATA and other applicable public transportations in connection with FCC employees participating in this public transportation fare, *e.g.,* Smartrip program at: *http://www.wmata.com/riding/smartrip.cfm;*

Routine Use (3) ''Adjudication and Litigation'' is unchanged.

Revision of the language in Routine Use (4) ''Law Enforcement and Investigation'' to expand the categories to include government agencies and officials, the purposes that include but are not limited to sharing records in this system, and the reasons for disclosure, and to note that records may be referred for investigation, enforcement, or prosecution by the Commission (or another agency), regarding why a record from this system that may be disclosed:

Where there is a real or suspected indication of a violation or potential violation of a statute, regulation, rule, or order, records from this system may be shared with appropriate Federal, State, and/or local agencies, authorities, and officials for purposes that include but are not limited to obtaining additional information relevant to a FCC decision, referring the record for investigation, enforcement, or prosecution by the Commission or another agency;

Revision of the language in Routine Use (5) ''Congressional Investigations and Inquiries'' to change the title of the routine use and expand the categories of information to include investigations and inquiries, regarding a record from this system that may be disclosed:

To Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, for the purposes of an official Congressional investigation, including but not limited to, a request by a Congressional office in response to an inquiry made by an individual to the Congressional office for the individual's own records;

Revision of the language in Routine Use (6) ''Government-wide Program Management and Oversight'' to expand the number of Federal agencies and categories of information concerning a record from this system that may be disclosed, as follows:

To the General Services Administration (GSA), the National Archives and Records Administration (NARA), the Office of Personnel Management (OPM), and/or the Government Accountability Office (GAO) for the purpose of records management studies conducted under authority of 44 U.S.C. 2904 and 2906; to the Department of Justice (DOJ) in order to obtain that department's advice regarding disclosure obligations under the Freedom of Information Act (FOIA); or to the Office of Management and Budget (OMB) in order to obtain that office's advice regarding obligations under the Privacy Act. Such a disclosure shall not be used to make a determination about individuals;

Routine Use (7) ''Labor Relations'' is unchanged.

Addition of Routine Use (8) ''Breach Notification,'' as follows:

A record from this system may be disclosed to appropriate agencies, entities, and persons when: (1) The Commission suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the Commission has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Commission or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;

Addition of Routine Use (9) ''Vanpool, Carpool, and Ridesharing,'' as follows:

Vanpool, Carpool, and Ridesharing—Vanpool, carpool, and rideshare information, *i.e.,* names and residential information (home address and personal home and cell phone number(s)) of FCC and non-FCC Federal employees and FCC contractors in the ridesharing database, who wish to participate in in a vanpool, carpool, and/or other ridesharing arrangements for daily

commuting to the FCC Headquarters. This information is provided to the ridesharing coordinator for the purposes of scheduling ride-sharing arrangements;

Addition of Routine Use (10) ''Statistical Reports on Commuting,'' as follows:

Statistical Reports on Commuting—To Federal, state, local, and related organizations, Metropolitan Washington Council of Governments, that are studying local traffic commuting patterns (*i.e.,* compiling commuting statistics and reports) by those who use metrorail (WMATA), commuter bus, commuter rail (*e.g.,* VRS and MARC), vanpools, carpools, and/or ridesharing in their commute to and from work;

Addition of Routine Use (11) ''Department of Justice (DOJ),'' as follows:

To DOJ or in a proceeding before a court or adjudicative body when:

(a) The United States, the Commission, a component of the Commission, or, when represented by the government, an employee of the Commission is a party to litigation or anticipated litigation or has an interest in such litigation, and

(b) The Commission determines that the disclosure is relevant or necessary to the litigation;

Addition of Routine Use (12) ''Medical Certification,'' as follows:

To a physician who is making a determination on a person's eligibility for a handicapped parking permit.

Addition of Routine Use (13) ''Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by the Agency,'' as follows:

To a Federal, State, local, foreign, tribal, or other public agency or authority maintaining civil, criminal, or other relevant enforcement records, or other pertinent records, or to another public authority or professional organization, if necessary to obtain information relevant to an investigation concerning the retention of an employee or other personnel action, the retention of a security clearance, the letting of a contract, or the issuance or retention of a grant or other benefit;

Addition of Routine Use (11) ''Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by Other than the Agency,'' as follows:

To a Federal, State, local, foreign, tribal, or other public agency or authority of the fact that this system of records contains information relevant to the retention of an employee, the retention of a security clearance, the letting of a contract, or the issuance or retention of a license, grant, or other benefit. The other agency or licensing organization may then make a request supported by the written consent of the individual for the entire records if it so chooses. No disclosure will be made unless the information has been determined to be sufficiently reliable to support a referral to another office within the agency or to another Federal agency for criminal, civil, administrative, personnel, or regulatory action; and

Addition of Routine Use (15) ''Parking Garage Contractors,'' as follows:

To the owners, managers, and staff who manage the garage parking for their use in assigning or checking the parking permits, checking credentials, assigning spaces, assisting with accidents, or other parking issues to ensure that the parking program functions properly and that parking privileges are not abused.

In each of these cases, the FCC will determine whether disclosure of the records is compatible with the purpose(s) for which the records were collected.

Revision of the language in the policies and practices regarding Storage of the information in this system, for clarity, to specify that the information in this system includes both paper and electronic records, to describe the Administrative Services Center's (ASC) current storage procedures, and to note that:

Paper records, files, and documents, which pertain to the information concerning the transit benefits and parking program that are maintained at the FCC, are stored in file folders in the ASC office suite.

The electronic records, files, and data are housed in the FCC's computer network databases, which are reserved for the transit benefit and parking permit program, and in the WMATA database that is associated with the Smartrip program.

Revision of the language in the policies and practices regarding the Retrievability of the information in this system, for clarity, and to specify that both paper and electronic records are retrievable, as follows:

Both the paper documents and electronic records and data are retrieved by the employer's name, or by the FCC Badge identification number, tag, and/or parking permit number.

Revision of the language in the policies and practices regarding the Safeguards for protecting the information in this system, for clarity, and to comply with the FCC's current safety and security protocols and procedures, including information noting that these FCC standards adhere to the requirements of the National Institutes of Standards and Technology (NIST) and the Federal Information Security Management Act (FISMA), as follows:

The safeguards for the information pertaining to the transit benefit and parking permit programs, which is maintained by the FCC, are as follows:

1. The paper documents, files, and records are kept in a locked cash box contained in a (cylinder lock) drawer. At the close of the business day, the cash box is secured in a government issued safe with a combination lock. Only authorized ASC supervisors, staff, and contractors may have access to these file cabinets. The ASC office suite is protected by a card-coded main door to limit access to the suite.

2. The electronic records, files, and data that are stored in the FCC computer network databases are secured by limited access card readers. Access to the electronic files is restricted to authorized ASC supervisors, staff, and contractors, and to the Information Technology (IT) staff and contractors, who maintain the FCC's computer network. Other FCC employees and contractors may be granted access only on a ''need-to-know'' basis. The FCC's computer network databases are protected by the FCC's security protocols, which include controlled access, passwords, and other IT security features and requirements as required under the IT guidelines issued by the National Institutes of Standards and Technology (NIST) and the Federal Information Security Management Act (FISMA) regulations. A *PRIVACY ACT WARNING NOTICE* appears on the monitor screen when records containing information on individuals are first displayed. Information resident on the Transit Benefits and Parking Program database servers is backed-up routinely onto magnetic media. Back-up tapes are stored at secured locations.

3. Safeguards in place adhere to Federal standards, including the NIST, FISMA, and FCC standards.

Revision of the language in the policies and practices regarding the Retention and Disposal of the information in this system, for clarity, and to specify that they comply with the current NARA requirements for both paper and electronic records, as follows:

Records under the control of the FCC are retained for three years in accordance with the General Records Schedule 6 (GRS 6) established by NARA at *http://www.archives.gov/records-mgmt/ardor/grs06.html.* Paper records are then shredded. Electronic records are destroyed physically (electronic storage media) or by electronic erasure.

Revision of the language regarding the System Manager(s) and Address, for clarity, and to note the current address of the system managers where they may be contacted, as follows:

Administrative Services Center (ASC), Office of the Managing Director (OMD), Federal Communications Commission (FCC), 445 12th Street SW., Washington, DC 20554.

Revision of the language regarding the Notification, Record Access, and Contesting Procedures concerning information in this system, for clarity, and to comply with the Commission's current policies and practices for notifying individuals under the requirements of the Privacy Act, 5 U.S.C. 552a(d), as follows:

Notification Procedures: Privacy Manager, Federal Communications Commission (FCC), 445 12th Street SW., Room 1–A804, Washington, DC 20554; (202) 418–0217 or *Leslie.Smith@fcc.gov.*

Record Access Procedures: Privacy Manager, Federal Communications Commission (FCC), 445 12th Street SW., Room 1–A804, Washington, DC 20554; (202) 418–0217 or *Leslie.Smith@fcc.gov.*

Contesting Records Procedures: Privacy Manager, Federal Communications Commission (FCC), 445 12th Street SW., Room 1–A804, Washington, DC 20554; (202) 418–0217 or *Leslie.Smith@fcc.gov.*

Revision of the language in the Record Source Categories, for clarity, and to expand the sources of and details concerning the information in this system, as follows:

Information in the system is obtained from:

1. One or more FCC Forms, including, but not limited to FCC Forms A–27, A–30, A–75, and/or A–75–A, which are submitted by individuals who apply to participate in the FCC Transit Benefit and Parking Permit Programs, including but not limited to metrorail, bus, commuter rail, vanpools, carpools, and/or ridesharing arrangements.

2. WMATA and other agencies concerning individuals (including both FCC and non-FCC individuals) who have applied for and/or participate in the FCC's transit benefits program and/or the carpool/vanpool programs; and

3. Ride-Share Bike Program information.

This notice meets the requirement documenting the changes to the system of records that the FCC maintains, and provides the public, OMB, and Congress an opportunity to comment.

FCC/OMD–7

SYSTEM NAME:

FCC Transit Benefit and Parking Permit Programs.

SECURITY CLASSIFICATION:

The FCC's CIO team will provide a security classification to this system based on NIST FIPS–199 standards.

SYSTEM LOCATION:

Administrative Services Center (ASC), Office of the Managing Director (OMD), Federal Communications Commission (FCC), 445 12th Street SW., Washington, DC 20554.

Information related to those employees who participate in the Smartrip portion of the benefits program is also stored in a database administered by the Washington Metropolitan Area Transit Authority WMATA, headquartered at 600 Fifth Street NW., Washington, DC 20001.

CATEGORIES OF INDIVIDUALS COVERED BY THIS SYSTEM:

The categories of individuals in this system include those individuals who voluntarily apply for and/or participate in one of the FCC Transit Benefit and Parking Permit Programs, which include, but are not limited to:

1. FCC employees who have applied for and received monthly transit fare subsidies;

2. FCC employees and contractors who hold monthly FCC garage parking permits;

3. FCC employees, employee spouses, paid interns and co-op students, contractors, and non-FCC Federal agency employees who are members of carpools and vanpools that park in the FCC parking garage;

4. FCC employees who have applied for and received handicap status for FCC garage parking assignments as a ''reasonable accommodation'';[1] and

5. FCC employees who participate in ridesharing, including the Capital Bikeshare Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

The FCC uses the records in this system to administer the Transit Benefit and Parking Permit Programs. These records include, but are not limited to, the information that is required to be submitted on the following forms and any related documentation that pertains to transit benefit subsidies, parking permits, ride-sharing, bike-sharing, and other, related transit and commuting programs available to FCC employees, contractors, and other individuals, which are sponsored and/or hosted by the FCC:

1. Form A–27, ''FCC Pre-Tax Parking Benefit Form,'' including, but not limited to:

Employee Information: FCC employee's name; effective date; pay period; parking location; and monthly/daily fee; Benefit: carpool/vanpool), metro parking, commercial lot, privately-owned lot, parking garage, or parking meter; and requested amount; whether the application is new, a cancellation, or a change; and effective date; and Certification: employee signature; date; and attachments;

2. Form A–30, ''FCC Parking Application,'' including, but not limited to: Applicant's name, FCC bureau/office/division; address (required for carpool); FCC badge number; FCC telephone number; FCC employee/contractor/paid intern; vehicle year, make, model, state, and license plate; handicap perm (yes/no); FCC title (executives only); transit benefit participant (yes/no); van pool/car pool riders (FCC and Non-FCC employees): name, address, bureau/office or agency, telephone number, FCC ID number, and signature; applicant's signature and date; and attachments, *e.g.,* handicap certification, etc.;

3. Form A–75, ''FCC Headquarters Employee Transit Benefit Application,'' including, but not limited to:

A. Applicant Information: applicant's name, home address, bureau/office, office room number, telephone number, FCC badge number, and WMATA Smartrip Card serial number;

B. Employment Status: full time, part time, paid intern/co-op student; and bargaining/non-bargaining unit status;

C. Mode(s) of Transportation (costs): metro (rail only) and station name; metro (rail and bus) and station name; metro (bus only); one-way transit user; commuter bus; commuter rail; and/or vanpool;

D. Telework: approved telework agreement (yes/no); and telework days (Monday–Friday);

E. Employee certification: employee signature and date; and

F. Transit benefit office action: approved (yes and amount/no), disapproved (reason), signature and data; and attachments;

4. Form A–75–A, ''FCC Employee Transit Benefit Change Request Form,'' including, but not limited to:

A. Applicant Information: applicant's name, home address, bureau/office, office room number, office telephone number, and FCC badge number;

B. Employment Status: full time, part time, paid intern, or co-op student;

C. Change(s) Requested:

1. Mode(s) of transportation: metro rail, metro bus, commuter rail,

[1] FCC/OWD–1, ''Reasonable Accommodation Requests under the Rehabilitation Act of 1973,'' may also cover individuals who request a special parking arrangement as a ''reasonable accommodation.''

commuter bus, one-way transit user, vanpool, other, and transit provider name;

2. Monthly commuting cost: old and new;

3. Badge number: old and new;

4. Address change: home address;

5. Name change: from/to; and

6. Smartrip Card serial number: old and new; and

D. Employee Certification: signature; date; and attachments.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 5 U.S.C. 5701–5733; 5 U.S.C. 7905; 26 U.S.C. 132(f); 40 U.S.C. 101 and 121; 44 U.S.C. 2104 41 CFR 101–20.104–2, 102–74.205–210 (Ridesharing), and 102–74.265–310 (Parking Facilities); Executive Order 9397, as amended by Executive Order 13478; Executive Order 13150; Pub. L. 103–172; and the *Federal Property and Administrative Services Act of 1949,* as amended.

PURPOSE(S):

The FCC will use information in this system, including the PII, to administer the Transit Benefit and Parking Permit Programs. This information enables the FCC to facilitate the timely processing of requests for parking permits, transit benefit subsidies, ride-sharing and bike-sharing programs and similar commuting arrangements, and other, related program, policies, and activities, which include, but are not limited to:

1. Managing the FCC's transit benefits program that provides transportation subsidies for public transit, including but not limited to, WMATA Metro train and bus fares; Commuter rail services—Maryland Area Rail Commuters MARC and Virginia Railway Express VRE fares; Commuter bus services—DASH fares, etc.; One-way transit users; Vanpool fares; and other parking and transit subsidies to Federal employees as allowed under 5 U.S.C. 7905, 5 U.S.C. 301, and Executive Order 13150 employee's request to participate in the transit subsidy or FCC garage parking program;

2. Managing the FCC's employee parking, executive parking, handicapped parking, and ridesharing programs (vanpools/carpools) for FCC employees, contractors, and non-FCC agency employees;

3. Conducting audits, reviews, oversight, and/or investigations of the transit benefits, parking, ridesharing programs (vanpools and carpools) to ensure their accuracy and integrity of the Transit Benefits and Parking Program, which includes but is not limited to cross-checking the Commission's data on parking assignees and transit benefit recipients to ensure that they are not participating in both programs, unless authorized; and, when appropriate, matching this information with the lists of other Federal agencies to ensure that the Commission's participants are not registered for a drive-alone, carpool, or other parking assignments with any other Federal agency, and to identify and locate former employees;

4. Administering, qualifying, and/or certifying the beneficiaries of the Transit Benefits and Parking Program, which includes but is not limited to ensure the eligibility of transit subsidy participants and to prevent misuse of the funds involved;

5. Preparing and administering listings and reports for use by the FCC and the other Federal, state, and local agencies charged with management and oversight of and/or contribution to the Transit Benefits and Parking Program subsidies, etc.; and

6. Ensuring that those non-FCC individuals who are participating in the ride-sharing and bike-sharing programs do not pose a security threat to FCC Headquarter garage facilities

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information about individuals in this system of records may routinely be disclosed under the following conditions:

1. Financial Obligations as required by the National Finance Center *et al.*—When the National Finance Center (the FCC's designated payroll office), the Department of the Treasury Debt Management Services, and/or a current employer to effect a salary, IRS tax refund, pre-tax benefit(s), or administrative offset to satisfy an indebtedness; and to Federal agencies to identify and locate former employees for the purposes of collecting such indebtedness, including through administrative, salary, or tax refund offsets. Identifying and locating former employees, and the subsequent referral to such agencies for offset purposes, may be accomplished through authorized computer matching programs. Disclosures will be made only when all procedural steps established by the Debt Collection Act of 1982 and the Debt Collection Improvement Act of 1996 or the Computer Matching and Privacy Protection Act of 1988, as appropriate, have been taken;

2. Program Partner—To WMATA and other applicable public transportations in connection with FCC employees participating in this public transportation fare, *e.g.,* Smartrip program at: *http://www.wmata.com/riding/smartrip.cfm;*

3. Adjudication and Litigation—Where by careful review, the agency determines that the records are both relevant and necessary to litigation and the use of such records is deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records, these records may be used by a court or adjudicative body in a proceeding when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States Government is a party to litigation or has an interest in such litigation;

4. Law Enforcement and Investigation—Where there is a real or suspected indication of a violation or potential violation of a statute, regulation, rule, or order, records from this system may be shared with appropriate Federal, State, and/or local agencies, authorities, and officials for purposes that include but are not limited to obtaining additional information relevant to a FCC decision, referring the record for investigation, enforcement, or prosecution by the Commission or another agency;

5. Congressional Investigations and Inquiries—To Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, for the purposes of an official Congressional investigation, including but not limited to, a request by a Congressional office in response to an inquiry made by an individual to the Congressional office for the individual's own records;

6. Government-wide Program Management and Oversight—To the General Services Administration (GSA), the National Archives and Records Administration (NARA), the Office of Personnel Management (OPM), and/or the Government Accountability Office (GAO) for the purpose of records management studies conducted under authority of 44 U.S.C. 2904 and 2906; to the Department of Justice (DOJ) in order to obtain that department's advice regarding disclosure obligations under the Freedom of Information Act (FOIA); or to the Office of Management and Budget (OMB) in order to obtain that office's advice regarding obligations under the Privacy Act. Such a disclosure shall not be used to make a determination about individuals;

7. Labor Relations—To officials of labor organizations recognized under 5 U.S.C. Chapter 71 upon receipt of a formal request and in accord with the

conditions of 5 U.S.C. 7114 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions;

8. Breach Notification–To appropriate agencies, entities, and persons when: (1) The Commission suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the Commission has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Commission or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;

9. Vanpool, Carpool, and Ridesharing—Vanpool, carpool, and rideshare information, *i.e.,* names and residential information (home address and personal home and cell phone number(s)) of FCC and non-FCC Federal employees and FCC contractors in the ridesharing database, who wish to participate in in a vanpool, carpool, and/or other ridesharing arrangements for daily commuting to the FCC Headquarters. This information is provided to the ridesharing coordinator for the purposes of scheduling ride-sharing arrangements;

10. Statistical Reports on Commuting—To Federal, state, local, and related organizations, Metropolitan Washington Council of Governments, that are studying local traffic commuting patterns (*i.e.,* compiling commuting statistics and reports) by those who use metrorail (WMATA), commuter bus, commuter rail (*e.g.,* VRS and MARC), vanpools, carpools, and/or ridesharing in their commute to and from work;

11. Department of Justice (DOJ)—To DOJ or in a proceeding before a court or adjudicative body when:

(a) The United States, the Commission, a component of the Commission, or, when represented by the government, an employee of the Commission is a party to litigation or anticipated litigation or has an interest in such litigation, and

(b) The Commission determines that the disclosure is relevant or necessary to the litigation; and

12. Medical Certification—To a physician who is making a determination on a person's eligibility for a handicapped parking permit;

13. Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by the Agency—To a Federal, State, local, foreign, tribal, or other public agency or authority maintaining civil, criminal, or other relevant enforcement records, or other pertinent records, or to another public authority or professional organization, if necessary to obtain information relevant to an investigation concerning the retention of an employee or other personnel action, the retention of a security clearance, the letting of a contract, or the issuance or retention of a grant or other benefit;

14. Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by Other than the Agency—To a Federal, State, local, foreign, tribal, or other public agency or authority of the fact that this system of records contains information relevant to the retention of an employee, the retention of a security clearance, the letting of a contract, or the issuance or retention of a license, grant, or other benefit. The other agency or licensing organization may then make a request supported by the written consent of the individual for the entire records if it so chooses. No disclosure will be made unless the information has been determined to be sufficiently reliable to support a referral to another office within the agency or to another Federal agency for criminal, civil, administrative, personnel, or regulatory action; and

15. Parking Garage Contractors—To the owners, managers, and staff who manage the garage parking for their use in assigning or checking the parking permits, checking credentials, assigning spaces, assisting with accidents, or other parking issues to ensure that the parking program functions properly and that parking privileges are not abused.

In each of these cases, the FCC will determine whether disclosure of the records is compatible with the purpose(s) for which the records were collected.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records, files, and documents, which pertain to the information concerning the transit benefits and parking program that are maintained at the FCC, are stored in file folders in the ASC office suite.

The electronic records, files, and data are housed in the FCC's computer network databases, which are reserved for the transit benefit and parking permit program, and in the WMATA database that is associated with the Smartrip program.

RETRIEVABILITY:

Both the paper documents and the electronic records and data are retrieved by the employee's name, or by the FCC Badge identification number, tag, and/or permit number.

SAFEGUARDS:

The safeguards for the information pertaining to the transit benefit and parking permit program, which is maintained by the FCC, are as follows:

1. The paper documents, files, and records are kept in a locked cash box contained in a (cylinder lock) drawer. At the close of the business day, the cash box is secured in a government issued safe with a combination lock. Only authorized ASC supervisors, staff, and contractors may have access to these file cabinets. The ASC office suite is protected by a card-coded main door to limit access to the suite.

2. The electronic records, files, and data that are stored in the FCC computer network databases are secured by limited access card readers. Access to the electronic files is restricted to authorized ASC supervisors, staff, and contractors, and to the Information Technology (IT) staff and contractors, who maintain the FCC's computer network. Other FCC employees and contractors may be granted access only on a ''need-to-know'' basis. The FCC's computer network databases are protected by the FCC's security protocols, which include controlled access, passwords, and other IT security features and requirements as required under the IT guidelines issued by the National Institutes of Standards and Technology (NIST) and the Federal Information Security Management Act (FISMA) regulations. A *PRIVACY ACT WARNING NOTICE* appears on the monitor screen when records containing information on individuals are first displayed. Information resident on the Transit Benefits and Parking Program database servers is backed-up routinely onto magnetic media. Back-up tapes are stored at secured locations.

3. Safeguards in place adhere to Federal standards, including the NIST, FISMA, and FCC standards.

RETENTION AND DISPOSAL:

Records under the control of the FCC are retained for three years in accordance with the General Records Schedule 6 (GRS 6) established by NARA at *http://www.archives.gov/records-mgmt/ardor/grs06.html.* Paper records are then shredded. Electronic records are destroyed physically (electronic storage media) or by electronic erasure.

SYSTEM MANAGER(S) AND ADDRESS:

Administrative Services Center (ASC), Office of the Managing Director (OMD), Federal Communications Commission (FCC), 445 12th Street SW., Washington, DC 20554.

NOTIFICATION PROCEDURE:

Privacy Manager, Federal Communications Commission (FCC), 445 12th Street SW., Room 1–A804, Washington, DC 20554.

RECORD ACCESS PROCEDURES:

Privacy Manager, Federal Communications Commission (FCC), 445 12th Street SW., Room 1–A804, Washington, DC 20554.

CONTESTING RECORD PROCEDURES:

Privacy Manager, Federal Communications Commission (FCC), 445 12th Street SW., Room 1–A804, Washington, DC 20554.

RECORD SOURCE CATEGORIES:

Information in the system is obtained from:

1. One or more FCC Forms, including but not limited to FCC Forms A–27, A–30, A–75, and/or A–75–A, which are submitted by individuals who apply to participate in the FCC Transit Benefit and Parking Permit Programs, including but not limited to metrorail, bus, commuter rail, vanpools, carpools, and/or ridesharing arrangements.

2. WMATA and other agencies concerning individuals (including both FCC and non-FCC individuals) who have applied for and/or participate in the FCC's transit benefits program and/or the carpool/vanpool programs; and

3. Ride-Share Bike Program information.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–06815 Filed 3–24–16; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–CSE–2016–02; Docket No. 2016–0002; Sequence No. 7]

Notice of the General Services Administration's Labor-Management Relations Council Meeting

AGENCY: Office of Human Resources Management (OHRM), General Services Administration (GSA).

ACTION: Notice of meeting.

SUMMARY: The General Services Administration's Labor-Management Relations Council (GLMRC), a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App., and Executive Order 13522, plans to hold a one and one-half day meeting that is open to the public.

DATES: The meeting will be held on Tuesday, April 12, 2016 from 9:30 a.m. to 4:30 p.m. and reconvene Wednesday, April 13, 2016 from 9:30 a.m. to 12:00 noon, Eastern Standard Time.

ADDRESSES: The meeting will be held in Room 1459, in the Conference Center located on the first floor of the General Services Administration's Headquarters Building located at 1800 F Street NW., Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Ms. Paula D. Lucak, GLMRC Designated Federal Officer (DFO), OHRM, General Services Administration, at telephone 202–739–1730, or email at *gmlrc@gsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The GLMRC is a forum for managers and the exclusive national labor Union representatives of the U.S. General Services Administration (GSA) employees. In this forum, managers and the Unions discuss Government operations to promote satisfactory labor relations and improve the productivity and effectiveness of GSA. The GLMRC serves as a complement to the existing collective bargaining process and allows managers and the Unions to collaborate in continuing to deliver the highest quality services to the public. The Council discusses workplace challenges and problems and recommends solutions that foster a more productive and cost-effective service to the taxpayer, through improving job satisfaction and employees' working conditions.

Agenda

The purpose of the meeting is for the GLMRC to build its collaborative labor-management relationship, discuss the Council's activities and direction ahead for the year, and to consider Agency initiatives. The topics to be discussed include Council metrics & GSA EVS results, employee engagement activities, and human resource initiative updates.

Meeting Access

This site is accessible to individuals with disabilities. In order to gain entry into the Federal building where the meeting is being held, public attendees who are Federal employees should bring their Federal employee identification cards. Members of the general public should bring their driver's license or another form of government-issued identification.

Availability of Materials for the Meeting

Please see the GLRMC Web site: *http://www.gsa.gov/portal/content/225831* for any materials available in advance of the meeting and for meeting minutes that will be made available after the meeting. Detailed meeting minutes will be posted within 90 days of the meeting.

Procedures for Providing Public Comments

The public is invited to submit written comments for the meeting until 5:00 p.m. Eastern Time on the Monday prior to the meeting on April 11, 2016, by either of the following methods: *Electronic or Paper Statements:* Submit electronic statements to Ms. Paula Lucak, Designated Federal Officer, at *paula.lucak@gsa.gov;* or send paper statements in triplicate to Ms. Lucak at 1800 F Street NW., Suite 7003A, Washington, DC 20405. In general, public comments will be posted on the GLMRC Web site. All comments, including attachments and other supporting materials received, are part of the public record and subject to public disclosure.

Any comments submitted in connection with the GLMRC meeting will be made available to the public under the provisions of the Federal Advisory Committee Act.

Dated: March 21, 2016.

Wade Hannum,

Office of Human Resources Management, OHRM Director, Office of HR Strategy and Services, Center for Talent Engagement (COE4), General Services Administration.

[FR Doc. 2016–06802 Filed 3–24–16; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10316]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are require; to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *May 24, 2016.*

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10316 Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* This data collection complements the satisfaction data collected through the Medicare Consumer Assessment of Healthcare Providers and Systems survey by providing dissatisfaction data in the form of reasons for disenrollment from a Prescription Drug Plan. The data collected in this survey can be used to improve the operation of Medicare Advantage (MA) (both MA and MA–PD) contracts and standalone prescription drug plans (PDPs) through the identification of beneficiary disenrollment reasons. Plans can use the information to guide quality improvement efforts. The data can also be used by beneficiaries who need to choose among the different MA and PDP options. To the extent that these data identify areas for improvement at the contract level they can be used for contract oversight. *Form Number:* CMS–10316 (OMB control number: 0938–1113); *Frequency:* Yearly; *Affected Public:* Individuals or households; *Number of Respondents:* 56,972; *Total Annual Responses:* 56,972; *Total Annual Hours:* 15,032. (For policy questions regarding this collection contact Beth Simon at 415–744–3780.)

Dated: March 22, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–06829 Filed 3–24–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–855O, CMS–10438, CMS–10439 and CMS–10440]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to

enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *April 25, 2016.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806, or Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Medicare Registration Application; *Use:* The primary function of the CMS–855O is to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications to be enrolled in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services and/or prescribing Medicare Part D drugs for Medicare beneficiaries. The application allows a physician or other eligible professional to enroll in Medicare without being approved for billing privileges. The required information is submitted when the applicant requests enrollment in Medicare for the sole purpose of ordering and certifying certain Medicare items and services or for prescribing Medicare Part D drugs. The application is used by Medicare contractors to collect data to help ensure that the applicant has the necessary credentials to order and certify certain Medicare items and services or to prescribe Medicare Part D drugs. This includes ensuring that the physician is not excluded debarred from the Medicare program. *Form Number:* CMS–855O (OMB control number: 0938–1135); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits), State, Local, or Tribal Governments; *Number of Respondents:* 448,000; *Number of Responses:* 24,000; *Total Annual Hours:* 243,600. (For questions regarding this collection contact Kimberly McPhillips (410) 786–8438.)

2. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations and Enrollment for Employers in the Small Business Health Options Program; *Use:* Section 1311(b)(1)(B) of the Affordable Care Act directs that the SHOP assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Section 1311(c)(1)(F) of the Affordable Care Act directs HHS to establish criteria for certification of health plans as QHPs and plans to utilize a uniform enrollment form for qualified employers. Further, section 1311(c)(5)(B) directs HHS to develop a Web site that assists employers in determining if they are eligible to participate in SHOP.

This proposed information collection was previously published in the **Federal Register** on December 11, 2015 (80 FR 76994) and allowed 60 days for public comment. No comments were received. *Form Number:* CMS–10439 (OMB control number 0938–1194); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 6,000; *Number of Responses:* 6,000; *Total Annual Hours:* 12,000. (For questions regarding this collection contact Christelle Jang at (410) 786–8438.)

3. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations and Enrollment for Employers in the Small Business Health Options Program; *Use:* Section 1311(b)(1)(B) of the Affordable Care Act directs that the SHOP assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Section 1311(c)(1)(F) of the Affordable Care Act directs HHS to establish criteria for certification of health plans as QHPs and plans to utilize a uniform enrollment form for qualified employers. Further, section 1311(c)(5)(B) directs HHS to develop a Web site that assists employers in determining if they are eligible to participate in SHOP.

This proposed information collection was previously published in the **Federal Register** on December 11, 2015 (80 FR 76994) and allowed 60 days for public comment. No comments were received. *Form Number:* CMS–10439 (OMB control number 0938–1194); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 6,000; *Number of Responses:* 6,000; *Total Annual Hours:* 12,000. (For questions regarding this collection contact Christelle Jang at (410) 786–8438.)

4. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and Children's Health Insurance Program Agencies; *Use:* Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each State a single, streamlined form that may be used to apply for coverage through the Exchange and Insurance Affordability Programs, including Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program, as applicable. The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who qualify for the programs. A State may develop and use its own single streamlined application if

approved by the Secretary in accordance with section 1413 and if it meets the standards established by the Secretary.

Section 155.405(a) of the Exchange Final Rule (77 FR 18310) provides more detail about the application that must be used by the Exchange to determine eligibility and to collect information necessary for enrollment. The regulations in § 435.907 and § 457.330 establish the requirements for State Medicaid and CHIP agencies related to the use of the single streamlined application. CMS is designing the single streamlined application to be a dynamic electronic application that will tailor the amount of data required from an applicant based on the applicant's circumstances and responses to particular questions. The paper version of the application will not be able to be tailored in the same way but is being designed to collect only the data required to determine eligibility. Individuals will be able to submit an application electronically, through the mail, over the phone through a call center, or in person, per § 155.405(c)(2) of the Exchange Final Rule, as well as through other commonly available electronic means as noted in § 435.907(a) and § 457.330 of the Medicaid Final Rule. The application may be submitted to an Exchange, Medicaid or CHIP agency. The electronic application process will vary depending on each applicant's circumstances, their experience with health insurance applications and online capabilities. The goal is to solicit sufficient information so that in most cases no further inquiry will be needed. *Form Number:* CMS–10440 (OMB control number: 0938–1191); *Frequency:* Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 7,200,000; *Total Annual Responses:* 7,200,000; *Total Annual Hours:* 2,410,767. (For policy questions regarding this collection contact Beth Liu at 301–492–4135.)

Dated: March 22, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–06830 Filed 3–24–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0785]

General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drugs Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' This draft guidance recommends studies, including comparative in vitro studies, which should be conducted to demonstrate that a proposed generic solid oral opioid drug product is no less abuse-deterrent than its reference listed drug.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 24, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–0785 for ''General Principles for Evaluating the Abuse-Deterrence of Generic Solid Oral Opioid Drugs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gail Schmerfeld, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9291, email: *gail.schmerfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' Prescription opioid analgesics are an important component of modern pain management. However, abuse and misuse of these drug products have created a serious and growing public health problem. One important step toward the goal of creating safer opioid analgesics has been the development of opioid drug products that are formulated to deter abuse. FDA considers the development of these products a high public health priority. It is important that generic versions of opioids that reference listed drugs whose labeling describes abuse-deterrent properties are available to help ensure availability of analgesics for patients who need them.

For FDA to approve an abbreviated new drug application (ANDA), the Agency must find, among other things, that the generic drug product has the same active ingredient(s), dosage form, route of administration, strength, and, with limited exceptions, labeling as the reference listed drug (RLD); is bioequivalent to its RLD; that the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are adequate to assure and preserve its identity, strength, quality, and purity; and that the inactive ingredients and composition of the generic drug are not unsafe for use under the conditions prescribed, recommended, or suggested in the labeling (see, *e.g.,* the Federal Food, Drug, and Cosmetic Act (the FD&C Act) 505(j)(2)(A) and (j)(4) (21 U.S.C. 355(j)(2)(A) and (j)(4))). FDA classifies as ''therapeutically equivalent'' those products that meet the following general criteria: (1) They are approved as safe and effective; (2) they are pharmaceutical equivalents in that they: (a) Contain identical amounts of the same active ingredient in the same dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent; (4) they are adequately labeled; and (5) they are manufactured in compliance with current good manufacturing practices regulations. (See preface of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the Orange Book).) FDA believes that a product classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the reference product.

Accordingly, if the RLD's labeling describes abuse-deterrent properties, the ANDA applicant should evaluate its product to show that it is no less abuse-deterrent than the RLD with respect to all potential routes of abuse. Marketing a generic opioid drug product that is less abuse-deterrent than the RLD could lead opioid abusers to preferentially seek out and abuse generics.

This draft guidance describes FDA's current thinking about the studies that should be conducted by a potential ANDA applicant and submitted to FDA in an ANDA to demonstrate that a generic solid oral opioid drug product is no less abuse-deterrent than its RLD with respect to all potential routes of abuse.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the principles for evaluating the abuse-deterrence of generic solid oral opioid drug products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA intends to hold a public meeting following the close of the comment period to discuss further the evaluation of the abuse deterrence of generic opioid drug products and related issues, as appropriate. Further details will follow in a notice of public meeting published in the **Federal Register**.

II. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06766 Filed 3–24–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Fitness, Sports, and Nutrition

AGENCY: President's Council on Fitness, Sports, and Nutrition, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the President's Council on Fitness, Sports, and Nutrition (PCFSN) will hold its annual meeting. The meeting will be open to the public.

DATES: The meeting will be held on May 16, 2016, from 9:00 a.m. to 12:00 p.m.

ADDRESSES: Hubert H. Humphrey Building, 200 Independence Avenue SW., Great Hall, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Shellie Pfohl, Executive Director, Office of the President's Council on Fitness, Sports, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276–9567. Information about PCFSN, including details about the upcoming meeting, can be obtained at *www.fitness.gov.*

SUPPLEMENTARY INFORMATION: The primary functions of the PCFSN include (1) advising the President, through the Secretary, concerning progress made in carrying out the provisions of Executive Order 13545 and recommending to the President, through the Secretary, actions to accelerate progress; (2) advising the Secretary on ways to promote regular physical activity, fitness, sports

participation, and good nutrition. Recommendations may address, but are not necessarily limited to, public awareness campaigns; federal, state, and local physical activity; fitness, sports participation, and nutrition initiatives; and partnership opportunities between public- and private-sector health promotion entities; (3) functioning as a liaison to relevant state, local, and private entities in order to advise the Secretary regarding opportunities to extend and improve physical activity, fitness, sports, and nutrition programs and services at the local, state, and national levels; and (4) monitoring the need to enhance programs and educational and promotional materials sponsored, overseen, or disseminated by the Council, and shall advise the Secretary, as necessary, concerning such need. In performing its functions, the Council shall take into account the Federal Dietary Guidelines for Americans and the Physical Activity Guidelines for Americans.

The PCFSN will hold, at a minimum, one meeting per fiscal year. The meeting will be held to (1) assess ongoing Council activities; and, (2) discuss and plan future projects and programs. The agenda for the planned meeting is being developed and will be posted at *www.fitness.gov* when it has been finalized.

The meeting that is scheduled to be held on May 16, 2016, is open to the public. Every effort will be made to provide reasonable accommodations for persons with disabilities and/or special needs who wish to attend the meeting. Persons with disabilities and/or special needs should call (240) 276–9567 no later than close of business on May 2, 2016, to request accommodations. Members of the public who wish to attend the meeting are asked to pre-register by sending an email to *rsvp.fitness@hhs.gov* or by calling (240) 276–9567. Registration for public attendance must be completed before close of business on May 9, 2016.

Dated: March 11, 2016.

Tasha Bradley,

Director of Communications, Office of the President's Council on Fitness, Sports, and Nutrition, U.S. Department of Health and Human Services.

[FR Doc. 2016–06810 Filed 3–24–16; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting conducted as a telephone conference call. This call will be open to the public. Preregistration is required for both public participation and comment. Any individual who wishes to participate in the call should email *OMH-ACMH@hhs.gov* by April 12, 2016. Instructions regarding participating in the call and how to provide verbal public comments will be given at the time of preregistration.

Information about the meeting is available from the designated contact and will be posted on the Web site for the Office of Minority Health (OMH), *www.minorityhealth.hhs.gov.* Information about ACMH activities can be found on the OMH Web site under the heading *About OMH.*

DATES: The conference call will be held on April 14, 2016, 11:00 a.m.–1:00 p.m. ET

ADDRESSES: Instructions regarding participating in the call will be given at the time of preregistration.

FOR FURTHER INFORMATION CONTACT: Dr. Minh Wendt, Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240–453–8222; fax: 240–453–8223; email *OMH-ACMH@hhs.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the OMH.

Topics to be discussed during this conference call include planning for upcoming in-person meetings and finalizing the charge and the formation of the data workgroup.

This call will be limited to 125 participants. The OMH will make every effort to accommodate persons with special needs. Individuals who have special needs for which special accommodations may be required should contact Professional and Scientific Associates at (703) 234–1700 and reference this meeting. Requests for special accommodations should be made at least ten (10) business days prior to the meeting.

Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per speaker during the time allotted. Individuals who would like to submit written statements should email, mail, or fax their comments to the designated contact at least seven (7) business days prior to the meeting.

Any members of the public who wish to have electronic or printed material distributed to ACMH members should email *OMH-ACMH@hhs.gov* or mail their materials to the Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, prior to close of business on April 8, 2016.

Dated: March 2, 2016.

Minh Wendt,

Designated Federal Officer, Office of Minority Health, U.S. Department of Health and Human Services.

[FR Doc. 2016–06809 Filed 3–24–16; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Battelle Laboratories-King Avenue in Columbus, Ohio, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384*l*(14)(C).

On February 18, 2016, as provided for under 42 U.S.C. 7384l(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employees who worked at the facility owned by the Battelle Laboratories at the King Avenue site in Columbus, Ohio, during the period from July 1, 1956, through December 31, 1970, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation became effective on March 19, 2016. Therefore, beginning on March 19, 2016, members of this class of employees, defined as reported in this notice, became members of the SEC.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2016–06797 Filed 3–24–16; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Aging.

Date: May 10–11, 2016.

Closed: May 10, 2016, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Open: May 11, 2016, 8:00 a.m. to 12:15 p.m.

Agenda: Call to order and report from the Director; discussion of future meeting dates; consideration of minutes of last meeting; reports from Task Force on Minority Aging Research, Working Group on Program; Program Highlights.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Robin Barr, Ph.D., Director, National Institute on Aging, Office of Extramural Activities, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20814, (301) 496–9322, *barrr@nia.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nih.gov/nia/naca/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 21, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06763 Filed 3–24–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Menopause and Alzheimer's Disease II.

Date: April 20, 2016.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C218, Bethesda, MD 20892, 301–496–9374, *grimaldim2@mail.nih.gov*.

Name of Committee: National Institute on Aging Special Emphasis Panel; Mitochondria, Antioxidants and Aging II.

Date: April 21, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov*.

Name of Committee: National Institute on Aging Special Emphasis Panel; Principle of Stem Cell Maturation II.

Date: May 9, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Ave., Bethesda, MD 20892.

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov*.

Name of Committee: National Institute on Aging Special Emphasis Panel; Proteostasis of Elderly.

Date: May 16, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 21, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06761 Filed 3–24–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: Request for Human Embryonic Stem Cell Line To Be Approved for Use in NIH Funded Research (OD)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Ellen Gadbois, Office of Science Policy, Office of the Director, NIH, Building 1, Room 218, MSC 0166, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 496–9838 or Email your request, including your address to: *gadboisel@od.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Request for Human Embryonic Stem Cell Line to be approved for Use in NIH Funded Research. OMB No. 0925–0601—Expiration Date 5/31/2016—Extension-Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: The form is used by applicants to request that human embryonic stem cell lines be approved for use in NIH funded research. Applicants may submit applications at any time.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,550.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
NIH grantees and others with hESC lines	50	3	17	2,550
Total	50	150	.....	2,550

Dated: March 18, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–06812 Filed 3–24–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Loan Repayment 2016.

Date: May 5, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 21, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06762 Filed 3–24–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of

proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 2017 National Survey on Drug Use and Health

(OMB No. 0930–0110)—Revision

The National Survey on Drug Use and Health (NSDUH) is a survey of the U.S. civilian, non-institutionalized population aged 12 years old or older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, the Office of National Drug Control Policy (ONDCP), Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

While NSDUH must be updated periodically to reflect changing substance use and mental health issues and to continue producing current data, for the 2017 NSDUH only the following minor changes are planned: (1) Updated questions so respondents who report no use of alcohol are not asked about misuse of prescription drugs with alcohol; and (2) included other minor wording changes to improve the flow of the interview, increase respondent comprehension or to be consistent with text in other questions.

As with all NSDUH/NHSDA [1] surveys conducted since 1999, the sample size of the survey for 2017 will be sufficient to permit prevalence estimates for each of the fifty States and the District of Columbia. The total annual burden estimate is shown below in Table 1.

TABLE 1—ANNUALIZED ESTIMATED BURDEN FOR 2017 NSDUH

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Household Screening	131,983	1	131,983	0.083	10,955
Interview	67,507	1	67,507	1.000	67,507
Screening Verification	3,755	1	3,755	0.067	252
Interview Verification	10,126	1	10,126	0.067	678
Total	131,983		213,371		79,932

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 15E57B, 5600 Fishers Lane, Rockville, MD 20857 *OR* email a copy at *summer.king@samhsa.hhs.gov.*

Written comments should be received by May 24, 2016.

Summer King,

Statistician.

[FR Doc. 2016–06736 Filed 3–24–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0142]

Towing Safety Advisory Committee

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Towing Safety Advisory Committee and its subcommittees will meet to discuss matters relating to shallow-draft inland and coastal waterway navigation and towing safety. The meetings will be open to the public.

DATES: Subcommittees are scheduled to meet on April 13, 2016, from 8 a.m. to 5:30 p.m., and the full Committee is scheduled to meet on April 14, 2016, from 8 a.m. to 5:30 p.m. Please note that these meetings may adjourn early if the Committee has completed its business.

ADDRESSES: The meetings will be held at the OMNI Riverfront Hotel, 701 Convention Center Boulevard, New Orleans, LA 70130. The telephone number for the hotel is 504–524–8200 and the Web site is: *http://www.omnihotels.com/hotels/new-orleans-riverfront.*

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the Alternate Designated Federal Officer as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Committee as listed in the ''Agenda'' section below. Written comments for distribution to Committee members must be submitted no later than April 2, 2016, if you want the Committee members to be able to review your comments before the meeting, and must be identified by Docket No. USCG–2016–0142. Written comments may be submitted using the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the Alternate Designated Federal Officer for alternate instructions.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. All comments will be posted without alteration at *http://www.regulations.gov* including any personal information provided. You may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Docket: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov,* type USCG–2016–0142 in the Search box, press Enter, and then click on the item you wish to view.

[1] Prior to 2002, the NSDUH was referred to as the National Household Survey on Drug Abuse (NHSDA).

FOR FURTHER INFORMATION CONTACT: Mr. William J. Abernathy, Alternate Designated Federal Officer of the Towing Safety Advisory Committee; Commandant (CG–OES–2), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Stop 7509, Washington, DC 20593–7509; telephone 202–372–1363, fax 202–372–8382; or email *William.J.Abernathy@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* Title 5 U.S.C. Appendix. This Committee is established in accordance with, and operates under the provisions of the *Federal Advisory Committee Act.* As stated in 33 U.S.C. 1231a, the Towing Safety Advisory Committee provides advice and recommendations to the Secretary of the Department of Homeland Security on matters relating to shallow-draft inland and coastal waterway navigation and towing safety.

Agenda

Day 1

The subcommittees will meet on April 13, 2016, from 8 a.m. to 5:30 p.m., to work on their specific task assignments:

(1) Recommendations regarding Automation Equipment, Testing, Assessment, and Trial Periods on Towing Vessels.

(2) Recommendations for the Maintenance, Repair, and Utilization of Towing Equipment, Lines, and Couplings.

(3) Recommendations concerning the MODU KULLUK Report of Investigation.

(4) Recommendations regarding Articulated Tug/Barge Manning and Operations.

(5) Recommendations for Electronic Charting Systems.

Day 2

On April 14, 2016, from 8 a.m. to 5:30 p.m., the Towing Safety Advisory Committee will meet and receive reports concerning the following:

(1) Recommendations regarding Automation Equipment, Testing, Assessment, and Trial Periods on Towing Vessels, progress report,

(2) Recommendations for the Maintenance, Repair and Utilization of Towing Equipment, Lines and Couplings, final report,

(3) Recommendations concerning the MODU KULLUK Report of Investigation, final report,

(4) Recommendations regarding Articulated Tug/Barge Manning and Operations, progress report, and,

(5) Recommendations for Electronic Charting Systems, progress report.

In addition, the Committee will hear a presentation from the U.S. Coast Guard, District 8.

There will be a comment period for Towing Safety Advisory Committee members and a comment period for the public after each report presentation, but before each is voted on by the Committee. The Committee will review the information presented on each issue, deliberate on any recommendations presented in the Subcommittees' reports, and formulate recommendations for the Secretary's consideration.

A copy of all meeting documentation will be available at: *https://homeport.uscg.mil/tsac* no later than April 2, 2016. Alternatively, you may contact Mr. William Abernathy as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

An opportunity for oral comments by the public will be provided during the meeting on April 14, 2016. Speakers are requested to limit their comments to 3 minutes. Please note the public oral comment period may end before 5:30 p.m. if the Committee has finished its business earlier than scheduled. Please contact Mr. William J. Abernathy, listed above in the **FOR FURTHER INFORMATION CONTACT** section to register as a speaker.

Minutes

Minutes from the meeting will be available for public review and copying within 90 days following the close of the meeting and can be accessed from the Coast Guard Homeport Web site *http://homeport.uscg.mil/tsac.*

Notice of Future 2016 Towing Safety Advisory Committee Meetings

To receive automatic email notices of any future Towing Safety Advisory Committee meetings in 2016, go to the online docket, USCG–2016–0142 (*http://www.regulations.gov/#!docketDetail;D=USCG-2016-0142*), and select the sign-up-for-email-alerts option. We plan to use the same docket number for all Towing Safety Advisory Committee meeting notices in 2016, so if another 2016 meeting notice is published you will receive an email alert from *www.regulations.gov* when the notice appears in this docket.

Dated: March 22, 2016.

F.J. Sturm,

Acting Director of Commercial Regulations and Standards, United States Coast Guard.

[FR Doc. 2016–06822 Filed 3–24–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0031]

Chemical Transportation Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Chemical Transportation Advisory Committee. The Chemical Transportation Advisory Committee provides advice and makes recommendations reflecting its independent judgment to the Commandant of the United States Coast Guard on matters concerning the safe and secure marine transportation of hazardous materials, including industry outreach approaches.

DATES: Completed applications should reach the Coast Guard on or before May 24, 2016.

ADDRESSES: Applicants should send a cover letter expressing interest in an appointment to the Chemical Transportation Advisory Committee that identifies which membership category the applicant is applying under, along with a resume detailing the applicant's experience via one of the following methods:

- *By Email*: *Patrick.a.Keffler@uscg.mil.*
- *By Mail*: Mr. Patrick Keffler, Alternate Designated Federal Official of the Chemical Transportation Advisory Committee, Commandant, Hazardous Materials Division (CG–ENG–5), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Stop 7509, Washington, DC 20593–7509.

FOR FURTHER INFORMATION CONTACT: Mr. Patrick Keffler, Alternate Designated Federal Official of the Chemical Transportation Advisory Committee; telephone (202) 372–1424, email *Patrick.a.Keffler@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Chemical Transportation Advisory Committee is established under the authority of Section 871 of the Homeland Security Act of 2002, 6 U.S.C. 451. The Chemical Transportation Advisory Committee is an advisory committee established in accordance with and operating under the provisions of the Federal Advisory Committee Act (Title 5 U.S.C. Appendix).

The Committee provides advice and makes recommendations reflecting its independent judgment to the

Commandant of the United States Coast Guard on matters concerning the safe and secure marine transportation of hazardous materials, including industry outreach approaches.

The Chemical Transportation Advisory Committee meets at least twice per year, typically every six months. It may also meet for extraordinary purposes. Its subcommittees may meet to consider specific tasks as required.

The Coast Guard will consider applications for seven positions that will be vacant on September 17, 2016.

The membership categories are: Marine Handling and Transportation, Marine Environmental Protection, Safety and Security, Vessel Design and Construction, and Chemical Manufacturing.

To be eligible, applicants should have experience in chemical manufacturing, marine handling or transportation of chemicals, vessel design and construction, marine safety or security, or marine environmental protection. Each member serves for a term of three years. Committee members are limited to serving no more than two consecutive three-year terms. A member appointed to fill an unexpired term may serve the remainder of that term. All members serve at their own expense and receive no salary, reimbursement of travel expenses, or other compensation from the Federal Government.

Registered lobbyists are not eligible to serve on federal advisory committees in an individual capacity. See ''Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards and Commissions'' (79 FR 47482, August 13, 2014). Registered lobbyists are lobbyists required to comply with provisions contained in 2 U.S.C. 1605.

The Department of Homeland Security does not discriminate in selection of Committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disabilities and genetic information, age, membership in an employee organization, or any other non-merit factor. The Department of Homeland Security strives to achieve a widely diverse candidate pool for all of its recruitment actions.

If you are interested in applying to become a member of the Committee, send your cover letter and resume to Mr. Patrick Keffler, Alternate Designated Federal Officer of the Chemical Transportation Advisory Committee, via one of the transmittal methods in the **ADDRESSES** section by the deadline in the **DATES** section of this notice.

All email submittals will receive email receipt confirmation.

Dated: March 21, 2016.

F.J. Sturm,

Acting Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2016–06749 Filed 3–24–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5907–N–13]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: COAST GUARD: Commandant, United States Coast Guard, Attn: Jennifer Stomber, 2703 Martin Luther King Jr. Avenue SE., Stop 7741, Washington, DC 20593–7714; (202) 475–5609; NASA: Mr. Frank T. Bellinger, Facilities Engineering Division, National Aeronautics & Space Administration, Code JX, Washington, DC 20546, (202) 358–1124; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).

Dated: March 17, 2016.

Tonya Proctor,

Deputy Director, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 03/25/2016

Unsuitable Properties

Building

Hawaii

Building 473
Marine Corps Base
Kaneohe Bay HI 96863
Landholding Agency: Navy
Property Number: 77201610031
Status: Excess
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Massachusetts

Generator Shed
5025 CG Air Station Cape Cod
Sandwich MA 02563
Landholding Agency: Coast Guard
Property Number: 88201610001
Status: Excess
Comments: Documented deficiencies: significant holes in the exterior of the building; unsound foundation; clear threat to physical safety.
Reasons: Extensive deterioration

Ohio

0132 Noise Reduction Test
Facility—Glenn Research Center
21000 Brook Park Rd.
Brook Park OH 44135
Landholding Agency: NASA
Property Number: 71201610005
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

0127 Detonation Test
Facility—Glenn Research Center
21000 Brook Park Rd.
Brook Park OH 44135
Landholding Agency: NASA
Property Number: 71201610006
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

0068 PSL Secondary Cooler (1)
Glenn Research Center
21000 Brook Park Rd.
Brook Park OH 44135
Landholding Agency: NASA
Property Number: 71201610007
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Tennessee

2 Buildings
3001 Harbor Ave.
Memphis TN 38113
Landholding Agency: Navy
Property Number: 77201610032
Status: Excess
Directions: Naval Support Activity Mid-South, Naval Surface Warfare Center, Carderock Division (NSWCCD) Large Cavitation Channel; Bldgs. 02 and 08; approx. 44 acres of land.
Comments: Documented deficiencies: tree has fallen onto roof which has compromised the integrity of the structures; clear threat to physical safety.
Reasons: Extensive deterioration

[FR Doc. 2016–06489 Filed 3–24–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5910–N–03]

60-Day Notice of Proposed Information Collection: Surveys of Community Development Marketplace Project Inventory and Recipients and Providers of HUD Technical Assistance and Training

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* May 24, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Evan Gross, Office of the Deputy Assistant Secretary for Economic Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Evan Gross at *CDM@hud.gov* or telephone 202–402–4889. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Mr. Gross.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Survey of Community Development Marketplace Project Inventory and Survey of Recipients and Providers of Direct and Remote Technical Assistance and Training.

OMB Approval Number: 2506-new.

Type of Request: New collection of information.

Form Number: Pending Assignment.

Description of the need for the information and proposed use: This Notice covers three types of information HUD is proposing to collect in order to improve the effectiveness of technical assistance programs and operations:

a. Survey of Community Development Marketplace Project Inventory

The Community Development Marketplace Project Inventory survey (''CDM Survey'') will serve as a vehicle to target cohort learning using remote tools and technical assistance products, as well as provide information in a useful, sortable way to foundations and investors who are seeking community development investment opportunities and researching trends. An example of how the CDM Survey information could

be presented to interested stakeholders and the public can be viewed via *https://www.hudexchange.info/resource/4479/promise-zones-community-development-marketplace,* and questions can be addressed to *cdm@hud.gov.*

If HUD decides to proceed with the CDM survey after public comment, HUD may embed the survey in max.gov, or the HUD Exchange Web site, or another online platform. HUD may also continue to ask for user feedback through online suggestions and surveys on HUD Exchange or similar Web sites that HUD may use in the future.

b. Survey of Recipients and Providers of HUD Technical Assistance

HUD proposes to survey the recipients and providers of technical assistance, including city and state grantees of HUD funds, public housing authorities, tribes, owners and operators of multifamily housing, Continuums of Care and other non-profit recipients of HUD funding. Technical assistance is provided by third-party organizations awarded funding through cooperative agreements or contracts with HUD. The survey responses will allow HUD and its providers to improve the way it delivers technical assistance HUD proposes to survey one representative from the recipient TA organization and one representative from each TA provider organization for either all or the majority of the TA engagements in a year. The number of engagements varies based on demand for TA and available funding to provide it, but based on past years' trends, HUD expects to survey approximately 200 representatives each from recipient organizations and TA providers, for a total of 400 respondents annually.

The survey will ask respondents to rate quality of the TA they received, their progress toward intended goals, and provide other feedback about the TA engagement including any challenges faced. At least annually, HUD will analyze the survey data to identify program strengths and opportunities for program improvements. HUD may follow up on surveys to secure additional qualitative information through interviews and focus groups.

c. Survey of HUD Training Participants

HUD proposes to survey training participants in order to assess satisfaction with the course content and delivery. Participants include city and state HUD grantees, public housing authorities, tribes, owners and operators of multifamily housing, Continuums of Care (CoCs), and other non-profit recipients of HUD funding. Training is provided by third-party organizations awarded funding through cooperative agreements or contracts with HUD. The survey responses will allow HUD and its providers to improve the content and delivery of its training. All training participants will be offered the opportunity to provide feedback via a brief survey following the training. HUD estimates, based on past years' data, that about 7,000 training participants will be offered the opportunity to complete a feedback survey annually. The survey will ask respondents to rate their satisfaction with the training, including the relevance of the content to their job responsibilities, perceived knowledge gained, and quality of training delivery, and will provide space for comments regarding the training and suggestions to improve future training. At least annually, HUD will analyze the survey data to identify program strengths and opportunities for program improvements.

HUD may follow up on all of the surveys listed above to secure additional qualitative information through interviews and focus groups. HUD may also survey users of online tools and products to assess the usefulness and quality of these offerings.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
CDM project intake survey and follow up feedback	332	4	1328	2.25	2988	$40	$119,520
Survey of Recipients and Providers of HUD Technical Assistance	400	[1]1.1	440	.33	145.2	$15 (rcpnts) $38 (prvdrs) = average of $26.50	3,847.80
Survey of HUD Training Participants	7,000	[2]1.3	9,100	.25	2275	15	34,125
Total	7732	6.4	10868	2.83	5408.20	<40	157,492.80

[1] HUD anticipates that a small percentage of TA recipients will complete a follow-up survey on progress toward intended outcomes, and therefore be asked to complete two surveys.

[2] HUD anticipates that a small percentage of trainees will complete multiple trainings, and therefore be asked to complete more than one survey.

A. Paperwork Burden

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

B. CDM Survey

For potential users, including foundations, investors, researchers, other stakeholders:

(5) What kind of potential user are you? HUD has heard from foundations, investors, communities, researchers and national intermediaries and stakeholder networks, but there may be others who can use this data.

(6) Does the Project Intake Survey template capture information that would be useful to you? If yes, how is this information useful to you? If the information captured by the CDM Survey is not useful to you, how could

we adjust this survey to better suit your information needs?

(7) Please review the list of policy codes, financing types, funding source types, asset classes, and types of project sponsors that respondents are asked to select to categorize their project details. Would these options assist you in filtering and searching for information you would like to have? Are there any codes or options that would help you that missing? Are there any codes or options that are redundant?

(8) Does the project intake survey capture the information useful to organizations working in your community? Please elaborate on what is useful or what could be done to make it more useful.

(9) What are the typical information gaps that interfere with your organization's ability to target suitable funding opportunities? How can the project intake survey be enhanced to yield relevant information for your purposes?

(10) With regard to geography filters, projects in the draft database would be searchable by city, state, zip code, and census tract (where known by the respondent). Do these filters allow for geographic searches that would be useful to you?

(11) How can HUD better engage foundation, philanthropic, and impact investor community?

For potential respondents:

(12) Please review the questions in the proposed Project Intake Survey at [link]. If you are managing a local community development project or intervention, would you be willing and able to respond to the survey questions and to make your responses public for purposes of potentially connecting you to federal and private partners and/or peers that could facilitate your work? If not, why not?

(13) Do you perceive the benefits of responding to the CDM Survey as adequate and sufficiently motivating for you to respond? If not, what additional benefits would motivate you to respond?

(14) With regard to your and your partners' community revitalization efforts, please explain what particular types of information, peer exchange, introductions or other non-competitive assistance would be helpful to you as you move your work forward?

(15) With regard to geography filters, projects in the draft database would be searchable by city, state, zip code, and census tract (where known by the respondent). Do these filters allow for geographic searches that would be useful to you?

C. Surveys of Recipients and Providers of HUD Technical Assistance and Training (Available Upon Request)

The goal of HUD's technical assistance and training is to help customers navigate challenges associated with HUD funding and programs and points them in the right direction to best serve their communities. HUD provides TA and training across its portfolio of programs, including public housing, Native American housing, community development, rental housing, and fair housing. HUD does not currently have a mechanism to systematically solicit TA or training recipient feedback.

The goal of the proposed survey(s) are to systematically collect information across TA and training engagements to learn how effectively they achieved the desired outcomes identified at the start of the engagement. From the information collected, HUD will be able to understand which types of TA and training are preferred by recipients and which seem to be most effective in achieving specific outcomes, and hold TA providers accountable for the quality of TA and training provided. It will provide information that will help HUD continuously improve the way it provides TA and training.

HUD is particularly interested in comments that address the following questions:

For survey of recipients and providers of HUD technical assistance:

(16) Is an online survey sent after the TA engagement a practical way to capture feedback about the TA?

(17) Is a rating system (*e.g.* rank the TA on a scale of 1–4) an appropriate way to assess customer satisfaction with the TA?

(18) What type(s) of survey question(s) would best measure customer satisfaction with the quality of TA provided?

(19) What other methods besides a survey could be employed to assess the quality of TA provided?

For survey of HUD training participants:

(20) How can HUD most accurately measure customer satisfaction and outcomes of training?

(21) Should the survey of online or virtual training participants be different from the survey for in-person training participants?

(22) Are there any other questions that the survey should ask of HUD training recipients to measure the effectiveness of HUD training?

HUD encourages interested parties to submit comment in response to these questions. Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: March 21, 2016.

Harriet Tregoning,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2016–06849 Filed 3–24–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5909–N–19]

30-Day Notice of Proposed Information Collection: Information Resource Center Customer Satisfaction Survey

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* April 25, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding

this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on December 7, 2015 at 80 FR 76029.

A. Overview of Information Collection

Title of Information Collection: Information Resource Center Customer Satisfaction Survey.

OMB Approval Number: 2577–New.

Type of Request: New Collection.

Form Number: None.

Description of the need for the information and proposed use: The information will be used by Public and Indian Housing to rate the customer satisfaction of the users of the Information Resource Center (IRC). Collection of this information is needed to ensure that the customers using the IRC are receiving the correct and useful information that addresses their concerns when they call in for information. The Information Resource Center provides technical assistance, primarily in the form of general information, to provide access to resources of federal, public, Indian and assisted housing programs of the Department of Housing and Urban Development. This service is provided through a multi-channel contact center with inquires received and responded to via phone, email, mail and fax.

Respondents: Individuals or households, State, Tribal or local governments.

Estimated Number of Respondents: 10,800.

Estimated Number of Responses: 10,800.

Frequency of Response: 1.

Average Hours per Response: 1 minute.

Total Estimated Burdens: 10,800.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: *March 22, 2016.*

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2016–06850 Filed 3–24–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2016–0053][FXIA16710900000–156–FF09A30000]

Endangered Species; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before April 25, 2016.

ADDRESSES: *Submitting Comments:* You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2016–0053.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2016–0053; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

When submitting comments, please indicate the name of the applicant and the PRT# you are commenting on. We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see the Public Comments section below for more information). *Viewing Comments:* Comments and materials we receive will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

III. Permit Applications

Endangered Species

Applicant: Mountain Gorilla Veterinary Project, Inc., Baltimore, MD; PRT–73578B

The applicant requests a permit to re-export biological samples from wild mountain gorilla (*Gorilla beringei*) to the United Kingdom for the purpose of scientific research.

Applicant: Wildlife Conservation Society, Bronx, NY; PRT–77252B

The applicant requests a permit to re-export biological samples from wild Amur tigers (*Panthera tigris altaica*) to the United Kingdom for the purpose of scientific research.

Applicant: Veterinary Initiative for Endangered Wildlife, Bozeman, MT; PRT–75654B

The applicant requests a permit to import biological samples from Bengal tigers (*Panthera tigris tigris*) and Indian rhinoceros (*Rhinoceros unicornis*) from National Trust for Nature Conservation, Sauraha, Nepal, for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Creation Kingdom Zoo Inc., Gate City, VA; PRT–84452B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Ring-tailed lemur (*Lemur catta*), black and white ruffed lemur (*Varecia variegata*), red ruffed lemur (*Varecia rubra*), white-fronted lemur (*Eulemur albifrons*), cotton-headed tamarin (*Saguinus oedipus*), mandrill (*Mandrillus sphinx*), Lar gibbon (*Hylobates lar*), and leopard (*Panthera pardus*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Clara Geissler, San Diego, CA; PRT–74736B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Radiated tortoise (*Astrochelys radiata*) and Galapagos tortoise (*Chelonoidis nigra*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Evan Rosenoff, Cary, NC; PRT–51920A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Radiated tortoise (*Astrochelys radiata*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: University of California, Davis, CA; PRT–84562B

The applicant requests a permit to import egg samples from wild leatherback sea turtle (*Dermochelys coriacea*) from St. Ketts and Nevis, for the purpose of scientific research. This notification coverts activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Arthur Webber, Glenside, PA; PRT–88754B

Applicant: Douglas Wyatt, Amarillo, TX; PRT–88758B

Applicant: Armour Mellon, Ligonier, PA; PRT–88822B

Applicant: Matthew Saulsbury, Odessa, TX; PRT–88755B

Applicant: Roger Turner, Midland, TX; PRT–88670B

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2016–06786 Filed 3–24–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–R–2015–N089; 1265–0000–10137–S3]

Deer Flat National Wildlife Refuge, Canyon, Payette, Owyhee, and Washington Counties, ID, and Malheur County, OR; Comprehensive Conservation Plan and Record of Decision for Final Environmental Impact Statement

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the Deer Flat National Wildlife Refuge (Refuge) comprehensive conservation plan (CCP) and record of decision (ROD) for the final environmental impact statement (EIS). The CCP describes the Refuge's management direction for the next 15 years, and includes the ROD, which explains our selection of Alternative 2 as the Refuge's management direction.

DATES: The Regional Director, Pacific Region, U.S. Fish and Wildlife Service, signed the ROD on April 3, 2015.

ADDRESSES: The libraries providing public viewing of the CCP/ROD are listed under **SUPPLEMENTARY**

INFORMATION. You may view or download a copy of the CCP/ROD at the Refuge's Web site at *http://www.fws.gov/deerflat/refugeplanning.html,* or request a CD–ROM copy of the CCP/ROD by one of the following methods:

Email: deerflat@fws.gov. Include ''Deer Flat Refuge draft CCP/EIS'' in the subject line of the message.

Fax: Attn: Refuge Manager, 208–467–1019.

U.S. Mail: Deer Flat National Wildlife Refuge, 13751 Upper Embankment Road, Nampa, ID 83686.

In-Person Viewing or Pickup: Call 208–467–9278 to make an appointment during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Refuge Manager, 208–467–9278 (phone).

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we finalize the CCP process for Deer Flat Refuge. We started this process by publishing a notice of intent in the **Federal Register** on July 15, 2010 (75 FR 41232). We requested public comments on the draft CCP/EIS in a notice of availability published in the **Federal Register** on March 15, 2013 (78 FR 16526). For more information about the history and purposes of the Refuge, see that notice.

We completed a thorough analysis of impacts on the human environment and responded to public comments in the final CCP/EIS released to the public through a **Federal Register** notice published on February 20, 2015 (80 FR 9279).

We announce our decision and the availability of the CCP and ROD in accordance with National Environmental Policy Act (NEPA) (40 CFR 1506.6(b)) requirements. Alternative 2, as we described it in the final CCP/EIS, was selected for implementation at the Refuge. The CCP will guide Refuge management for 15 years.

Background

The National Wildlife Refuge System Administration Act of 1966, 16 U.S.C. 668dd–668ee (Refuge Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to complete a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Refuge Administration Act.

CCP/ROD

Based on our comprehensive review and analysis of Deer Flat Refuge's resources and issues, the Service selected Alternative 2, our preferred alternative, for implementation, as it is described in the final CCP/EIS, with two modifications described below. In reaching our decision to implement Alternative 2, we identified and analyzed its impacts to the Refuge environment in the Draft and Final CCPs/EISs. Issues, comments, concerns, and opportunities identified by all stakeholders throughout the planning process were considered and addressed. A summary of public comments and our responses is available in the CCP, in Appendix H.

Changes Made to the Selected Alternative

The following changes were made to wildlife-dependent public uses in the Lake Lowell Unit in Alternative 2 after the final CCP/EIS was released:

▪ Noncompetitive jogging, bicycling, and horseback riding groups of 10 or fewer people are allowed without a special use permit (SUP). An SUP is still required for groups larger than 10, and competitive events are still prohibited.

▪ Boats using wake-generating devices (wake-boats) are compatible with stipulations, including requiring wake-boats to use ballast filtering systems to prevent invasive species introductions. Wakes that impact grebe nests are a concern; however, the new no-wake zones will provide some additional protection, and we will continue to evaluate effects on wildlife to ensure the use remains compatible.

Other CCP Actions

We will protect Lake Lowell's shoreline feeding and nesting sites for wintering and migratory birds by closing the lake October 1–April 14, establishing a 200-yard no-wake zone on the south side and in the Narrows, and expanding the southeast no-wake zone to Gotts Point.

Fishing and wildlife interpretation will be emphasized, and with increased law enforcement, Gotts Point will open to vehicles. We will increase wildlife inventory and monitoring, invasive species control, and restoration on the Snake River Islands Unit, and we will adjust closures to protect nesting and wading birds. Wildlife observation and hunting for deer, upland species, and waterfowl will be allowed on the unit, and most islands will be open for shoreline fishing and free-roam activities June 15–January 31; and heron- and gull-nesting islands will be open July 1–January 31. For additional details, the CCP/ROD is available on the Refuge's Web site: *www.fws.gov/deerflat/refugeplanning.html.* Implementing some of the CCP actions will be subject to the availability of funding and any additional compliance requirements.

Public Availability of Documents

Review the CCP/ROD at the following libraries and sources under **ADDRESSES**.

▪ Caldwell Public Library, 1010 Dearborn St., Caldwell, ID 83605.

▪ Homedale Public Library, 125 W Owyhee Ave., Homedale, ID 83628.

▪ Lizard Butte District Library, 111 3rd Ave. W, Marsing, ID 83639.

▪ Nampa Public Library, 101 11th Ave. S, Nampa, ID 83651.

▪ Payette Public Library, 24 S 10th St., Payette, ID 83661.

▪ Ada County District Library, 10664 W Victory Rd., Boise, ID 83709.

Richard Hannan,

Acting Regional Director, Pacific Region, Portland, Oregon.

[FR Doc. 2016–06628 Filed 3–24–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–WSFR–2016–N052; FVWF94100900000–XXX–FF09W23000; FVWF51100900000–XXX–FF09W23000]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Annual Certification of Hunting and Sport Fishing Licenses Issued

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on March 31, 2016.

We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before April 25, 2016.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail), or *hope_grey@fws.gov (*email). Please include ''1018–0007'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey at *hope_grey@fws.gov* (email) or 703–358–2482 (telephone). You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

Information Collection Request

OMB Control Number: 1018–0007.

Title: Annual Certification of Hunting and Sport Fishing Licenses Issued, 50 CFR 80, subpart D.

Service Form Numbers: 3–154a and 3–154b.

Type of Request: Extension of a currently approved collection.

Estimated Number of Respondents: 56.

Description of Respondents: States, territories (Commonwealth of Puerto Rico, Commonwealth of the Northern Mariana Islands, Guam, U.S. Virgin Islands, and American Samoa), and District of Columbia.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually.

Activity	Number of responses	Completion time per response (hours)	Total annual burden hours
FWS Form 3–154a	56	12	672
FWS Form 3–154b	56	20	1,120
Totals	112	.....	1,792

Estimated Annual Nonhour Burden Cost: None.

Abstract: The Pittman-Robertson Wildlife Restoration Act (16 U.S.C. 669 *et seq.*) and the Dingell-Johnson Sport Fish Restoration Act (16 U.S.C. 777 *et seq.,* except 777e–1) provide authority for Federal assistance to the States for management and restoration of fish and wildlife. These Acts and our regulations in the Code of Federal Regulations (CFR) at 50 CFR 80, subpart D, require that States, territories, and the District of Columbia annually certify their hunting and fishing license sales. States, territories, and the District of Columbia that receive grants under these Acts use FWS Forms 3–154a (Part I–Certification) and 3–154b (Part II–Summary of Hunting and Sport Fishing Licenses Issued) to certify the number of hunting and fishing licenses sold and the amount of sales. We use the information collected to apportion and distribute funds according to the formula specified in each Act.

Comments Received and Our Responses

Comments: On December 23, 2015, we published in the **Federal Register** (80 FR 79924) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on February 22, 2016. We received one comment in response to this notice. The respondent objected to the Wildlife Restoration Act, but did not address the information collection requirements. We did not make any changes to our requirements.

Request for Public Comments

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB and us in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: March 21, 2016.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2016–06781 Filed 3–24–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2016–N037]; [40120–1112–0000–F2]

Draft Environmental Impact Statement; Eastern Collier Multi-Species Habitat Conservation Plan; Collier County, Florida

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent; announcement of public meeting.

SUMMARY: Under the National Environmental Policy Act (NEPA), we, the Fish and Wildlife Service (Service), advise the public that we intend to gather information necessary to prepare a draft environmental impact statement (dEIS) related to an anticipated permit application from nine Collier County, Florida, landowners (prospective applicants) for the incidental take of federally listed species. The permit application would include an Eastern Collier Multiple Species Habitat Conservation Plan (ECMSHCP) prepared

in accordance with the Endangered Species Act of 1973, as amended (Act). We provide this notice to (1) describe the anticipated action; (2) advise other Federal and State agencies, affected Tribes, and the public of our intent to prepare a dEIS; (3) announce the initiation of a public scoping period; and (4) obtain suggestions and information on the scope of issues and alternatives to be included in the dEIS as well as any other written data, views, or arguments with respect to the anticipated permit application.

DATES: *Comments:* We must receive any written comments at our Field Office (see **ADDRESSES**) on or before April 25, 2016.

Public Meetings: One public scoping meeting will be held on April 12, 2016: From 5 to 7 p.m.

ADDRESSES: *Public Meeting:* University of Florida/Institute of Food and Agricultural Sciences Collier County Extension, 14700 Immokalee Road, Naples, Florida. *Document Availability:* Documents will be available for public inspection by appointment during normal business hours at the South Florida Ecological Services Office, 1339 20th Street, Vero Beach, FL 32960. Documents are also available at: *www.easterncollierHCPEIS.com*.

Comments: For how and where to submit comments, see Public Comments under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kenneth McDonald, (*Kenneth_mcdonald@fws.gov*) Project Manager, at the South Florida Ecological Services Office (see **ADDRESSES**), telephone: 772/469–4284.

SUPPLEMENTARY INFORMATION: Under NEPA (42 U.S.C. 4321 *et seq.*), we announce our intention to gather information necessary to prepare a dEIS on the anticipated permit application under the Act (16 U.S.C. 1531 *et seq.*). The Department of the Army, through its bureau the U.S. Army Corps of Engineers, will be a cooperating agency in the development of the dEIS.

Background

Section 9 of the Act and the Service's implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR Part 17 prohibit the ''take'' of federally listed ''endangered'' and ''threatened'' species (16 U.S.C. 1538). The Act defines the term ''take'' as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed species or to attempt to engage in such conduct (16 U.S.C. 1532). ''Harm'' includes an act that actually kills or injures a listed species and may include significant habitat modification or degradation that actually kills or injures a species by significantly impairing essential behavioral patterns, including breeding, feeding, and sheltering (50 CFR 17.3). Under section 10(a)(1)(B) (16 U.S.C. 1539) of the Act, the Service may issue permits authorizing ''incidental take'' of listed species. ''Incidental take'' is defined as take otherwise prohibited but incidental to, and not the purpose of, carrying out an otherwise lawful activity (50 CFR 17.3). Regulations governing incidental take permits for endangered species and threatened species, respectively, are found in 50 CFR 17.22 and 50 CFR 17.32.

Eastern Collier Multiple Species Habitat Conservation Plan (ECMSHCP)

The prospective applicants intend to seek an incidental take permit (ITP) that would authorize take resulting from the residential and commercial development and earth mining activities described in the ECMSHCP on certain lands (''covered lands''). The ECMSHCP would include measures to avoid, minimize, and mitigate for incidental take with an emphasis on preserving some of the lands to maintain the viability and continued existence of populations of federally- listed threatened and endangered species.

The ECMSHCP also would include a funding mechanism for the avoidance, minimization, and mitigation measures, such as land acquisition, habitat mitigation, establishment of wildlife crossings, ecological restoration, land management, and actions to assist in the conservation of species through research. The proposed term of the ITP would be 50 years.

The prospective applicants are expected to seek incidental take authorization for the following federally listed species: The Florida scrub-jay (*Aphelocoma coerulescens*), Audubon's crested caracara (*Polyborus plancus*) (alternatively identified as the northern crested caracara (*Caracara cheriway*)), wood stork (*Mycteria americana*), red-cockaded woodpecker (*Picoides borealis*), Everglade snail kite (*Rostrhamus sociabilis plumbeus*), eastern indigo snake (*Drymarchon corais couperi*), Florida bonneted bat (*Eumops floridanus*), and Florida panther (*Puma concolor coryi*) (''covered species''). The gopher tortoise (*Gopherus polyphemus*), which is a candidate species, would also be included as a covered species for which the prospective applicants would seek incidental take authorization. The prospective applicants' ECMSHCP would also cover the following State listed and unlisted species: The burrowing owl (*Athene cunicularia*), eastern diamondback rattlesnake (*Crotalus adamanteus*), Florida sandhill crane (*Grus canadensis pratensis*), little blue heron (*Egretta caerulea*), Southeastern American kestrel (*Falco sparverius paulus*), tricolored heron (*Egretta tricolor*), and the Big Cypress fox squirrel (*Sciurus niger avicennia*).

The covered lands of the ECMSHCP encompass approximately 152,124 acres in northeastern Collier County, Florida, that surround the town of Immokalee. The covered lands are bordered to the south by the Florida Panther National Wildlife Refuge and Big Cypress National Preserve, to the north and east by the Okaloacoochee Slough State Forest, and to the northwest by the Audubon Corkscrew Swamp Sanctuary. The prospective applicants are expected to propose a conservation strategy in the ECMSHCP that would preserve a large portion of the covered lands as habitat for the covered species while conducting activities on smaller, clustered portions of the covered lands.

Biologically, the ECMSHCP would focus on maintaining areas of high-value habitat for the covered species while engaging in residential and commercial development and earth mining on 45,000 acres of the lands. The prospective applicants also would maintain suitable habitat within the impacted areas to ensure the availability of corridors for dispersal of the covered species.

Draft Environmental Impact Statement

The dEIS will consider a range of alternatives, including the proposed action (*i.e.*, the issuance of an ITP to the prospective applicants, no action (non-issuance of an ITP), variations in the scope and location of the covered activities or a combination of both. It will also provide a detailed description of the proposed action and alternatives, as well as identify and analyze the potential significance of direct and indirect impacts from the proposed action and alternatives to biological resources, land use, air quality, water quality, water resources, economics, and other environmental resources. We also will consider different strategies for avoiding, minimizing, and mitigating the impacts of incidental take from the proposed action. The primary purpose of the scoping process is to allow the public to identify important issues associated with the proposed action.

Public Comments

Outside of the public scoping meeting, we will accept comments in written form only. To assist us in identifying the full range of issues related to the prospective permit

application, we invite written comments from interested parties. Any comments submitted to us after the public meeting must be in writing. Please reference the ECMSHCP in such comments.

Comments may be submitted by any one of the following methods:

U.S. mail: South Florida Ecological Services Office (see **ADDRESSES**).

Email: comments-eastcollierhcp@fws.gov. Please include your name and return mailing address in your email message. If you do not receive a confirmation from us that we received your email, contact us directly at either of the telephone numbers listed (see **FOR FURTHER INFORMATION CONTACT**).

Hand delivery: To the South Florida Ecological Services Office (**ADDRESSES**).

Availability of Public Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, there is no guarantee that we will be able to do so.

Reasonable Accommodation

Persons needing reasonable accommodations in order to attend and participate in the public meeting should contact Vickie Scott at 813/675–6546 by no later than one week before the public meeting. Information regarding this proposed action is available in alternative formats upon request.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: March 2, 2016.

Mike Oetker,

Acting Regional Director, Southeast Region.

[FR Doc. 2016–06792 Filed 3–24–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2016–0054; FXIA16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have issued the following permits to conduct certain activities with endangered species, marine mammals, or both. We issue these permits under the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA).

ADDRESSES: Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION: On the dates below, as authorized by the provisions of the ESA (16 U.S.C. 1531 *et seq.*), as amended, and/or the MMPA, as amended (16 U.S.C. 1361 *et seq.*), we issued requested permits subject to certain conditions set forth therein. For each permit for an endangered species, we found that (1) The application was filed in good faith, (2) The granted permit would not operate to the disadvantage of the endangered species, and (3) The granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

ENDANGERED SPECIES

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
59838B	The Wild Animal Sanctuary	80 FR 47947; August 10, 2015	10/13/2015
63281B	University of Tennessee	80 FR 53323; September 3, 2015	11/5/2015
63550B	Houston Zoo, Inc	80 FR 55868; September 17, 2015	12/11/2015
756101	Rare Species Conservatory Foundation	80 FR 55868; September 17, 2015	01/04/2016
676508	Six Flags Discovery Kingdom	80 FR 55868; September 17, 2015	1/21/2016
64786B	Peter Langegger	80 FR 58768; September 30, 2015	01/13/2015
76168B	Luke Snyder	80 FR 58768; September 30, 2015	11/10/2015
75313B	Wildlife & Environmental Conservation, Inc	80 FR 58768; September 30, 2015	12/01/2015
63829B	City of Bridgeton/Cohanzick Zoo	80 FR 58768; September 30, 2015	12/26/2015
64101B	University of Colorado	80 FR 58768; September 30, 2015	12/11/2015
78222B	Michael Long	80 FR 62089; October 15, 2015	11/24/2015
76169B	Joshua Braun	80 FR 62089; October 15, 2015	11/25/2015
74563B	Cheadle Center for Biodiversity and Ecological Restoration.	80 FR 62089; October 15, 2015	12/08/2015
66556B	Abilene Zoological Gardens	80 FR 62089; October 15, 2015	12/09/2015
77387B	St. Catherines Island Foundation	80 FR 62089; October 15, 2015	12/15/2015
59839B	The Wild Animal Sanctuary	80 FR 62089; October 15, 2015	12/11/2015
61197B	Megan Cattau	80 FR 64441; October 23, 2015	12/02/15
68848B	Toledo Zoological Gardens	80 FR 68554; November 5, 2015	02/10/16
68850B	Toledo Zoological Gardens	80 FR 68554; November 5, 2015	02/09/16
73299B	Palm Beach Zoo and Conservation Society	80 FR 68554; November 5, 2015	02/18/2016
71725B	Fox Brown Outfitters	80 FR 68554; November 5, 2015	3/11/2016
78797B	David Hessler	80 FR 70249; November 13, 2015	02/11/2016
79073B	Margaret Williams	80 FR 70249; November 13, 2015	02/11/2016
71096B	Point Defiance Zoo & Aquarium	80 FR 70249; November 13, 2015	02/25/2016
677611	Sacramento Zoological Society, dba Sacramento Zoo.	80 FR 70249; November 13, 2015	2/24/2016
71724B	Fox Brown Outfitters	80 FR 70249; November 13, 2015	3/11/2016
66999B	Angelica Rodriquez/American Museum of Natural History.	80 FR 70249; November 13, 2015	2/23/2016
80785B	Kevin Poynter	80 FR 73207; November 24, 2015	1/27/2016
75301B	Big Cat Rescue Corporation	80 FR 73207; November 24, 2015	3/16/2016

ENDANGERED SPECIES—Continued

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
80817B	David Twiss	80 FR 76567; December 9, 2015	02/11/2016
73358B	The Ohio State University	80 FR 76567; December 9, 2015	02/24/2016
81679B	Gregory Fowler	80 FR 76567; December 9, 2015	1/27/2016
64789B	Serpentarium Magic Inc	80 FR 76567; December 9, 2015	01/28/2016
81224B	Erhardt Steinborn	80 FR 76567; December 9, 2015	1/27/2016
61689B	Memphis Zoo	80 FR 79607; December 22, 2015	02/11/16
094332	Molecular Anthropology Laboratory, ASU	81 FR 791; January 7, 2016	02/17/2016
084874	University of New Mexico	81 FR 791; January 7, 2016	02/11/2016
80481B	Duke Lemur Center	81 FR 2899; January 19, 2016	02/23/2016
81711B	Toledo Zoological Gardens	81 FR 5778; February 3, 2016	02/24/2016
78584B	Zoological Society of San Diego	81 FR 5778; February 3, 2016	03/16/16

MARINE MAMMALS

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
68000B	John Downer Productions Ltd	80 FR 62089; October 15, 2015	3/16/2016

Availability of Documents

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2016–06787 Filed 3–24–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167A2100DD/AADD001000/A0A501010.999900]

Contract Support Costs

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of tribal consultation.

SUMMARY: This notice announces that the Office of the Assistant Secretary—Indian Affairs (AS–IA) will be hosting tribal consultation sessions on a streamlined draft policy that will address contract support costs (CSC) incurred by Tribes under Indian Self-Determination and Education Assistance Act (ISDEAA) self-determination contracts and Self-Governance funding agreements.

DATES: Written comments on the draft policy must be received the Department of the Interior (Department) by July 29, 2016. Please see the **SUPPLEMENTARY INFORMATION** section of this notice for dates of the tribal consultation sessions.

ADDRESSES: A copy of the draft policy is available for review at: *http://www.bia.gov/WhoWeAre/AS–IA/Consultation/index.htm.* Submit comments by email to: *consultation@bia.gov* or by U.S. mail to: Office of the Assistant Secretary—Indian Affairs, attn.: CSC Comments, 1849 C Street NW., MS–3071–MIB, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Ms. Hankie Ortiz, Deputy Bureau Director—Indian Services, Bureau of Indian Affairs, at (202) 513–7640 or via email: *hankie.ortiz@bia.gov.*

SUPPLEMENTARY INFORMATION: Indian Affairs has conducted several tribal consultations and listening sessions over the past two years regarding funding to tribes for CSC and is now presenting a draft policy to provide full funding for CSC incurred by tribes under ISDEAA self-determination contracts and Self-Governance funding agreements. The draft policy provides a streamlined approach to calculating CSC that reflects the Department's commitment to paying all Tribes full CSC.

We will be hosting the following consultation sessions to discuss this draft CSC policy and invites Tribes' participation:

Date	Time (Local time zone)	Location
Wednesday, April 27, 2016	2:00 pm–4:00 pm	Buena Vista Palace and Resort, 1900 E Buena Vista Drive, Lake Buena Vista, FL 32830. Meeting Room: Great Hall North (in conjunction with the 2016 Annual Tribal Self-Governance Consultation Conference).
Tuesday, May 17, 2016	9:00 am–1:00 pm	DOI University—National Indian Programs Training Center, 1011 Indian School Road NW., Albuquerque, NM 87104. Meeting Room: 231–233.
Thursday, May 19, 2016	9:00 am–1:00 pm	Hilton San Francisco Union Square, 333 O'Farrell Street, San Francisco, CA 94102. Meeting Room: Taylor AB.

Date	Time (Local time zone)	Location
Friday, June 10, 2016	9:00 am–1:00 pm	The Skirvin Hilton Oklahoma City, One Park Avenue, Oklahoma City, OK 73102. Meeting Room: Continental Room.

Dated: March 22, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2016–06841 Filed 3–24–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/ A0A501010.999900]

Yavapai-Apache Nation of the Camp Verde Indian Reservation Liquor Code

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the liquor code of the Yavapai-Apache Nation of the Camp Verde Indian Reservation. The liquor code allows the Nation to govern, control and regulate liquor possession, distribution, sales, and service within the Nation's reservation to serve the best interests of the Nation.

DATES: This code shall become effective March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlot Johnson, Tribal Government Services Officer, Western Regional Office, Bureau of Indian Affairs, 2600 North Central Avenue, Phoenix, Arizona 85004, Telephone: (602) 379–6786, Fax: (602) 379–4100; or Laurel Iron Cloud, Chief, Division of Tribal Government Services, Office of Indian Services, Bureau of Indian Affairs, 1849 C Street NW., MS–4513–MIB, Washington, DC 20240, Telephone: (202) 513–7641.

SUPPLEMENTARY INFORMATION: Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice* v. *Rehner,* 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor ordinances for the purpose of regulating liquor transactions in Indian country. The Yavapai-Apache Nation of the Camp Verde Indian Reservation duly adopted Resolution 147–15 on August, 27, 2015.

This notice is published in accordance with the authority delegated by the Secretary of the Interior to the Assistant Secretary-Indian Affairs. I certify that the Yavapai-Apache Nation of the Camp Verde Indian Reservation Tribal Council duly adopted the Yavapai-Apache Nation Liquor Cody by Resolution No. 147–15 on August 27, 2015.

Dated: March 21, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary–Indian Affairs.

YAVAPAI-APACHE NATION LIQUOR CODE

SECTION 101: TITLE

This Liquor Code is adopted by the Yavapai-Apache Nation (''YAN'' or ''Nation'') and shall be known as the Yavapai-Apache Nation Liquor Code (referred to herein as ''Liquor Code'' or ''Code'').

SECTION 102: FINDINGS

The Tribal Council finds as follows:

A. The introduction, possession, and sale of liquor in Indian Country is a matter of particular concern to Indian tribes and the United States. Consistent with the laws of the United States, the control of liquor on the Yavapai-Apache Nation Reservation remains subject to the legislative enactments of the Nation in the exercise of its governmental powers over the Reservation.

B. Federal law prohibits the introduction of liquor into Indian Country (18 U.S.C. § 1154), and authorizes tribal governments to decide when and to what extent liquor possession, sales, and service shall be permitted within their reservations (18 U.S.C. § 1161) in a manner deemed consistent with state liquor laws.

C. The Tribal Council, as the governing body of the Nation under Article IV, Section 1 of the Constitution of the Yavapai-Apache Nation (hereinafter ''Tribal Council''), has approved the issuance of liquor licenses in accordance with the liquor control laws of the state of Arizona. The limitation and regulation of liquor sales as provided in this Code will increase the Nation's ability to control possession and distribution of liquor within the Nation's Reservation.

SECTION 103: AUTHORITY AND PURPOSE

A. This Code is enacted under authority of the Act of August 15, 1953, 67 Stat. 586, (18 U.S.C. Section 1161) and under authority of the Constitution of the Yavapai-Apache Nation (''YAN Constitution''), which authorizes the Tribal Council to exercise the following powers relevant to the adoption of this Liquor Code:

1. YAN Constitution, Article V(a), ''To represent the Tribe and act in all matters that concern the health and welfare of the Tribe, and to make decisions not inconsistent with or contrary to this constitution.''

2. YAN Constitution, Article V (o), to enact codes and ordinances governing law enforcement on lands within the jurisdiction of the Tribe.''

3. YAN Constitution, Article V (u), ''To exercise civil jurisdiction over all tribal members and any non-member of the Tribe to the extent permitted by federal law.''

4. YAN Constitution, Article V (v), ''To enact laws, ordinances and resolutions necessary or incidental to the exercise of its legislative powers.''

B. This Liquor Code is adopted for the purpose of governing, controlling and regulating liquor possession, distribution, sales and service within the Nation's reservation.

SECTION 104: DEFINITIONS

A. Unless otherwise required by the context in which it is used, the following words and phrases shall have the following meanings.

1. ''Alcohol'' means the substance known as ethyl alcohol, hydrated oxide of ethyl, ethanol, or spirits of wine, from whatever source or by whatever process produced, and includes ''spirituous Liquor'' as defined below under Section 104(A)(7).

2. ''Alcoholic Beverage'' is synonymous with the term ''liquor'' as defined in this Section 104. (4) below.

3. ''Beer'' means any beverage obtained by the alcoholic fermentation, infusion, or decoction of barley malt, hops, or other ingredients not drinkable, or any combination thereof.

4. ''Liquor'' or ''Liquor Products'' includes the four varieties of liquor herein defined (alcohol, spirituous liquor, wine, and beer) and means all fermented, spirituous, vinous, or malt liquor, or a combination thereof, and mixed liquor, a part of which is fermented, spirituous, vinous, or malt liquor or otherwise intoxicating in every liquid or solid or semi-solid or other substance patented or not containing alcohol, spirits, wine, or beer, and all

drinks of potable liquids and all preparations or mixtures capable of human consumption, and any liquid, semi-solid, solid, or other substance, which contains more than one-half of one percent (.5%) of alcohol by volume.

5. ''Liquor License'' means the Liquor License approved by the Tribal Council and issued by the state of Arizona upon application by the Nation to such Subordinate Economic Organization or Enterprise of the Nation as the Council may authorize by resolution to hold such license and exercise the rights and privileges thereunder.

6. ''Sale'' and ''Sell'' means any transaction that includes any exchange, barter, sale and traffic; and also includes the selling, supplying or distributing, by any means whatsoever, of liquor by any person to any other person.

7. ''Spirituous Liquor'', ''Spirits'', or ''Distilled Spirits'' includes alcohol, brandy, whiskey, rum, tequila, mescal, gin, wine, porter, ale, beer, any malt liquor or malt beverage, absinthe, a compound or mixture of any of them or of any of them with any vegetable or other substance, alcohol bitters, bitters containing alcohol, any liquid mixture or preparation, whether patented or otherwise, which, when consumed in sufficient quantities, produces intoxication to any degree, fruits preserved in ardent spirits, and beverages containing more than one-half of one percent of alcohol by volume, and including wines exceeding twenty-four percent (24%) of alcohol by volume.

8. ''Wine'' means the product obtained by the fermentation of grapes or other agricultural products containing natural or added sugar or any such alcoholic beverage fortified with grape brandy and containing not more than twenty-four percent (24%) of alcohol by volume, including sweet wines fortified with wine spirits, such as port, sherry, muscatel, and angelica, not exceeding twenty-four percent (24%) of alcohol by volume.

SECTION 105: JURISDICTION

In accordance with the law of the United States as set out at 18 U.S.C. 1161, the Nation asserts its jurisdiction to control and regulate liquor sales and service within the boundaries of the Yavapai-Apache Nation Reservation. For purposes of this Liquor Code ''Reservation'' or ''Jurisdiction'' means those lands within the exterior boundaries of the Yavapai-Apache Nation, any lands that are held in trust by the United States of America for the benefit of the Yavapai-Apache Nation or any of its members, both now and in the future, any other Yavapai-Apache Nation land constituting ''Indian Country'' within the meaning of 18 U.S.C. 1151 or any successor provision, and all lands falling within the Nation's Jurisdiction as provided under Article I of the Constitution of the Yavapai-Apache Nation as approved by the United states Secretary of Interior on April 13, 1992.

SECTION 106: CONFORMITY WITH STATE LAW

A. Authorized liquor sales and service within the Nation's Reservation and Jurisdiction shall comply with the State of Arizona's liquor laws to the extent required by 18 U.S.C. 1161 and other applicable law of the United States.

B. The Nation's Attorney General shall ensure that all liquor license requirements under this Code and under the laws of the State of Arizona are satisfied, that the license(s) authorized by the Tribal Council under this Code are renewed on an annual basis, and that all sales and service of liquor as authorized under this Code are carried out in a manner consistent with this Code and applicable laws of the Nation, and under Arizona law to the extent required by applicable law of the United States.

SECTION 107: REPEAL OF PRIOR LAWS

All prior codes, ordinances and resolutions of the Yavapai-Apache Nation regulating, authorizing, prohibiting, or in any way dealing with the sale or service of liquor, including, but not limited to the ''Ordinance Legalizing the Introduction, Sale or Possession of Intoxicants'', as adopted under Tribal Council Resolution 91–85 on October 19, 1985, are hereby repealed and are declared to be of no further force or effect.

SECTION 108: AUTHORIZED SALES AND SERVICE OF LIQUOR

A. Liquor License Required. Liquor may be offered for sale and served on the Yavapai-Apache Nation Reservation only under a Liquor License as expressly authorized by the Tribal Council in accordance with this Code and applicable federal law.

B. The Council, through the adoption of Council resolutions consistent with this Code, may authorize liquor sales at such additional locations as the Council deems appropriate.

C. Sales for Personal Consumption Only. All liquor sales shall be for the personal use and consumption of the purchaser and not for the purchaser's resale. Any resale of any alcoholic beverage within the Jurisdiction of the Nation is prohibited. Any person or entity that is not licensed under this Code who purchases or possesses an alcoholic beverage within the Nation's Jurisdiction and sells it, whether in the original container or not, shall be guilty of a violation of this Code and shall be subject to such penalties as are prescribed by this Code.

D. License Not Transferable. Except as may be permitted under this Code, Liquor Licenses may not be transferred and said License may only be utilized by the entity holding the License under Section 108 A. above.

E. Inspections. All businesses and their premises holding a Liquor License under this Code shall be open for inspection by the Nation, acting through its officials, agents, employees or other designated representatives, at all reasonable times for the purpose of determining whether said business is complying with this Code.

SECTION 109: ENFORCEMENT

A. In enforcing this Code, the Tribal Council, acting on behalf of the Nation, may take the following actions:

1. Publish and enforce such rules and regulations as deemed necessary by the Council to govern the manufacture, distribution, sale, and possession of liquor within the Nation's Jurisdiction.

2. Revoke any Liquor License approved by the Council under this Code, following a determination by the Council that the holder of said License has violated any provision of this Code or that the License is no longer in the best interest of the Nation. The holder of the License shall be provided notice and an opportunity to be heard in any such revocation action.

3. Bring suit in the Nation's Tribal Court, or any other court of competent jurisdiction, to enforce this Code.

4. Hold such hearings as the Council deems necessary to administer and enforce this Code.

5. Delegate to the Nation's Tribal Court such authority as may be necessary to enforce the civil penalties arising under this Code. Except as may otherwise be provided by applicable federal law, the Nation's Tribal Court shall have exclusive jurisdiction to enforce this Code.

6. Take all such actions as are within the Council's authority under the laws and Constitution of the Yavapai-Apache Nation in the enforcement of this Code.

SECTION 110: PROHIBITIONS AND VIOLATIONS

A. General Prohibition. Except as authorized under a Liquor License issued under Section 107 of this Code, the introduction or possession of Liquor for sales, distribution or service is

prohibited within the Yavapai-Apache Nation's Jurisdiction, and any such possession, sale, distribution or service without such License shall be a violation under this Code. Any person who, without a Liquor License authorized under this Code, introduces or possesses liquor within the Nation's jurisdiction with the intent to sell the same shall be in violation of this Code. In any proceeding under this Code, the conviction of any person in a criminal matter of one unlawful sale, possession or distribution of liquor under any law of the Nation, or a determination by the Tribal Court in a civil matter that said person has engaged in one unlawful sale, possession or distribution under this Code, shall establish prima facie intent of said person to unlawfully keep liquor for sale, selling liquor or distributing liquor in violation of this Code. Federal liquor laws applicable to Indian Country shall remain applicable to any person, act, or transaction which is not authorized by this Code and violators of this Code shall be subject to federal prosecution as well as to legal action in accordance with this Code and the laws of the Nation.

B. Any person who shall sell or offer for sale or distribute or transport in any manner, liquor in violation of this Code, or who shall have liquor for sale in his possession without a Liquor License, shall be in violation of this Code.

C. Any person who, within the Nation's Jurisdiction, buys liquor from any person other than a properly licensed business under Section 108.A. of this Code shall be in violation of this Code.

D. Any person who knowingly keeps or possesses liquor upon his person or in any place or upon any premises conducted or maintained by his employer or principal or agent with the intent to sell or distribute the same contrary to the requirements of this Code, shall be in violation of this Code.

E. No person shall be authorized to sell or serve liquor within the Reservation unless they are at least 21 years of age, except as may be authorized under Arizona liquor control laws. No person may be sold or served liquor unless they are 21 years of age. Any person acting contrary to this prohibition shall be in violation of this Code.

F. No person under the age of 21 years shall consume, acquire or have in his/her possession any liquor. No person shall knowingly permit any other person under the age of 21 years to consume liquor on his/her premises or any premises under his/her control. Any person acting contrary to these prohibitions shall be in violation of this Code, with a separate violation accruing for every drink so consumed by the person under the age of 21 years.

G. Any person who shall sell or provide any liquor to any person under the age of 21 years shall be in violation of this Code for each such drink so provided.

H. Any person who lends, gives or in any way transfers in any manner an identification card or other representation of age to a person under the age of 21 years for the purpose of permitting such person to purchase or otherwise obtain liquor shall be in violation of this Code; provided that corroborative evidence from a source other than the underage person shall be a requirement for finding such violation.

I. Any person who purchases or attempts to purchase liquor through the use of false or altered identification, which falsely purports to show the person to be over the age of 21 years shall be in violation of this Code.

J. When requested by any business or entity holding a liquor license under this Code, any person shall be required to present, and shall present official documentation of the person's age, signature and photograph. This requirement may be satisfied by presentation of one of the following:

i. An unexpired driver license issued by any state, the District of Columbia, any territory of the United States or Canada if the license includes a picture of the licensee and the person's date of birth. A driver license issued to a person who is under twenty-one years of age is no longer an acceptable type of identification under this paragraph thirty days after the person turns twenty-one years of age.

ii. An unexpired non-operating identification license issued by any state, the District of Columbia, any territory of the United States or Canada if the license includes a picture of the person and the person's date of birth. An unexpired non-operating license issued to a person who is under twenty-one years of age is no longer an acceptable type of identification under this paragraph thirty days after the person turns twenty-one years of age.

iii. An unexpired armed forces identification card that includes the person's picture and date of birth.

iv. A valid unexpired passport or a valid unexpired resident alien card that contains a photograph of the person and the person's date of birth.

K. Off Premises Consumption of Liquor—Cliff Castle Casino. All liquor sales and service authorized by this Code at the Cliff Castle Casino and Hotel shall be fully consumed within the premises of the Cliff Castle Casino and Hotel. At the Cliff Castle Casino and Hotel, no open containers of liquor, or unopened containers of liquor in bottles, cans, cups or other containers, or otherwise shall be permitted outside of the above-described premises, except as provided in accordance with the liquor license(s) maintained by the Nation for the Cliff Castle Casino and Hotel, or under such special event license or permit as may be obtained consistent with said license(s). Any person acting contrary to these prohibitions shall be in violation of this Code.

L. No Credit Liquor Sales. The sales and service of liquor authorized by this Code shall be made upon a cash basis only. For purposes of this Code, payment for liquor on a cash basis shall include payment by cash, credit card, or check, including but not limited to any such cash sale of liquor for consumption on a retail licensed premises where the sale is included on bills provided to registered guest in hotels and motels. Any person making liquor sales contrary to this prohibition shall be in violation of this Code.

M. All Liquor which is possessed, including for any distribution, consumption or sale, in violation of the requirements of this Code is hereby declared to be contraband. Any officer of the Yavapai-Apache Nation Police Department shall seize all such contraband and preserve it in accordance with such provisions as apply to the preservation of evidence and impounded property. Upon being found to be in violation of this Code, the person from whom the contraband was seized shall forfeit all right, title and interest in the contraband seized and the same shall become the property of the Nation to be disposed of as it chooses.

SECTION 111: JUDICIAL ENFORCEMENT, REMEDIES AND CIVIL PENALTIES

A. The Nation's Tribal Court is hereby vested with exclusive jurisdiction to hear and determine all violations arising under Section 110 of this Code, including the determination of any violation by any person of the provisions of this Code and the imposition of any penalties arising from said violations.

B. Any person or entity found by the Tribal Court to have violated any provision of this Code shall be liable to pay to the Nation a civil penalty in an amount not less than $250.00 or greater than $500.00 for each such violation. The Tribal Court shall issue such further orders as are within its powers to ensure collection of said penalties by the

Nation. Persons who are not enrolled members of the Nation and who are determined to have violated this Code shall be subject to exclusion from the Yavapai-Apache Nation Reservation under such procedure as is provided under the Nation's Exclusion Ordinance. In addition, persons or entities subject to the criminal jurisdiction of the Nation who violate this Code shall be subject to such criminal punishment as may be provided in the Nation's Criminal Code and nothing in this Liquor Code shall be construed to deprive the Tribal Court of its criminal jurisdiction over such matters in any respect.

C. DECLARATORY AND INJUNCTIVE RELIEF

In addition to all other remedies, whether at law or in equity, available to the Nation's Tribal Court under the Constitution and Laws of the Yavapai-Apache Nation in the enforcement of this Code, the Tribal Court may employ such declaratory and/or injunctive relief as may be necessary to determine the rights and liabilities arising under this Code and to otherwise provide for enforcement of this Code to the fullest extent possible under the Nation's laws.

SECTION 112: SOVEREIGN IMMUNITY PRESERVED

A. Nothing in this Liquor Code is intended or shall be construed as a waiver of the sovereign immunity of the Yavapai-Apache Nation. No official or employee of the Nation or any of the Subordinate Economic Organizations and Enterprises of the Nation shall be authorized, nor shall they attempt, to waive the sovereign immunity of the Nation in any manner under this Code.

SECTION 113: SEVERABILITY

A. If any provision or provisions in this Code are held invalid by a court of competent jurisdiction, this Code shall continue in effect as if the invalid provision(s) were not a part hereof.

SECTION 114: EFFECTIVE DATE

A. This Code shall be effective immediately upon its approval by the Yavapai-Apache Nation Tribal Council, subject only to the certification of the United States Secretary of the Interior, or his/her designee, and its publication in the **Federal Register** as provided by federal law at 18 U.S.C § 1161.

[FR Doc. 2016–06840 Filed 3–24–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[167D0102R2 DR2000000.IMD000 DS63605000]

Privacy Act of 1974, as Amended; Notice To Amend an Existing System of Records

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of an amendment to an existing system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Interior is issuing a public notice of its intent to amend the Privacy Act system of records, ''Mineral Lease and Royalty Accounting Files—Interior, MMS–1'', to update the system name, system location, categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, routine uses, storage, safeguards, retention and disposal, system manager and address, notification procedures, records access and contesting procedures, and records source categories. The system name will be updated to ''Minerals Revenue Management Support System (MRMSS), OS–30'' to reflect new organizational management. The purpose of the system is to facilitate billing, accounts receivable, general ledger, compliance management, and collection of revenues.

DATES: Comments must be received by April 25, 2016. The amendments to the system will be effective April 25, 2016.

ADDRESSES: Any person interested in commenting on this notice may do so by: Submitting comments in writing to Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW., Mail Stop 5547 MIB, Washington, DC 20240; hand-delivering comments to Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW., Mail Stop 5547 MIB, Washington, DC 20240; or emailing comments to *Privacy@ios.doi.gov.*

FOR FURTHER INFORMATION CONTACT: Minerals Revenue Management Support System Program Manager, Information Management Center (IMC), Office of Natural Resources Revenue, U.S. Department of the Interior, P.O. Box 25165, Lakewood, CO 80225, or by telephone at 303–231–3177.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of the Interior (DOI) Office of Natural Resources Revenue (ONRR), within the Office of the Secretary, is responsible for the management of revenue associated with both Federal offshore and onshore mineral leases, and revenue management services for mineral leases on Indian lands in partnership with the Bureau of Indian Affairs. ONRR maintains the ''Mineral Lease and Royalty Accounting Files—Interior, MMS–1,'' system of records to manage these responsibilities in support of ONRR's mission to collect, disburse, and verify Federal and Indian energy and other natural resource revenues on behalf of Americans. Due to the restructuring of the Minerals Management Service and ONRR within the Office of the Secretary, DOI is proposing to revise the system name to ''Minerals Revenue Management Support System (MRMSS), OS–30'' to reflect the new organizational management. Other proposed amendments to the system include updating the system location, categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, routine uses, storage, safeguards, retention and disposal, system manager and address, notification procedures, record access and contesting record procedures, and records source categories. The Mineral Lease and Royalty Accounting Files—Interior, MMS–1 system notice was last published in the **Federal Register** on March 17, 1986 (51 FR 9121).

The MRMSS system facilitates mineral lease revenue management including billing, accounts receivable, rents, royalty payments, general ledger activity, compliance management, reporting, and the collection of revenues. The system also supports ONRR Outreach program activities for Indian mineral owners, to foster communication and enhance ONNR's trust responsibilities, and resolve royalty-related problems in partnership with the Bureau of Indian Affairs, Bureau of Land Management, and Office of the Special Trustee for American Indians. The MRMSS system helps ONRR meet its fiduciary responsibilities to manage revenues from energy and mineral leases for the use of public natural resources. The records in the MRMSS are related to both business entities and individuals, though records concerning corporations and other business entities are not subject to the Privacy Act.

The amendments to the system notice will be effective as proposed at the end of the comment period (the comment period will end 30 days after the publication of this notice in the **Federal**

Register), unless comments are received which would require a contrary determination. DOI will publish a revised notice if changes are made based upon a review of the comments received.

II. Privacy Act

The Privacy Act of 1974, as amended (5 U.S.C. 552a), embodies fair information practice principles in a statutory framework governing the means by which Federal agencies collect, maintain, use, and disseminate individuals' personal information. The Privacy Act applies to records about individuals that are maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency for which information about an individual is retrieved by the name or by some identifying number, symbol, or other identifier assigned to the individual. The Privacy Act defines an individual as a U.S. citizen or lawful permanent resident. As a matter of policy, DOI extends administrative Privacy Act protections to all individuals. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DOI by complying with DOI Privacy Act regulations at 43 CFR part 2, subpart K.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, the routine uses of each system to make agency record keeping practices transparent, to notify individuals regarding the uses of their records, and to assist individuals to more easily find such records within the agency. The amended Minerals Revenue Management Support System (MRMSS), OS–30 system of records notice is published in its entirety below.

In accordance with 5 U.S.C. 552a(r), DOI has provided a report of this system of records to the Office of Management and Budget and to Congress.

III. Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: March 22, 2016.

Teri Barnett,

Departmental Privacy Officer.

System Name:

Minerals Revenue Management Support System (MRMSS), OS–30.

SYSTEM CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records in this system are located at the Office of Natural Resources Revenue Center, Denver Federal Center, P.O. Box 25165, MS6055A, Denver, Colorado 80225, and at Office of Natural Resources Revenue contractor facilities that process electronic Minerals Revenue Management Support System records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system include lease and permit holders, current and former landowners and lessees, royalty payors and production operators, individuals who have reported rents, royalties, and bonuses from oil or other minerals or gas from producing or nonproducing Federal or Indian leases, current and former Federal employees and contractors, state and local government employees, and Tribal government officials. The system also contains records concerning corporations and other business entities that are not subject to the Privacy Act. However, records pertaining to individuals acting on behalf of corporations and other business entities may reflect personal information.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains records relating to the general administration of the MRMSS, and records relating to minerals revenue asset management, compliance management, and financial management. These records are related to business entities and individuals and includes leases, permits, correspondence, forms, disbursements, reports, and other documents which may contain first and last names, addresses, telephone numbers, fax numbers, email addresses, other contact information, lease numbers, revenues collected, outreach information of individual Indian owners, dates due, customer identification number, owner identification number, location of land, type of lease, lessee and/or payor information, allottee production volume, commodity, reported revenues, sales value, royalty amounts, tax identification number, rate billed, amount charged, interest and penalty, collection actions, bank account number, check number, amount paid, contract number, agreement number, allotment number, well number, and other information that may be generated or maintained during the processing and administration of minerals revenue management responsibilities. The records concerning corporations and other business entities are compliance activities and are not subject to the Privacy Act. However, records pertaining to individuals acting on behalf of corporations and other business entities may reflect personal information.

ONRR Outreach program activities include phone calls, email, and correspondence, as well as meetings with individual Indian owners that have ownership in revenues that come from mineral leases. These records may include first and last name, email address, phone number, individual owner identification, allocated ownership percentage, estimated revenues from leases, and other information that may be contained in correspondence with or requests from individuals generated through outreach activities to support and provide a response to customer inquiries.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Federal Oil and Gas Royalty Management Act of 1982, 30 U.S.C. 1701–1759; Chapter 12 of Title 25 of the U.S. Code, addressing the lease, sale, or surrender of allotted or unallotted lands, found at 25 U.S.C. 391–416j; Chapter 3A of Title 30 of the U.S. Code, addressing leases and prospecting permits, found at 30 U.S.C. 181–196; and the Outer Continental Shelf Lands Act, 43 U.S.C. 1331–1356b.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The purposes of the system are to collect royalties and rents; control revenues; distribute funds collected; maintain records of royalty accounts and associated sales and production information; provide data to facilitate comparative auditing of mineral production, royalties due, revenues collected, and funds distributed; gather statistics for managing the mineral leasing program; provide informational access to external users including states, Indian tribes or agencies, and Federal agencies; and provide outreach services to the Indian community.

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be

disclosed outside DOI as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

(1) (a) To any of the following entities or individuals, when the circumstances set forth in paragraph (b) are met:

(i) The U.S. Department of Justice (DOJ);

(ii) A court or an adjudicative or other administrative body;

(iii) A party in litigation before a court or an adjudicative or other administrative body; or

(iv) Any DOI employee acting in his or her individual capacity if DOI or DOJ has agreed to represent that employee or pay for private representation of the employee;

(b) When:

(i) One of the following is a party to the proceeding or has an interest in the proceeding:

(A) DOI or any component of DOI;

(B) Any other Federal agency appearing before the U.S. Department of the Interior's Office of Hearings and Appeals;

(C) Any DOI employee acting in his or her official capacity;

(D) Any DOI employee acting in his or her individual capacity if DOI or DOJ has agreed to represent that employee or pay for private representation of the employee;

(E) The United States, when DOJ determines that DOI is likely to be affected by the proceeding; and

(ii) DOI deems the disclosure to be:

(A) Relevant and necessary to the proceeding; and

(B) Compatible with the purpose for which the records were compiled.

(2) To a congressional office in response to a written inquiry that an individual covered by the system, or the heir of such individual if the covered individual is deceased, has made to the office.

(3) To any criminal, civil, or regulatory law enforcement authority (whether Federal, state, local, tribal or foreign) when a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature, and the disclosure is compatible with the purpose for which the records were compiled.

(4) To an official of another Federal agency to provide information needed in the performance of official duties related to reconciling or reconstructing data files or to enable that agency to respond to an inquiry by the individual to whom the record pertains.

(5) To Federal, state, local, tribal, or foreign agencies that have requested information relevant or necessary to the hiring, firing or retention of an employee or contractor, or the issuance of a security clearance, license, contract, grant or other benefit, when the disclosure is compatible with the purpose for which the records were compiled.

(6) To representatives of the National Archives and Records Administration (NARA) to conduct records management inspections under the authority of 44 U.S.C. 2904 and 2906.

(7) To state, territorial and local governments and tribal organizations to provide information needed in response to court order and/or discovery purposes related to litigation, when the disclosure is compatible with the purpose for which the records were compiled.

(8) To an expert, consultant, or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on DOI's behalf to carry out the purposes of the system.

(9) To appropriate agencies, entities, and persons when:

(a) It is suspected or confirmed that the security or confidentiality of information in the system of records has been compromised; and

(b) DOI has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interest, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DOI or another agency or entity) that rely upon the compromised information; and

(c) The disclosure is made to such agencies, entities and persons who are reasonably necessary to assist in connection with DOI's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

(10) To the Office of Management and Budget (OMB) during the coordination and clearance process in connection with legislative affairs as mandated by OMB Circular A–19.

(11) To the Department of the Treasury to recover debts owed to the United States.

(12) To the news media and the public, with the approval of the Public Affairs Officer in consultation with counsel and the Senior Agency Official for Privacy, where there exists a legitimate public interest in the disclosure of the information, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

(13) To other Federal agencies for the purpose of submitting reports, data and information related to the production of minerals such as oil, gas and solids associated with the management of revenues.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Pursuant to 5 U.S.C. 552a(b)(12), disclosures may be made to a consumer reporting agency as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1996 (31 U.S.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in paper form in file folders stored in file cabinets, and electronic media such as computers, magnetic disk, diskette, compact discs and computer tapes. The electronic records are maintained in removable drives, computer servers, email and electronic databases.

RETRIEVABILITY:

Customer records are retrieved by name or customer identification number, owner name, or owner identification number; land information is retrieved by location and whether or not the lease is an Indian lease or a Federal onshore or offshore lease. Records are indexed by lease or contract number; lessee and/or payor; permittee; production reporter; and/or commodity.

SAFEGUARDS:

The records contained in this system are safeguarded in accordance with 43 CFR 2.226 and other applicable security and privacy rules and policies. During normal hours of operation, paper records are maintained in locked filed cabinets under the control of authorized personnel. Computerized records systems follow the National Institute of Standards and Technology standards as developed to comply with the Privacy Act of 1974, 5 U.S.C. 552a; Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521; Federal Information Security Modernization Act of 2014, 44 U.S.C. 3551–3558; and the Federal Information Processing Standards 199: Standards for Security Categorization of Federal Information and Information Systems. Computer servers in which electronic records are stored are located in secured contractor facilities with physical, technical and administrative levels of security to prevent unauthorized access to the DOI network and information assets. Security controls include

encryption, firewalls, audit logs, and network system security monitoring.

Electronic data is protected through user identification, passwords, database permissions and software controls. Access to records in the system is limited to authorized personnel who have a need to access the records in the performance of their official duties, and each user's access is restricted to only the functions and data necessary to perform that person's job responsibilities. System administrators and authorized users are trained and required to follow established internal security protocols and must complete all security, privacy, and records management training and sign the DOI Rules of Behavior. A privacy impact assessment was conducted to ensure appropriate controls and safeguards are in place to protect the information within the system.

RETENTION AND DISPOSAL:

Records in this system are maintained under the Minerals Management Service (MMS) Comprehensive Schedule approved by NARA (NC1–057–84–07), which include both permanent and temporary dispositions. These records are subject to litigation holds and permanent retention. Administrative records and general correspondence files have temporary dispositions and are maintained in accordance their respective records schedules dependent on the specific subject matter or function and retention requirements. Temporary mission files related to mineral resource, lease and royalty management activities are cut off at the close of the fiscal year then transferred to a Federal records center, one year after cutoff, and destroyed 7 years after cutoff. Approved disposition methods include shredding or pulping paper records, and degaussing or erasing electronic records in accordance with 384 Department Manual 1 and NARA guidelines.

SYSTEM MANAGER AND ADDRESS:

MRMSS Program Manager, Information Management Center (IMC), Office of Natural Resources Revenue, U.S. Department of the Interior, P.O. Box 25165, Lakewood, Colorado 80225.

NOTIFICATION PROCEDURES:

An individual requesting notification of the existence of records on himself or herself should send a signed, written inquiry to the System Manager identified above. The request envelope and letter should both be clearly marked ''PRIVACY ACT INQUIRY.'' A request for notification must meet the requirements of 43 CFR 2.235.

RECORDS ACCESS PROCEDURES:

An individual requesting records on himself or herself should send a signed, written inquiry to the System Manager identified above. The signed request should describe the records sought as specifically as possible. The request envelope and letter should both be clearly marked ''PRIVACY ACT REQUEST FOR ACCESS.'' A request for access must meet the content requirements of 43 CFR 2.238.

CONTESTING RECORDS PROCEDURES:

An individual requesting corrections or the removal of material from his or her records should send a signed, written request to the System Manager identified above. A request for corrections or removal must meet the requirements of 43 CFR 2.246.

RECORD SOURCE CATEGORIES:

Information in the system is obtained directly from lease and permit holders, current and former landowners and lessees, royalty payors and production operators, individuals who have reported rents, royalties, and bonuses from oil or other minerals or gas from producing or nonproducing Federal or Indian leases, current and former Federal employees and contractors, state and local government employees, and Tribal government officials. Information may also be obtained from DOI bureau and office records supporting revenue management and outreach activities including the Bureau of Ocean Energy Management, Bureau of Safety and Environmental Enforcement, Bureau of Land Management, Bureau of Indian Affairs, Office of the Special Trustee for American Indians, other offices or programs providing support or data for this system, and other Federal, state, tribal or local agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2016–06813 Filed 3–24–16; 8:45 am]

BILLING CODE 4334–03–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORC01000.L63100000.HD0000. 16XL1116AF; HAG 16–0098]

Notice of Public Meeting for the Coastal Oregon Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, and the U.S. Department of the Interior, Bureau of Land Management (BLM), the Coastal Oregon Resource Advisory Council (RAC) will meet as indicated below:

DATES: The Coastal Oregon RAC will hold a public meeting Thursday, April 7th, 2016, from 12:30 p.m. to 5:00 p.m. and Friday, April 8th, 2016, from 8:00 a.m. to 2:30 p.m.

ADDRESSES: The Coastal Oregon RAC will meet at the Coos Bay District Office, 1300 Airport Lane, North Bend, Oregon 97459.

FOR FURTHER INFORMATION CONTACT: Megan Harper, Public Affairs Specialist, BLM Coos Bay District Office, 1300 Airport Lane, North Bend, Oregon 97459, (541) 751–4353, or email *m1harper@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1 (800) 877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Coastal Oregon RAC consists of 15 members chartered and appointed by the Secretary of the Interior. Their diverse perspectives are represented in commodity, conservation, and general interests. They provide advice to BLM resource managers regarding management plans and proposed resource actions on public land in coastal Oregon. Tentative agenda items for the April 7th and 8th, 2016, meeting include review and recommendation of projects to fund under Title II of the Secure Rural Schools and Community Self Determination Act, as reauthorized. Any other matters that may reasonably come before the Coastal Oregon RAC may also be addressed. This meeting is open to the public in its entirety.

A public comment period will be available on April 7th, 2016 at 3:45 p.m. Unless otherwise approved by the Coastal Oregon RAC Chair, the public comment period will last no longer than 30 minutes, and each speaker may address the Coastal Oregon RAC for a maximum of 5 minutes. Meeting times and the duration scheduled for public comment periods may be extended or altered when the authorized representative considers it necessary to accommodate necessary business and all who seek to be heard regarding matters before the Coastal Oregon RAC.

Before including your address, phone number, email address, or other personal identifying information in your

comments, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Patricia Burke,

Coos Bay District Manager.

[FR Doc. 2016–06799 Filed 3–24–16; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–20410; PPWOCRADP2, PCU00RP14.R50000]

National Historic Landmarks Committee of the National Park System Advisory Board Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16), and Part 65 of title 36 of the Code of Federal Regulations, that a meeting of the National Historic Landmarks Committee of the National Park System Advisory Board will be held beginning at 10:00 a.m. on May 9, 2016, at the Charles Sumner School Museum and Archives. The meeting will continue beginning at 9:30 a.m. on May 10, 2016.

DATES: The meeting will be held on Monday, May 9, 2016, from 10:00 a.m. to 4:30 p.m.; and Tuesday, May 10 from 9:30 a.m. to 4:30 p.m. (EASTERN).

Location: The Charles Sumner School Museum and Archives, 3rd Floor, the Richard L. Hurlbut Memorial Hall, 1201 17th Street NW., Washington, DC 20036.

Agenda: The National Park System Advisory Board and its National Historic Landmarks Committee may consider the following nominations:

California

CHICANO PARK, San Diego, CA
NEUTRA STUDIO AND RESIDENCES (VDL RESEARCH HOUSE), Los Angeles, CA

Iowa

KIMBALL VILLAGE SITE, Plymouth County, IA

Kansas

WYANDOTTE NATIONAL BURYING GROUND (ELIZA BURTON CONLEY BURIAL SITE), Kansas City, KS

Maryland

SHIFFERSTADT, Frederick, MD

Mississippi

MEDGAR WILEY AND MYRLIE EVERS HOUSE, Jackson, MS

New York

FRANKLIN D. ROOSEVELT LIBRARY, Hyde Park, NY
NEW YORK STATE BARGE CANAL HISTORIC DISTRICT

Albany County, NY

City of Cohoes
Colonie
Cayuga County
Aurelius
Brutus
Cato
Conquest
Mentz
Montezuma

Erie County, NY

City of Tonawanda
Amherst
Tonawanda

Herkimer County, NY

City of Little Falls
Danube
Frankfort
German Flatts
Herkimer
Little Falls
Manheim
Ohio
Russia
Schuyler
Village of Frankfort
Village of Herkimer
Village of Ilion
Village of Mohawk

Madison County, NY

Lenox
Sullivan

Monroe County, NY

City of Rochester
Brighton
Chili
Clarkson
Trenton
Verona
Vienna
Western
Village of Sylvan Beach

Onondaga County, NY

City of Syracuse
Cicero
Clay
Elbridge
Geddes
Lysander
Salina
Van Buren
Village of Baldwinsville
Village of Liverpool

Orleans County, NY

Albion
Gaines
Murray
Ridgeway
Shelby
Village of Albion
Village of Holley
Village of Medina

Oswego County, NY

City of Fulton
City of Oswego
Constantia
Granby
Hastings
Minetto
Schroeppel
Scriba
Volney
West Monroe
Village of Cleveland
Village of Phoenix

Rensselaer County, NY

City of Troy
Schaghticoke

Saratoga County, NY

City of Mechanicville
Clifton Park
Halfmoon
Moreau
Northumberland
Saratoga
Stillwater
Waterford
Village of Schuylerville
Village of Stillwater
Village of Waterford

Schenectady County, NY

City of Schenectady
Glenville
Niskayuna
Rotterdam
Village of Scotia

Seneca County, NY

Seneca Falls
Tyre
Waterloo
Village of Waterloo

Washington County, NY

Easton
Fort Ann
Fort Edward
Greenwich
Hartford
Kingsbury
Whitehall
Village of Fort Ann
Village of Fort Edward
Village of Whitehall

Wayne County, NY

Arcadia

Galen
Lyons
Macedon
Palmyra
Savannah
Village of Clyde
Village of Lyons
Village of Macedon
Village of Newark
Village of Palmyra
SCHOMBURG CENTER FOR RESEARCH IN BLACK CULTURE, New York, NY

Ohio

GREENHILLS HISTORIC DISTRICT, Greenhills, OH

Pennsylvania

KEIM HOMESTEAD, Oley, PA

Proposed Amendments to Existing Designations:

Arizona

TALIESIN WEST, Maricopa County, AZ (boundary change)

Illinois

RIVERSIDE HISTORIC DISTRICT, Village of Riverside, IL (boundary change)

Indiana

INDIANA WAR MEMORIALS HISTORIC DISTRICT, Indianapolis, IN (updated documentation, boundary and name change)

Louisiana

MAISON OLIVIER (ACADIAN HOUSE), St. Martinville, LA (updated documentation and name change)

Maryland

MONOCACY BATTLEFIELD, City of Frederick and Frederick County, MD (updated documentation and boundary change)

North Carolina

OLD SALEM HISTORIC DISTRICT, Winston-Salem, NC (updated documentation and boundary change)

Texas

CASA NAVARRO, San Antonio, TX

Virginia

BALL'S BLUFF BATTLEFIELD AND NATIONAL CEMETERY, Leesburg, VA (boundary change and updated documentation)
VIRGINIA STATE CAPITOL, Richmond, VA (name change)

Proposed Withdrawal of Designations:

Louisiana

KATE CHOPIN HOUSE, Cloutierville, LA

The committee may also consider the following historic trail:

REVISION OF FEASIBILITY STUDIES OF OREGON, CALIFORNIA, MORMON PIONEER AND PONY EXPRESS NATIONAL HISTORIC TRAILS, CA, CO, ID, IA, KS, MO, NE., NV, OK, OR, UT, WA, AND WY

FOR FURTHER INFORMATION CONTACT: Patricia Henry, Historian, National Historic Landmarks Program, National Park Service, 1849 C Street NW., Washington, DC 20240, email: (202) 354–2216 or email: *Patty_Henry@nps.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the meeting of the National Historic Landmarks Committee of the National Park System Advisory Board is to evaluate nominations of historic properties in order to advise the National Park System Advisory Board of the qualifications of each property being proposed for National Historic Landmark designation, and to make recommendations regarding the possible designation of those properties as National Historic Landmarks to the National Park System Advisory Board at a subsequent meeting at a place and time to be determined. The Committee also makes recommendations to the National Park System Advisory Board regarding amendments to existing designations and proposals for withdrawal of designation. The members of the National Historic Landmarks Committee are:

Dr. Stephen Pitti, Chair
Dr. James M. Allan
Dr. Cary Carson
Dr. Yong Chen
Mr. Douglas Harris
Ms. Mary Hopkins
Mr. Luis Hoyos, AIA
Dr. Sarah A. Leavitt
Dr. Barbara J. Mills
Dr. Michael E. Stevens
Dr. Amber Wiley
Dr. David Young

The meeting will be open to the public. Pursuant to 36 CFR part 65, any member of the public may file, for consideration by the National Historic Landmarks Committee of the National Park System Advisory Board, written comments concerning the National Historic Landmarks nominations, amendments to existing designations, or proposals for withdrawal of designation.

Comments should be submitted to J. Paul Loether, Chief, National Historic Landmarks Program and National Register of Historic Places, National Park Service, 1849 C Street NW., Washington, DC 20240, email: *Paul_Loether@nps.gov.*

Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: March 21, 2016.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2016–06848 Filed 3–24–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–GETT–20484; PPMPSPD1Z.YM0000, PPNEGETTS1]

Notice of 2016 Meeting Schedule for Gettysburg National Military Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Notice of meetings.

SUMMARY: This notice announces a schedule of upcoming meetings for the Gettysburg National Military Park Advisory Commission.

DATES: The Gettysburg National Military Park Advisory Commission will host two meetings on Thursday, April 28, 2016, and Thursday, September 15, 2016. Both scheduled meetings will begin at 7:00 p.m. and end at 9:00 p.m. (EASTERN). Efforts have been made locally to ensure that the interested public is aware of the meeting dates.

Locations: Both meetings will be held at the Gettysburg National Military Park Museum and Visitor Center in the Ford Education Center, 1195 Baltimore Pike, Suite 100, Gettysburg, Pennsylvania 17325.

FOR FURTHER INFORMATION CONTACT: Ed Clark, Superintendent and Designated Federal Official, Gettysburg National Military Park, 1195 Baltimore Pike, Suite 100, Gettysburg, Pennsylvania 17325, or telephone (717) 334–1124 or email *ed_w_clark@nps.gov.*

SUPPLEMENTARY INFORMATION: The Gettysburg National Military Park Advisory Commission was established by Public Law 101–377. The scheduled meetings will be open to the public. Each scheduled meeting will include presentations on the Gettysburg National Military Park Operational Update, and subcommittee reports. The April 28, 2016, meeting will also have the nomination of new officers. Any member of the public may file with the committee a written statement with

issues or concerns. The statement should be addressed to Gettysburg National Military Park Advisory Commission, 1195 Baltimore Pike, Gettysburg, PA 17325.

Before including your address, telephone number, email address, or other personal identifying information in your comments—you should be aware that your entire comment—including your personal identifying information may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Dated: March 21, 2016.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2016–06844 Filed 3–24–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SERO–NCPTT–20489; PPWOCRADTI–PCU00PT14.GT0000]

Notice of April 20–21, 2016, Meeting of the Preservation Technology and Training Board

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 1–16), that the Preservation Technology and Training Board (PTT Board) of the National Center for Preservation Technology and Training (NCPTT), National Park Service, will meet on April 20, 2016, and April 21, 2016, at Ball State University in Muncie, Indiana.

The PTT Board's meeting agenda will include: Review and comment on the NCPTT FY 2015 accomplishments, and operational priorities for FY 2016; FY 2015 and FY 2016 NCPTT budget and initiatives; recent research; and training programs.

DATES: Wednesday, April 20, 2016, 9:00 a.m. to 5:00 p.m. (CDT) and Thursday, April 21, 2016, 9:00 a.m. to 12:00 p.m. (CDT) in Muncie, Indiana.

ADDRESSES: The meeting location on Wednesday, April 20, 2016: Ball State University, L.A. Pittenger Student Center, Forum Room, 2nd Floor, Muncie, Indiana 47306. The meeting location on Thursday, April 21, 2016: Ball State University, Bracken Library, Room 215, 2nd Floor, Muncie, Indiana 47306.

FOR FURTHER INFORMATION CONTACT: Persons wishing more information concerning this meeting, or who wish to submit written statements, may contact: Kirk A. Cordell, Executive Director, National Center for Preservation Technology and Training, National Park Service, U.S. Department of the Interior, 645 University Parkway, Natchitoches, LA 71457, telephone (318) 356–7444 or via email *kirk_cordell@nps.gov.* In addition to U.S. mail or commercial delivery, written comments may be sent by fax to Mr. Cordell at (318) 356–9119.

SUPPLEMENTARY INFORMATION: The PTT Board was established by Congress to provide leadership, policy advice, and professional oversight to the NCPTT in compliance with Section 404 of the National Historic Preservation Act of 1966, as amended, (54 U.S.C. 305303).

The PTT Board meeting is open to the public. Facilities and space for accommodating members of the public are limited; however, visitors will be accommodated on a first-come, first-served basis. Any member of the public may file a written statement concerning any of the matters to be discussed by the PTT Board.

Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Minutes of the meeting will be available for public inspection no later than 90 days after the meeting at the office of the Executive Director, National Center for Preservation Technology and Training, National Park Service, U.S. Department of the Interior, 645 University Parkway, Natchitoches, LA 71457, telephone (318) 356–7444.

Dated: March 21, 2016.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2016–06846 Filed 3–24–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–GETT–20397; PPMPSPD1Z.YM0000] [PPNEGETTS1]

Request for Nominations for the Gettysburg National Military Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service (NPS), U.S. Department of the Interior, proposed to appoint new member to the Gettysburg National Military Park Advisory Commission (Commission). The NPS is requesting nominations for qualified persons to serve as members of the Commission.

DATES: Written nominations must be received by April 25, 2016.

ADDRESSES: Nominations or requests for further information should be sent to Catherine Lawhon, Management Assistant, Gettysburg National Military Park/Eisenhower National Historic Site, 1195 Baltimore Pike, Suite 100, Gettysburg, Pennsylvania, 17325, telephone at (717) 338–4402.

FOR FURTHER INFORMATION CONTACT: Catherine Lawhon, Management Assistant, Gettysburg National Military Park/Eisenhower National Historic Site, 1195 Baltimore Pike, Suite 100, Gettysburg, Pennsylvania, 17325, telephone at (717) 338–4402, email *katie_lawhon@nps.gov.*

SUPPLEMENTARY INFORMATION: The Commission was established by Public Law 101–377 (16 U.S.C. 430g–8), to advise the Secretary of the Interior on the coordination of the management of the Gettysburg National Military Park and Gettysburg Battlefield Historic District with local governmental jurisdictions.

The Commission is composed of 11 members, 10 of whom are appointed by the Secretary of the Interior, as follows: (a) One member representing each of the four townships surrounding the park (Cumberland, Mount Joy, Mount Pleasant, Straban Townships) and the Borough of Gettysburg; (b) one member representing the Adams County, Pennsylvania government; (c) one member representing the Pennsylvania State Historic Preservation Office; (d) two members who are residents of Adams County and are knowledgeable about the park and its resources, one of whom owns land or interests in land within the park boundary; and (e) one member with expertise in local historic preservation. The Director of the National Park Service or a designee, is an ex officio, non-voting member.

Each member shall be appointed for a term of three years. A member may serve after the expiration of that member's term until a successor has taken office. The Chairperson of the Commission shall be elected by the members.

We are currently seeking members representing Mount Joy Township, Straban Township, and the State Historic Preservation Office of the Commonwealth of Pennsylvania.

Nominations should be typed and should include a resume providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the Commission and permit the Department of the Interior to contact a potential member.

Members of the Commission serve without compensation. However, while away from their homes or regular places of business in the performance of services for the Commission as approved by the Designated Federal Officer, members may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in Government service are allowed such expenses under Section 5703 of Title 5 of the United States Code.

Individuals who are Federally registered lobbyists are ineligible to serve on all FACA and non-FACA boards, committees, councils in an individual capacity. The term ''individual capacity'' refers to individuals who are appointed to exercise their own individual best judgment on behalf of the government, such as when they are designated Special Government Employees, rather than being appointed to represent a particular interest.

Dated: March 15, 2016.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2016–06843 Filed 3–24–16; 8:45 am]

BILLING CODE 4310–EE–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Motorized Self-Balancing Vehicles, DN 3129;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,[1] and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.[2] The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.[3] Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Razor USA LLC, Inventist, Inc. and Shane Chen on March 22, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain motorized self-balancing vehicles. The complaint names as respondents Alibaba Group Holding Ltd. of Hong Kong; Alibaba Group Holding Ltd. (U.S.) of San Mateo, CA; Alibaba.com Ltd. of China; Alibaba Global Shipping Inc. a.k.a Alibaba Logistics, Inc. of Oakland, CA; Hangzhou Chic Intelligent Technology Co., Ltd. of China; Contixo of Ontario, CA; ZTO Store a.k.a. ZTO Trading, Inc. of Monterey Park, CA; CyBoard LLC a.k.a. Shark Empire Inc. of Glendale, CA; Genius Technologies a.k.a. Prime Capital of Hastings, MN; GyroGlyder.com of Stockton, CA; HoverTech of Hebron, KY; InMotion Entertainment Group LLC of Jacksonville, FL; Soibatian Corporation dba IO Hawk and dba Smart Wheels of Glendale, CA; Jetson Electric Bikes LLC of New York, NY; Joy Hoverboard, a.k.a. Huizhou Aoge Enterprize Co. Ltd. of China; Shenzhen Kebe Technology Co., Ltd. of China; Leray Group of China; Modell's Sporting Goods, Inc. of New York, NY; Newegg.com Inc. of City of Industry, CA; PhunkeeDuck, Inc. of Floral Park, NY; Powerboard a.k.a. Optimum Trading Co. of Hebron, KY; Shareconn International, Inc. of China; Shenzhen Chenduoxing Electronic Technology Ltd. of China; Shenzhen Jomo Technology Co., Ltd. of China ; Shenzhen R.M.T. Technology Co., Ltd. of China; Shenzhen Supersun Technology Co. Ltd., a.k.a. Aottom of China; Skque Products of Irwindale, CA; Spaceboard USA of Norcross, GA; Swagway LLC of Southbend, IN; Twizzle Hoverboard of La Puente, CA; and Uwheels of Santa Ana, CA. The complainant requests that the Commission issue a general exclusion order, or in the alternative, a limited exclusion order, and a cease and desist order.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third

[1] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[2] United States International Trade Commission (USITC): *http://edis.usitc.gov.*

[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3129'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [4]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[5]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: March 22, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–06816 Filed 3–24–16; 8:45 am]

BILLING CODE 7020–02–P

[4] Handbook for Electronic Filing Procedures: *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.*

[5] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–970]

Certain Height Adjustable Desk Platforms and Components Thereof Commission Determination Not To Review an Initial Determination Granting a Joint Motion To Terminate the Investigation on the Basis of Settlement; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 14) granting the joint motion of complainant Varidesk LLC of Coppell, Texas (''Varidesk'') and respondent Brunswick Corp. of Lake Forest, Illinois (''Brunswick'') to terminate the above-referenced investigation on the basis of a patent license, and settlement and release agreement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 6, 2015, based on a Complaint filed by Varidesk, as supplemented and amended. 80 *FR* 68877–78 (Nov. 6, 2015). The Complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain height adjustable desk platforms and components thereof by reason of infringement of certain claims of U.S. Patent No. 9,113,703. The Complaint further alleges the existence of a domestic industry. The Commission's Notice of Investigation named Brunswick as the only respondent. The Office of Unfair Import Investigations (''OUII'') was also named as a party to the investigation.

On February 17, 2016, Varidesk and Brunswick filed a joint motion to terminate this investigation based on a patent license, and settlement and release agreement. On February 25, 2016, OUII filed a response supporting the motion.

On February 25, 2016, the ALJ issued the subject ID, granting the joint motion for termination of the investigation. The ALJ found that the joint motion complied with the requirements of Commission Rule 210.21(b)(1) and that granting the motion would not be contrary to the public interest.

No petitions for review of the subject ID were filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: March 22, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–06808 Filed 3–24–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0031]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection Application for Registration Under Domestic Chemical Diversion Control Act of 1993, Renewal Application for Registration Under Domestic Chemical Diversion Control Act of 1993; DEA Forms 510, 510A

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information

collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** at 81 FR 2240, January 15, 2016, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until April 25, 2016.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Registration under Domestic Chemical Diversion Control Act of 1993; Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Forms: 510, 510A. The applicable component within the Department of Justice is the Drug Enforcement Administration, Office of Diversion Control.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): None.

Abstract: The DEA implements the Controlled Substances Act (CSA) which requires that every person who manufactures or distributes a list I chemical shall annually obtain a registration for that purpose.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

	Number of annual respondents	Average time per response	Total annual burden hours
DEA–510 (paper)	14	0.20 hours (12 minutes)	2.80
DEA–510 (electronic)	116	0.17 hours (8 minutes)	15.47
DEA–510A (paper)	97	0.2 hours (10 minutes)	16.17
DEA–510A (electronic)	827	0.07 hours (4 minutes)	55.13
Total	1,054		89.57

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates that this collection takes 89.57 annual burden hours.

If additional information is required please contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 3E.405B, Washington, DC 20530.

Dated: March 22, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–06790 Filed 3–24–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice Lodging of Proposed Consent Decree Under the Oil Pollution Act

On March 21, 2016, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Puerto Rico in the lawsuit entitled *United States et al.* v. *GMR Progress LLC et al.,* Civil Action No. 3:16–cv–01507.

The Consent Decree resolves the United States' and the Commonwealth of Puerto Rico's claims set forth in the complaint against Defendants GMR Progress LLC and General Maritime Management (Portugal) Lda for natural resource damages caused by an oil spill from the vessel Genmar Progress on August 29, 2007. Under the Consent Decree, the Defendants will pay a total of $2,750,000, including $83,090 in assessment costs and $2,666,910 to restore the injury to natural resources resulting from the Spill.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division and should refer to *United States et al.* v. *GMR Progress et al.,* D.J. Ref. No. 90–5–1–1–11218. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*

To submit comments:	Send them to:
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $13.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $5.25.

Robert E. Maher,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–06789 Filed 3–24–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Advisory Board; Notice of Meeting

This notice announces a forthcoming meeting of the National Institute of Corrections (NIC) Advisory Board. The meeting will be open to the public.

Name of the Committee: NIC Advisory Board.

General Function of the Committee: To aid the National Institute of Corrections in developing long-range plans, advise on program development, and to support NIC's efforts in the areas of training, technical assistance, information services, and policy/program development assistance to Federal, state, and local corrections agencies.

Date and Time: 8:00 a.m.–4:30 p.m. on Thursday, May 5, 2016. 8:00 a.m.–12:00 p.m. on Friday, May 6, 2016.

Location: National Institute of Corrections, 500 First Street NW., 2nd Floor, Washington, DC 20534, (202) 514–4222.

Contact Person: Shaina Vanek, Executive Assistant, National Institute of Corrections, 320 First Street NW., Room 5002, Washington, DC 20534. To contact Ms. Vanek, please call (202) 514–4222.

Agenda: On May 5–6, 2016, the Advisory Board will hear updates on the following topics: (1) Agency Report from the NIC Director, (2) a briefing from NIC Jails Division on current activities and future goals, (3) submission and discussion of the final report from the Staff Wellness Subcommittee, and (4) partner agency updates.

Procedure: On May 5–6, 2016, the meetings are open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations from the public will be scheduled between approximately 11:15 a.m. to 11:30 a.m. and 4:00 p.m. and 4:15 p.m. on May 5, 2016 and between 11:15 a.m. and 11:30 a.m. on May 6, 2016. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 27, 2016.

General Information: NIC welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shaina Vanek at least 7 days in advance of the meeting. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Jim Cosby,

Director, National Institute of Corrections.

[FR Doc. 2016–06625 Filed 3–24–16; 8:45 am]

BILLING CODE 4410–36–M

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Innovation and Opportunity Act (WIOA) 2014; Lower Living Standard Income Level (LLSIL)

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: Title I of WIOA (Pub. L.113–128) requires the U.S. Secretary of Labor (Secretary) to update and publish the LLSIL tables annually, for uses described in the law (including determining eligibility for youth). WIOA defines the term ''low income individual'' as one who qualifies under various criteria, including an individual in a family with total family income for a six-month period that does not exceed the higher level of the poverty line or 70 percent of the LLSIL. This issuance provides the Secretary's annual LLSIL for 2016 and references the current 2016 Health and Human Services ''Poverty Guidelines.''

DATES: This notice is effective March 25, 2016.

FOR FURTHER INFORMATION OR QUESTIONS ON LLSIL: Please contact Samuel Wright, Department of Labor, Employment and Training Administration, 200 Constitution Avenue NW., Room C–4526, Washington, DC 20210; Telephone: 202–693–2870; Fax: 202–693–3015 (these are not toll-free numbers); Email address: *wright.samuel.e@dol.gov.* Individuals with hearing or speech impairments may access the telephone number above via Text Telephone (TTY/TDD) by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

FOR FURTHER INFORMATION OR QUESTIONS ON FEDERAL YOUTH EMPLOYMENT PROGRAMS: Please contact Jennifer Kemp, Department of Labor, Employment and Training Administration, 200 Constitution Avenue NW., Room N–4464, Washington, DC 20210; Telephone: 202–693–3377; Fax: 202–693–3113 (these are not toll-free numbers); Email: *kemp.jennifer.n@dol.gov.* Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

SUPPLEMENTARY INFORMATION: The purpose of WIOA is to provide workforce investment activities through statewide and local workforce investment systems that increase the employment, retention, and earnings of participants. WIOA programs are intended to increase the occupational skill attainment by participants and the quality of the workforce, thereby reducing welfare dependency and enhancing the productivity and competitiveness of the Nation.

LLSIL is used for several purposes under the WIOA. Specifically, WIOA SEC.3(36) (A)(B)defines the term ''low income individual'' for eligibility purposes, and SEC.127(b)(2)(c), SEC.132(b)(1)(B)(IV),(V)(bb) define the terms ''disadvantaged youth'' and ''disadvantaged adult'' in terms of the poverty line or LLSIL for State formula allotments. The governor and state/local

workforce development boards (WDs) use the LLSIL for determining eligibility for youth and adults for certain services. ETA encourages governors and State/local boards to consult the WIOA regulations and the preamble to the WIOA Final Rule for more specific guidance in applying LLSIL to program requirements. The U.S. Department of Health and Human Services (HHS) published the most current poverty-level guidelines in the **Federal Register** on January 25, 2016 (Volume 81, Number 15), pp. 4036–4037. The HHS 2016 Poverty guidelines may also be found on the Internet at *https://aspe.hhs.gov/poverty-guidelines.* ETA plans to have the 2016 LLSIL available on its Web site at *http://www.doleta.gov/llsil.*

WIOA Section 3(36)(B) defines LLSIL as ''that income level (adjusted for regional, metropolitan, urban and rural differences and family size) determined annually by the Secretary [of Labor] based on the most recent lower living family budget issued by the Secretary.'' The most recent lower living family budget was issued by the Secretary in fall 1981. The four-person urban family budget estimates, previously published by the U.S. Bureau of Labor Statistics (BLS), provided the basis for the Secretary to determine the LLSIL. BLS terminated the four-person family budget series in 1982, after publication of the fall 1981 estimates. Currently, BLS provides data to ETA, which ETA then uses to develop the LLSIL tables, as provided in the Appendices to this **Federal Register** notice.

ETA published the 2015 updates to the LLSIL in the **Federal Register** of March 27, 2015, at Vol. 80, No.59 pp. 16450–16456. Last year, ETA also published a correction to three Regions in the **Federal Register** of July 16, 2015 at Vol. 80, No. 136 pp. 42123–42124. These notices again update the LLSIL to reflect cost of living increases for 2015, by calculating the percentage change in the most recent 2014 Consumer Price Index for All Urban Consumers (CPI–U) for an area to the 2015 CPI–U, and then applying this calculation to each of the March 27, 2015 LLSIL figures. This year, a Region and several metro areas had a negative CPI–U due mostly to the decline in gas prices.

The updated figures for a four-person family are listed in Appendix A, Table 1, by region for both metropolitan and non-metropolitan areas. Numbers in all of the Appendix tables are rounded up to the nearest dollar. Since program eligibility for low-income individuals, ''disadvantaged adults'' and ''disadvantaged youth'' may be determined by family income at 70 percent of the LLSIL, pursuant to WIOA Section 3 (36)(A)(ii) and Section 3(36)(B), respectively, those figures are listed as well.

I. Jurisdictions

Jurisdictions included in the various regions, based generally on the Census Regions of the U.S. Department of Commerce, are as follows:

A. Northeast

Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island,Vermont, Virgin Islands

B. Midwest

Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin,

C. South

Alabama, American Samoa, Arkansas, Delaware, District of Columbia, Florida, Georgia, Northern Marianas, Oklahoma, Palau, Puerto Rico, South Carolina, Kentucky, Louisiana, Marshall Islands, Maryland, Micronesia, Mississippi, North Carolina, Tennessee, Texas, Virginia, West Virginia

D. West

Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming

Additionally, separate figures have been provided for Alaska, Hawaii, and Guam as indicated in Appendix B, Table 2.

For Alaska, Hawaii, and Guam, the year 2016 figures were updated from the 2015 ''State Index'' based on the ratio of the urban change in the state (using Anchorage for Alaska and Honolulu for Hawaii and Guam) compared to the West regional metropolitan change, and then applying that index to the West regional metropolitan change.

Data on 23 selected Metropolitan Statistical Areas (MSAs) are also available. These are based on annual and semiannual CPI–U changes for a 12-month period ending in December 2015. The updated LLSIL figures for these MSAs and 70 percent of LLSIL are reported in Appendix C, Table 3.

Appendix D, Table 4 lists each of the various figures at 70 percent of the updated 2015 LLSIL for family sizes of one to six persons. Because Tables 1–3 only list the LLSIL for a family of four, Table 4 can be used to separately determine the LLSIL for families of between one and six persons. For families larger than six persons, an amount equal to the difference between the six-person and the five-person family income levels should be added to the six-person family income level for each additional person in the family. Where the poverty level for a particular family size is greater than the corresponding 70 percent of the LLSIL figure, the figure is shaded. A modified Microsoft Excel version of Appendix D, Table 4, with the area names, will be available on the ETA LLSIL Web site at *http://www.doleta.gov/llsil.* Appendix E, Table 5, indicates 100 percent of LLSIL for family sizes of one to six, and is used to determine self-sufficiency as noted at Section 3 (36)(a)(ii) and Section 3 (36)(B),(C)(ii) in WIOA.

II. Use of These Data

Governors should designate the appropriate LLSILs for use within the State from Appendices A, B, and C, containing Tables 1 through 3. Appendices D and E, which contain Tables 4 and 5, which adjust a family of four figure for larger and smaller families, may be used with any LLSIL designated area. The governor's designation may be provided by disseminating information on MSAs and metropolitan and non-metropolitan areas within the state or it may involve further calculations. For example, the State of New Jersey may have four or more LLSIL figures for Northeast metropolitan, Northeast non-metropolitan, portions of the state in the New York City MSA, and those in the Philadelphia MSA. If a workforce investment area includes areas that would be covered by more than one LLSIL figure, the governor may determine which is to be used.

A state's policies and measures for the workforce investment system shall be accepted by the Secretary to the extent that they are consistent with WIOA and WIOA regulations.

III. Disclaimer on Statistical Uses

It should be noted that publication of these figures is only for the purpose of meeting the requirements specified by WIOA as defined in the law and regulations. BLS has not revised the lower living family budget since 1981, and has no plans to do so. The four-person urban family budget estimates series has been terminated. The CPI–U adjustments used to update LLSIL for this publication are not precisely comparable, most notably because certain tax items were included in the 1981 LLSIL, but are not in the CPI–U. Thus, these figures should not be used for any statistical purposes, and are valid only for those purposes under WIOA as defined in the law and regulations.

Appendix A

TABLE 1—LOWER LIVING STANDARD INCOME LEVEL (FOR A FAMILY OF FOUR PERSONS) BY REGION [1]

Region [2]	2015 adjusted LLSIL	70 percent LLSIL
Northeast:		
Metro	$ 42,164	$ 29,514
Non-Metro [3]	41,826	29,279
Midwest:		
Metro	36,977	25,884
Non-Metro	35,740	25,018
South:		
* Metro	35,803	25,062
Non-Metro	35,568	24,898
* West:		
Metro	41,048	28,734
Non-Metro [4]	40,580	28,406

* The South Metro Region and the West Metro and Non-Metro Regions 2015 LLSIL were adjusted.
[1] For ease of use, these figures are rounded to the next highest dollar.
[2] Metropolitan area measures were calculated from the weighted average CPI–U's for city size classes A and B/C. Non-metropolitan area measures were calculated from the CPI–U's for city size class D.
[3] Non-metropolitan area percent changes for the Northeast region are no longer available. The Non-metropolitan percent change was calculated using the U.S. average CPI–U for city size class D.
[4] Non-metropolitan area percent changes for the West region are based on unpublished BLS data.

Appendix B

TABLE 2—LOWER LIVING STANDARD INCOME LEVEL (FOR A FAMILY OF FOUR PERSONS), FOR ALASKA, HAWAII AND GUAM [1]

Region [1]	2015 adjusted LLSIL	70 percent LLSIL
Alaska:		
Metro [2]	$ 47,899	$ 33,529
Non-Metro [3]	52,482	36,737
Hawaii, Guam:		
Metro	52,587	36,811
Non-Metro [3]	56,028	39,220

[1] For ease of use, these figures are rounded to the next highest dollar.
[2] The CPI–U change was negative.
[3] Non-Metropolitan percent changes for Alaska, Hawaii and Guam were calculated from the CPI–U's for all urban consumers for city size class D in the Western Region. Generally the non-metro areas LLSIL is lower than the LLSIL in metro areas. This year the non-metro area LLSIL incomes were larger because the change in CPI–U was smaller in the metro areas compared to the change in CPI–U in the non-metro areas of Alaska, Hawaii and Guam.

Appendix C

TABLE 3—LOWER LIVING STANDARD INCOME LEVEL (FOR A FAMILY OF FOUR PERSONS), FOR 23 SELECTED MSAS [1]

Metropolitan statistical areas (MSAs) [1]	2016 adjusted LLSIL	70 percent LLSIL
Anchorage, AK [2]	$49,096	$34,367
Atlanta, GA [2]	34,370	24,059
Boston—Brockton—Nashua, MA/NH/ME/CT	45,346	31,742
Chicago—Gary—Kenosha, IL/IN/WI	38,019	26,613
Cincinnati—Hamilton, OH/KY/IN	36,435	25,505
Cleveland—Akron, OH	37,800	26,460
Dallas—Ft. Worth, TX	34,141	23,899
Denver—Boulder—Greeley, CO	38,913	27,239
Detroit—Ann Arbor—Flint, MI [2]	35,202	24,641
Honolulu, HI	53,532	37,473
Houston—Galveston—Brazoria, TX	34,842	24,389
Kansas City, MO/KS	35,159	24,612
Los Angeles—Riverside—Orange County, CA [2]	42,146	29,502
Milwaukee—Racine, WI	36,705	25,694
Minneapolis—St. Paul, MN/WI	36,942	25,859
New York—Northern NJ—Long Island, NY/NJ/CT/PA [2]	45,008	31,506
Philadelphia—Wilmington—Atlantic City, PA/NJ/DE/MD	40,855	28,599
Pittsburgh, PA	44,940	31,458

TABLE 3—LOWER LIVING STANDARD INCOME LEVEL (FOR A FAMILY OF FOUR PERSONS), FOR 23 SELECTED MSAS [1]—Continued

Metropolitan statistical areas (MSAs) [1]	2016 adjusted LLSIL	70 percent LLSIL
St. Louis, MO/IL	34,557	24,190
San Diego, CA	46,922	32,846
San Francisco—Oakland—San Jose, CA	45,389	31,772
Seattle—Tacoma—Bremerton, WA	45,018	31,512
Washington—Baltimore, DC/MD/VA/WV [2]	45,551	31,885

[1] For ease of use, these figures are rounded to the next highest dollar.
[2] The CPI–U change was negative.
[2] Baltimore and Washington are calculated as a single metropolitan statistical area.

Appendix D

Table 4: 70 Percent of Updated 2015 Lower Living Standard Income Level (LLSIL), by Family Size

To use the 70 percent LLSIL value, where it is stipulated for the WIOA programs, begin by locating the region or metropolitan area where the program applicant resides. These are listed in Tables 1, 2 and 3. After locating the appropriate region or metropolitan statistical area, find the 70 percent LLSIL amount for that location. The 70 percent LLSIL figures are listed in the last column to the right on each of the three tables. These figures apply to a family of four. Larger and smaller family eligibility is based on a percentage of the family of four. To determine eligibility for other size families consult Table 4 and the instructions below.

To use Table 4, locate the 70 percent LLSIL value that applies to the individual's region or metropolitan area from Tables 1, 2 or 3. Find the same number in the ''family of four'' column of Table 4. Move left or right across that row to the size that corresponds to the individual's family unit. That figure is the maximum household income the individual is permitted in order to qualify as economically disadvantaged under the WIOA.

Where the HHS poverty level for a particular family size is greater than the corresponding LLSIL figure, the LLSIL figure appears in a shaded block. Individuals from these size families may consult the 2016 HHS poverty guidelines found on the Health and Human Services Web site at *https://aspe.hhs.gov/poverty-guidelines* to find the higher eligibility standard. Individuals from Alaska and Hawaii should consult the HHS guidelines for the generally higher poverty levels that apply in their States.

Family Of One	Family of Two	Family of Three	Family of Four	Family of Five	Family of Six
8,609	14,107	19,363	23,899	28,207	32,985
8,663	14,197	19,495	24,059	28,393	33,203
8,715	14,278	19,598	24,190	28,548	33,383
8,787	14,396	19,759	24,389	28,783	33,661
8,860	14,524	19,942	24,612	29,045	33,969
8,874	14,539	19,963	24,641	29,078	34,004
8,970	14,695	20,169	24,898	29,382	34,361
9,015	14,761	20,267	25,018	29,530	34,533
9,027	14,790	20,300	25,062	29,579	34,595
9,184	15,054	20,665	25,505	30,100	35,200
9,250	15,162	20,815	25,694	30,322	35,460
9,313	15,261	20,951	25,859	30,520	35,692
9,319	15,276	20,967	25,884	30,544	35,727
9,528	15,619	21,436	26,460	31,228	36,516
9,581	15,708	21,556	26,613	31,408	36,733
9,810	16,076	22,069	27,239	32,144	37,594
10,228	16,762	23,014	28,406	33,526	39,209
10,301	16,878	23,168	28,599	33,754	39,469
10,345	16,953	23,276	28,734	33,906	39,658
10,542	17,281	23,723	29,279	34,555	40,404
10,622	17,406	23,898	29,502	34,813	40,719
10,629	17,421	23,909	29,514	34,833	40,733
11,331	18,568	25,487	31,458	37,127	43,418
11,344	18,593	25,520	31,506	37,177	43,485
11,352	18,594	25,529	31,512	37,189	43,490
11,429	18,731	25,718	31,742	37,461	43,806

Family Of One	Family of Two	Family of Three	Family of Four	Family of Five	Family of Six
11,444	18,752	25,737	31,772	37,495	43,852
11,484	18,819	25,832	31,885	37,632	44,010
11,831	19,380	26,609	32,846	38,762	45,333
12,076	19,784	27,164	33,529	39,568	46,278
12,378	20,284	27,841	34,367	40,560	47,428
13,231	21,676	29,761	36,737	43,352	50,698
13,259	21,721	29,822	36,811	43,440	50,806
13,495	22,111	30,353	37,473	44,220	51,720
14,124	23,146	31,771	39,220	46,282	54,125

Appendix E

Table 5: Updated 2015 LLSIL (100 Percent), by Family Size

To use the LLSIL to determine the minimum level for establishing self-sufficiency criteria at the State or local level, begin by locating the metropolitan area or region from Table 1, 2 or 3. Then locate the appropriate region or metropolitan statistical area and then find the 2015 adjusted LLSIL amount for that location. These figures apply to a family of four. Locate the corresponding number in the family of four in the column below. Move left or right across that row to the size that corresponds to the individual's family unit. That figure is the minimum figure that States must set for determining whether employment leads to self-sufficiency under WIOA programs.

Family of one	Family of two	Family of three	Family of four	Family of five	Family of six
12,298	20,153	27,662	34,141	40,296	47,121
12,375	20,281	27,850	34,370	40,561	47,433
12,450	20,397	27,997	34,557	40,783	47,691
12,554	20,566	28,227	34,842	41,119	48,087
12,657	20,748	28,488	35,159	41,493	48,527
12,677	20,770	28,518	35,202	41,540	48,577
12,815	20,993	28,813	35,568	41,974	49,087
12,879	21,087	28,953	35,740	42,186	49,333
12,895	21,129	29,000	35,803	42,256	49,421
13,120	21,505	29,522	36,435	43,000	50,285
13,214	21,659	29,735	36,705	43,318	50,658
13,304	21,801	29,931	36,942	43,600	50,989
13,313	21,823	29,953	36,977	43,634	51,039
13,611	22,312	30,622	37,800	44,611	52,166
13,687	22,440	30,794	38,019	44,869	52,476
14,015	22,966	31,528	38,913	45,920	53,705
14,611	23,946	32,877	40,580	47,894	56,013
14,716	24,111	33,098	40,855	48,219	56,385
14,778	24,219	33,252	41,048	48,438	56,654
15,061	24,687	33,890	41,826	49,364	57,720
15,174	24,866	34,140	42,146	49,734	58,170
15,185	24,886	34,156	42,164	49,762	58,190
16,187	26,525	36,410	44,940	53,039	62,025
16,206	26,561	36,458	45,008	53,110	62,122
16,217	26,563	36,470	45,018	53,127	62,128
16,328	26,758	36,741	45,346	53,516	62,580
16,349	26,789	36,767	45,389	53,564	62,646
16,405	26,885	36,902	45,551	53,760	62,872
16,901	27,686	38,013	46,922	55,374	64,762
17,252	28,263	38,805	47,899	56,526	66,111
17,683	28,977	39,773	49,096	57,944	67,755
18,902	30,965	42,515	52,482	61,932	72,425
18,942	31,030	42,604	52,587	62,058	72,580
19,279	31,586	43,361	53,532	63,171	73,885

Family of one	Family of two	Family of three	Family of four	Family of five	Family of six
20,177	33,065	45,387	56,028	66,117	77,322

Portia Wu,

Assistant Secretary for Employment and Training Administration.

[FR Doc. 2016–06764 Filed 3–24–16; 8:45 am]

BILLING CODE 4510–FT–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2016–0009]

Advisory Committee on Construction Safety and Health (ACCSH)

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Announcement of special meeting of the ACCSH.

SUMMARY: ACCSH will hold a special meeting April 25–26, 2016, in Washington, DC, to draft a construction version of OSHA's planned Safety and Health Program Management Guidelines.

DATES: *ACCSH meeting:* ACCSH will meet from 1 to 5:00 p.m., Monday, April 25, 2016, and from 9:00 a.m. to 5:00 p.m., Tuesday, April 26, 2016.

Submit (postmark, send, transmit) comments, requests to address the ACCSH meeting, speaker presentations (written or electronic), and requests for special accommodations for the ACCSH meeting, by April 15, 2016.

ADDRESSES:

Submission of comments, requests to speak, and speaker presentations for the ACCSH meeting: Submit comments, requests to speak, and speaker presentations for the ACCSH meeting, using one of the following methods:

Electronically: Submit materials, including attachments, electronically at: *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the on-line instructions for submissions.

Facsimile (Fax): If the submission, including attachments, does not exceed 10 pages, you may fax it to the OSHA Docket Office at (202) 693–1648.

Regular mail, express mail, hand delivery, or messenger (courier) service: Submit materials to the OSHA Docket Office, Docket No. OSHA–2016–0009, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2350 (TTY (877) 889–5627). OSHA's Docket Office accepts deliveries (hand deliveries, express mail, and messenger service) during normal business hours, 8:15 a.m.–4:45 p.m., e.t., weekdays.

Instructions: Submissions must include the agency name and docket number for this **Federal Register** notice (Docket No. OSHA–2016–0009). Due to security-related procedures, submissions by regular mail may experience significant delays. Please contact the OSHA Docket Office for information about security procedures for making submissions. For additional information on submitting comments, requests to speak, and speaker presentations, see the **SUPPLEMENTARY INFORMATION** section of this notice.

OSHA will post comments, requests to speak, and speaker presentations, including any personal information provided, without change, at: *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting personal information such as Social Security numbers and birthdates.

Location of the ACCSH meeting: ACCSH will meet in Room N–3437 A–C, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Requests for special accommodations: Please submit requests for special accommodations to attend the ACCSH meeting to Ms. Gretta Jameson, OSHA, Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *jameson.grettah@dol.gov.*

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general information about ACCSH and ACCSH meetings: Mr. Damon Bonneau, OSHA, Directorate of Construction, Room N–3468, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2020; email: *bonneau.damon@dol.gov*.

Copies of this ***Federal Register*** *notice:* Electronic copies of this **Federal Register** notice are available at: *http://www.regulations.gov.* This notice, as well as news releases and other relevant information, also are available on the OSHA Web page at: *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

ACCSH Meeting

Background: ACCSH will meet April 25–26, 2016, in Washington, DC. The meeting is open to the public. OSHA transcribes ACCSH meetings and prepares detailed minutes of meetings. OSHA places the transcript and minutes in the public docket for the meeting. The docket also includes speaker presentations, comments, and other materials submitted to ACCSH.

ACCSH advises the Secretary of Labor and the Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) in the formulation of standards affecting the construction industry, and on policy matters arising in the administration of the safety and health provisions under the Contract Work Hours and Safety Standards Act (Construction Safety Act (CSA)) (40 U.S.C. 3701 *et seq.*) and the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) (see also 29 CFR 1911.10 and 1912.3). In addition, the OSH Act and CSA require that the Assistant Secretary consult with ACCSH before the Agency proposes any occupational safety and health standard affecting construction activities (29 CFR 1911.10; 40 U.S.C. 3704).

Meeting agenda: The tentative agenda for this meeting includes:

- Assistant Secretary's remarks;
- Drafting of the construction version of the OSHA Safety and Health Program Management Guidelines; and,
- Public Comment Period.

Attending the meeting: Individuals attending the meeting at the U.S. Department of Labor must enter the building at the visitors' entrance, 3rd and C Streets, NW., and pass through building security. Attendees must have valid government-issued photo identification (such as a driver's license) to enter the building. For additional information about building-security measures for attending ACCSH meetings, please contact Ms. Jameson (see ''*Requests for special accommodations''* in the **ADDRESSES** section of this notice).

Requests to speak and speaker presentations: Attendees who want to address ACCSH at the meeting must submit a request to speak, as well as any written or electronic presentation, by

April 15, 2016, using one of the methods listed in the **ADDRESSES** section. The request must state:

- The amount of time requested to speak;
- The interest you represent (*e.g.,* business, organization, affiliation), if any; and
- A brief outline of your presentation.

PowerPoint presentations and other electronic materials must be compatible with PowerPoint 2010 and other Microsoft Office 2010 formats.

Alternately, at the ACCSH meeting, you may request to address ACCSH briefly by signing the public-comment request sheet and listing the topic(s) you will address. You also must provide 20 hard copies of any materials, written or electronic, you want to present to ACCSH.

The ACCSH Chair may grant requests to address ACCSH as time and circumstances permit.

Public docket of the ACCSH meeting: OSHA will place comments, requests to speak, and speaker presentations, including any personal information you provide, in the public docket of this ACCSH meeting without change, and those documents will be available online at: *http://www.regulations.gov.* OSHA also places in the public docket the meeting transcript, meeting minutes, documents presented at the ACCSH meeting, and other documents pertaining to the ACCSH meeting. These documents are available online at: *http://www.regulations.gov.*

Access to the public record of the ACCSH meeting: To read or download documents in the public docket of this ACCSH meeting, go to Docket No. OSHA–2016–0009 at: *http://www.regulations.gov.* The *http://www.regulations.gov* index also lists all documents in the public record for this meeting; however, some documents (*e.g.,* copyrighted materials) are not publicly available through that Web page. All documents in the public record, including materials not available through *http://www.regulations.gov,* are available for inspection in the OSHA Docket Office (see **ADDRESSES** section). Contact the OSHA Docket Office for assistance in making submissions to, or obtaining materials from, the public docket.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice under the authority granted by 29 U.S.C. 656; 40 U.S.C. 3704; 5 U.S.C. App. 2; 29 CFR parts 1911 and 1912; 41 CFR 102–3; and Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012).

Signed at Washington, DC, on March 21, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–06780 Filed 3–24–16; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL CAPITAL PLANNING COMMISSION

Final Adoption of Updated Federal Elements of the Comprehensive Plan for the National Capital

AGENCY: National Capital Planning Commission.

ACTION: Notice of final adoption of updated *Federal Elements of the Comprehensive Plan for the National Capital.*

SUMMARY: The National Capital Planning Commission (NCPC) adopted updates to the Federal Elements of the *Comprehensive Plan for the National Capital* (Comprehensive Plan) on February 4, 2016. The updated elements will become effective on Tuesday, April 5, 2016.

NCPC is the central planning agency for the federal government in the National Capital Region and prepares and adopts a ''comprehensive, consistent, and coordinated plan for the National Capital.'' The Federal Elements guide planning and development, and address matters related to Federal properties and interests in the National Capital Region, which include the District of Columbia; Montgomery and Prince George's Counties in Maryland; Arlington, Fairfax, Loudoun, and Prince William Counties in Virginia; and all cities within the boundaries of these counties. The Federal Elements provide the policy framework for Commission actions on plans and proposals submitted for its review. The eight Federal Elements in the Comprehensive Plan include Urban Design, Federal Workplace, Foreign Missions & International Organizations, Transportation, Parks & Open Space, Federal Environment, Historic Preservation, and Visitors & Commemoration.

Dates and Time: The 2016 Federal Elements were adopted on February 4, 2016 and will become effective on Tuesday, April 5, 2016.

ADDRESSES: The updated Federal Elements of the *Comprehensive Plan for the National Capital* may be viewed at the National Capital Planning Commission, 401 9th Street NW., Suite 500N, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Angela Dupont at *compplan@ncpc.gov.*

SUPPLEMENTARY INFORMATION: The updated Federal Elements of the *Comprehensive Plan for the National Capital* may be viewed electronically at: *http://www.ncpc.gov/compplan.*

Authority: 40 U.S.C. 8721(a).

Dated: March 17, 2016.

Anne R. Schuyler,

General Counsel.

[FR Doc. 2016–06800 Filed 3–24–16; 8:45 am]

BILLING CODE 7520–01–P

OFFICE OF PERSONNEL MANAGEMENT

Notice of Submission for Approval: Information Collection 3206–0258; Questionnaire for Public Trust Positions (SF 85P) and Supplemental Questionnaire for Selected Positions (SF 85P–S)

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Federal Investigative Services (FIS), U.S. Office of Personnel Management (OPM) is notifying the general public and other federal agencies that OPM is seeking Office of Management and Budget (OMB) approval of a revised information collection control number 3206–0258, Questionnaire for Public Trust Positions, Standard Form 85P (SF 85P) and Supplemental Questionnaire for Selected Positions, Standard Form SF 85P–S (SF 85P–S). OPM is soliciting comments for this collection as required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who

are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

DATES: Comments are encouraged and will be accepted until May 24, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Federal Investigative Services, U.S. Office of Personnel Management, 1900 E Street NW., Washington, DC 20415, Attention: Donna McLeod or by electronic mail at *FISFormsComments@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Federal Investigative Services, U.S. Office of Personnel Management, 1900 E Street NW., Washington, DC 20415, Attention: Donna McLeod or by electronic mail at *FISFormsComments@opm.gov.*

SUPPLEMENTARY INFORMATION: Questionnaire for Public Trust Positions, SF 85P and Supplemental Questionnaire for Selected Positions, SF 85P–S, including accompanying releases, housed in a system named e-QIP (Electronic Questionnaires for Investigative Processing), are information collections completed by applicants for, or incumbents of, Federal Government civilian positions, or positions in private entities performing work for the Federal Government under contract (SF 85P only). The collections are used as the basis of information for background investigations to establish that such persons are:

- Suitable for employment or retention in Federal employment in a public trust position or fit for employment or retention in Federal employment in the excepted service when the duties to be performed are equivalent in degree of trust reposed in the incumbent to a public trust position;
- Fit to perform work on behalf of the Federal Government pursuant to the Government contract, when the duties to be performed are equivalent in degree of trust reposed in the individual to a public trust position;
- Eligible for physical and logical access to federally controlled facilities or information systems, when the duties to be performed by the individual are equivalent to the duties performed by an employee in a public trust position.

The SF 85P and SF 85P–S are completed by applicants for, or incumbents of, Federal Government civilian positions, or positions in private entities performing work for the Federal Government under contract. For applicants, the SF 85P and SF 85P–S are to be used only after a conditional offer of employment has been made. The SF 85P–S is supplemental to the SF 85P and is used only as approved by OPM, for certain positions such as those requiring carrying of a firearm. e-QIP (Electronic Questionnaires for Investigations Processing) is a web-based system application that houses the SF 85P and SF 85P–S. A variable in assessing burden hours is the nature of the electronic application. The electronic application includes branching questions and instructions which provide for a tailored collection from the respondent based on varying factors in the respondent's personal history. The burden on the respondent is reduced when the respondent's personal history is not relevant to particular question, since the question branches, or expands for additional details, only for those persons who have pertinent information to provide regarding that line of questioning. Accordingly, the burden on the respondent will vary depending on whether the information collection relates to the respondent's personal history.

OPM proposes new changes to the SF 85P. The proposed changes identified in this notice represent modifications to the last approved version of this collection which were published in a 60-day notice in the **Federal Register** on December 29, 2010 (**Federal Register** Notices/Volume 75, Number 249, pages 82095–82097) and in a 30-day notice in the **Federal Register** on August 20, 2012, (**Federal Register** Notices/Volume 77, Number 161, pages 50175–50184). A copy of the latest approved version of this collection and the new proposed changes is available upon request, as noted above. The instructional portion of the form will be modified to provide additional explanatory information regarding the collection of the spouse or cohabitant's social security number. OPM will remove instructions that were needed only for persons completing a paper form, as the form is only collected by OPM through electronic means. OPM will request, in section 7, ''Your Contact Information'' that the respondent provide three contact numbers to facilitate contact between investigative personnel and the respondent; however respondents will be advised that only one number is required. Section 9, ''Citizenship'' will be expanded to collect additional information to assist in verifying derived citizenship of respondents born outside of the U.S. Section 18, ''Relatives'' will include additional categories of relatives about which information will be collected, namely ''Half-brother, Half-sister, Father-in-law, Mother-in-law, and Guardian'' to align the collection with the information required per investigative standards for public trust positions. Section 19, ''Foreign Countries You Have Visited'' will be amended to clarify that travel solely for U.S. Government business is travel ''on official Government orders.'' Section 21, ''Illegal Use of Drugs and Drug Activity'' will include instruction to clarify that drug use or activity illegal under Federal laws must be reported, even if that use or activity is legal under state or local law(s). Changes are proposed in section 26, ''Involvement in Non-Criminal Court Actions to collect information regarding the respondent's participation in non-criminal court actions whereas the previous collection was limited to the respondent's participation in such court actions when he or she was the defendant. The general ''Authorization for Release of Information'' includes clarifying language noting that ''other sources of information'' from which information is gathered during the investigation may include publically available electronic information, including public posts on social media. The ''Fair Credit Reporting Disclosure and Authorization'' includes an updated reference to the noted Executive Order.

OPM proposes changes to the SF 85P–S. Question 3, 'Your Use of Illegal Drugs and Drug Activity'' will also include clarifying instruction that drug use or activity illegal under Federal laws must be reported, even if that use or activity is legal under state or local law(s). It is possible that there will be additional changes to conform language on the SF 85P–S to language in similar forms.

This ICR also requests categorizing these forms as common forms. OPM will continue to estimate the burden based on all Federal agencies that submit the SF 85P and SF 85P–S to OPM for investigation. If and when approves the use of common forms, all Federal agencies using these forms not in connection with an OPM investigation may request the use of these common forms without additional 60 or 30 day notice and comment requirements. At that point, each such agency will account for its number of respondents and the burden associated with the agency's use.

Analysis

Agency: Federal Investigative Services, U.S. Office of Personnel Management.

Title: Questionnaire for Public Trust Positions (SF 85P) and Supplemental Questionnaire for Selected Positions (SF 85P–S).

OMB Number: 3206–0258.

Affected Public: The SF 85P and SF 85P–S are information collections completed by applicants for, or incumbents of, Federal Government civilian positions, or positions in private entities performing work for the Federal Government under contract. The SF 85P will be used by the Federal Government in conducting background investigations and reinvestigations of persons under consideration for, or retention of, public trust positions. The form may also be used by agencies in determining whether a subject performing work for, or on behalf of, the Government under a contract, should be deemed eligible for logical or physical access. For applicants, the SF 85P and SF 85P–S are to be used only after a conditional offer of employment has been made. The SF 85P–S is supplemental to the SF 85P and is used only as approved by OPM, for certain positions such as those requiring carrying of a firearm.

Number of Respondents: 112,894 (SF 85P); 11,717 (SF 85P–S).

Estimated Time per Respondent: 155 minutes (SF 85P); 10 minutes (SF 85P–S).

Total Burden Hours: 282,235 (SF 85P); 1,953 (SF 85P–S).

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–06811 Filed 3–24–16; 8:45 am]

BILLING CODE 6325–53–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–99 and CP2016–127; Order No. 3171]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 198 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* March 28, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 198 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–99 and CP2016–127 to consider the Request pertaining to the proposed Priority Mail Contract 198 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than March 28, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–99 and CP2016–127 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than March 28, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–06732 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail Contract 198 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, March 18, 2016 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–105 and CP2016–133; Order No. 3173]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail & First-Class Package Service Contract 16 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* March 28, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail & First-Class Package

Service Contract 16 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–105 and CP2016–133 to consider the Request pertaining to the proposed Priority Mail & First-Class Package Service Contract 16 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than March 28, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–105 and CP2016–133 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than March 28, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–06738 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 16 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, March 18, 2016 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–98 and CP2016–126; Order No. 3172]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 197 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* March 28, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 197 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

[1] Request of the United States Postal Service to Add Priority Mail Contract 197 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, March 18, 2016 (Request).

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–98 and CP2016–126 to consider the Request pertaining to the proposed Priority Mail Contract 197 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than March 28, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Jennaca D. Upperman to serve as Public Representative in these dockets.

III. Request for Supplemental Information

The version of the contract provided to the Commission under seal appears to redact information in Section F. The Postal Service is requested to provide an explanation and, if necessary, file an errata. The Postal Service response is due no later than March 23, 2016.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–98 and CP2016–126 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. The Postal Service's response to the request for supplemental information is due no later than March 23, 2016.

4. Comments are due no later than March 28, 2016.

5. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–06733 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a

domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 197 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–98, CP2016–126.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06743 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Select Contract 14 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–102, CP2016–130.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06751 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 16 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–105, CP2016–133.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06752 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 200 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–101, CP2016–129.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06741 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add First-Class Package Service Contract 46 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–103, CP2016–131.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06739 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add First-Class Package Service Contract 47 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–104, CP2016–132.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06740 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express Contract 35 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–107, CP2016–135.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06754 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 198 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–99, CP2016–127.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06750 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 199 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–100, CP2016–128.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06742 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 18, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 28 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–106, CP2016–134.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–06753 Filed 3–24–16; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32033; 812–14555]

Premise Capital, LLC, et al.; Notice of Application

March 21, 2016.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940, as amended (the ''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.

SUMMARY OF APPLICATION: Applicants request an order that would permit (a) series of certain open-end management investment companies to issue shares (''Shares'') redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Shares to be effected at negotiated market prices rather than at net asset value (''NAV''); (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days after the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares beyond the limits of Section 12(d)(1)(A) and (B) the Act.

APPLICANTS: Premise Capital, LLC (the ''Initial Adviser''), ETF Series Solutions (the ''Trust'') and Quasar Distributors, LLC (''Quasar'').

FILING DATES: The application was filed on September 30, 2015, and amended on January 22, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission

orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 15, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: Premise Capital, LLC, 300 E. 5th Ave. Suite 265, Naperville, IL, 60563; The Trust and Quasar, 615 East Michigan Street, 4th Floor, Milwaukee, Wisconsin 53202, c/o W. John McGuire, Esq., Morgan Lewis & Bockius LLP, 1111 Pennsylvania Avenue NW., Washington, DC 20004–2541 and Michael D. Barolsky, Esq., U.S. Bancorp Fund Services, LLC, 615 Michigan Street Milwaukee, WI 53202.

FOR FURTHER INFORMATION CONTACT: Rachel Loko, Senior Counsel, at (202) 551–6883, or Holly Hunter-Ceci, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is a Delaware statutory trust and is registered under the Act as an open-end management investment company with multiple series. Each series will operate as an exchange traded fund (''ETF'').

2. The Initial Adviser will be the investment adviser to the new series of the Trust (''Initial Fund''). The Initial Adviser is, and any other Adviser (as defined below) will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Adviser may enter into sub-advisory agreements with one or more investment advisers to act as sub-advisers to particular Funds (each, a ''Sub-Adviser''). Any Sub-Adviser will either be registered under the Advisers Act or will not be required to register thereunder.

3. The Trust will enter into a distribution agreement with one or more distributors. Each distributor for a Fund will be a broker-dealer (''Broker'') registered under the Securities Exchange Act of 1934 (''Exchange Act'') and will act as distributor and principal underwriter (''Distributor'') for one or more of the Funds. No Distributor is or will be affiliated with any national securities exchange, as defined in Section 2(a)(26) of the Act (''Exchange''). The Distributor for each Fund will comply with the terms and conditions of the requested order. Quasar, a Delaware limited liability company and broker-dealer registered under the Exchange Act, will act as the initial Distributor of the Funds.

4. Applicants request that the order apply to the Initial Fund and any additional series of the Trust, and any other open-end management investment company or series thereof, that may be created in the future (''Future Funds'' and together with the Initial Fund, ''Funds''), each of which will operate as an ETF and will track a specified index comprised of domestic or foreign equity and/or fixed income securities (each, an ''Underlying Index''). Any Future Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each, an ''Adviser'') and (b) comply with the terms and conditions of the application.[1]

5. Each Fund will hold certain securities, currencies, other assets, and other investment positions (''Portfolio Holdings'') selected to correspond closely to the performance of its Underlying Index. Certain Underlying Indexes will be comprised of equity and/or fixed income securities issued by one or more of the following categories of issuers: (i) Domestic issuers and (ii) non-domestic issuers meeting the requirements for trading in U.S. markets. Other Funds will be based on Underlying Indexes that will be comprised of foreign and domestic, or solely foreign, equity and/or fixed income securities (''Foreign Funds'').

6. Applicants represent that each Fund will invest at least 80% of its assets (excluding collateral held from securities lending) in the component securities of its respective Underlying Index (''Component Securities'') and TBA Transactions,[2] and in the case of Foreign Funds, Component Securities and Depositary Receipts [3] representing Component Securities. Each Fund may also invest up to 20% of its assets in certain index futures, options, options on index futures, swap contracts or other derivatives, as related to its respective Underlying Index and its Component Securities, cash and cash equivalents, other investment companies, as well as in securities and other instruments not included in its Underlying Index but which the Adviser believes will help the Fund track its Underlying Index. A Fund may also engage in short sales in accordance with its investment objective.

7. Each Trust may issue Funds that seek to track Underlying Indexes constructed using 130/30 investment strategies (''130/30 Funds'') or other long/short investment strategies (''Long/Short Funds''). Each Long/Short Fund will establish (i) exposures equal to approximately 100% of the long positions specified by the Long/Short Index [4] and (ii) exposures equal to approximately 100% of the short positions specified by the Long/Short Index. Each 130/30 Fund will include strategies that: (i) Establish long positions in securities so that total long exposure represents approximately 130% of a Fund's net assets; and (ii) simultaneously establish short positions in other securities so that total short exposure represents approximately 30% of such Fund's net assets. Each Business Day, for each Long/Short Fund and 130/30 Fund, the Adviser will provide full portfolio transparency on the Fund's publicly available Web site (''Web site'') by making available the Fund's Portfolio

[1] All existing entities that intend to rely on the requested order have been named as applicants. Any other existing or future entity that subsequently relies on the order will comply with the terms and conditions of the order. A Fund of Funds (as defined below) may rely on the order only to invest in Funds and not in any other registered investment company.

[2] A ''to-be-announced transaction'' or ''TBA Transaction'' is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree upon general trade parameters such as agency, settlement date, par amount and price. The actual pools delivered generally are determined two days prior to settlement date.

[3] Depositary receipts representing foreign securities (''Depositary Receipts'') include American Depositary Receipts and Global Depositary Receipts. The Funds may invest in Depositary Receipts representing foreign securities in which they seek to invest. Depositary Receipts are typically issued by a financial institution (a ''depositary bank'') and evidence ownership interests in a security or a pool of securities that have been deposited with the depositary bank. A Fund will not invest in any Depositary Receipts that the Adviser or any Sub-Adviser deems to be illiquid or for which pricing information is not readily available. No affiliated person of a Fund, the Adviser or any Sub-Adviser will serve as the depositary bank for any Depositary Receipts held by a Fund.

[4] Underlying Indexes that include both long and short positions in securities are referred to as ''Long/Short Indexes.''

Holdings (defined below) before the commencement of trading of Shares on the Listing Exchange (defined below).[5] The information provided on the Web site will be formatted to be reader-friendly.

8. A Fund will utilize either a replication or representative sampling strategy to track its Underlying Index. A Fund using a replication strategy will invest in the Component Securities of its Underlying Index in the same approximate proportions as in such Underlying Index. A Fund using a representative sampling strategy will hold some, but not necessarily all of the Component Securities of its Underlying Index. Applicants state that a Fund using a representative sampling strategy will not be expected to track the performance of its Underlying Index with the same degree of accuracy as would an investment vehicle that invested in every Component Security of the Underlying Index with the same weighting as the Underlying Index. Applicants expect that the returns of each Fund will have an annual tracking error of less than 5% relative to its Underlying Index.

9. Each Fund will be entitled to use its Underlying Index pursuant to either a licensing agreement with the entity that compiles, creates, sponsors or maintains the Underlying Index (each, an ''Index Provider'') or a sub-licensing arrangement with the Adviser, which will have a licensing agreement with such Index Provider.[6] A ''Self-Indexing Fund'' is a Fund for which an affiliated person, as defined in section 2(a)(3) of the Act (''Affiliated Person''), or an affiliated person of an Affiliated Person (''Second-Tier Affiliate''), of the Trust or a Fund, of the Adviser, of any Sub-Adviser to or promoter of a Fund, or of the Distributor (each, an ''Affiliated Index Provider'') will serve as the Index Provider. In the case of Self-Indexing Funds, an Affiliated Index Provider will create a proprietary, rules-based methodology to create Underlying Indexes (each an ''Affiliated Index'').[7] Except with respect to the Self-Indexing Funds, no Index Provider is or will be an Affiliated Person, or a Second-Tier Affiliate, of a Trust or a Fund, of the Adviser, of any Sub-Adviser to or promoter of a Fund, or of the Distributor.

10. Applicants recognize that Self-Indexing Funds could raise concerns regarding the ability of the Affiliated Index Provider to manipulate the Underlying Index to the benefit or detriment of the Self-Indexing Fund. Applicants further recognize the potential for conflicts that may arise with respect to the personal trading activity of personnel of the Affiliated Index Provider who have access to or knowledge of changes to an Underlying Index's composition methodology or the constituent securities in an Underlying Index prior to the time that information is publicly disseminated.

11. Applicants propose that each Self-Indexing Fund will post on its Web site, on each day the Fund is open, including any day when it satisfies redemption requests as required by Section 22(e) of the Act (a ''Business Day''), before commencement of trading of Shares on the Listing Exchange, the identities and quantities of the Portfolio Holdings that will form the basis for the Fund's calculation of its NAV at the end of the Business Day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will also provide an effective additional mechanism for addressing any such potential conflicts of interest.

12. In addition, Applicants do not believe the potential for conflicts of interest raised by the Adviser's use of the Underlying Indexes in connection with the management of the Self Indexing Funds and the Affiliated Accounts will be substantially different from the potential conflicts presented by an adviser managing two or more registered funds. Both the Act and the Advisers Act contain various protections to address conflicts of interest where an adviser is managing two or more registered funds and these protections will also help address these conflicts with respect to the Self-Indexing Funds.[8]

13. Each Adviser and any Sub-Adviser has adopted or will adopt, pursuant to Rule 206(4)–7 under the Advisers Act, written policies and procedures designed to prevent violations of the Advisers Act and the rules thereunder. These include policies and procedures designed to minimize potential conflicts of interest among the Self-Indexing Funds and the Affiliated Accounts, such as cross trading policies, as well as those designed to ensure the equitable allocation of portfolio transactions and brokerage commissions. In addition, the Initial Adviser will adopt policies and procedures as required under section 204A of the Advisers Act, which are reasonably designed in light of the nature of its business to prevent the misuse, in violation of the Advisers Act or the Exchange Act or the rules thereunder, of material non-public information by the Initial Adviser or an associated person (''Inside Information Policy''). Any other Adviser or Sub-Adviser will be required to adopt and maintain a similar Inside Information Policy. In accordance with the Code of Ethics [9] and Inside Information Policy of the Adviser and any Sub-Adviser, personnel of those entities with knowledge about the composition of the Portfolio Deposit [10] will be prohibited from disclosing such information to any other person, except as authorized in the course of their employment, until such information is made public. In addition, an Index Provider will not provide any information relating to changes to an Underlying Index's methodology for the inclusion of component securities, the inclusion or exclusion of specific component securities, or methodology for the calculation or the return of component securities, in advance of a public announcement of such changes by the Index Provider.[11] The Adviser will also

[5] Under accounting procedures followed by each Fund, trades made on the prior Business Day (''T'') will be booked and reflected in NAV on the current Business Day (T+1). Accordingly, the Funds will be able to disclose at the beginning of the Business Day the portfolio that will form the basis for the NAV calculation at the end of the Business Day.

[6] The licenses for the Self-Indexing Funds will specifically state that the applicable Affiliated Index Provider (as defined below), or in case of a sub-licensing agreement, the applicable Adviser, must provide the use of the Affiliated Indexes (as defined below) and related intellectual property at no cost to the Trust and the Self-Indexing Funds.

[7] The Affiliated Indexes may be made available to registered investment companies, as well as separately managed accounts of institutional investors and privately offered funds that are not deemed to be ''investment companies'' in reliance on section 3(c)(1) or 3(c)(7) of the Act of which the Adviser acts as adviser or subadviser (''Affiliated Accounts'') as well as other such registered investment companies, separately managed accounts and privately offered funds for which it does not act either as adviser or subadviser (''Unaffiliated Accounts''). The Affiliated Accounts and the Unaffiliated Accounts, like the Funds, would seek to track the performance of one or more Underlying Index(es) by investing in the constituents of such Underlying Indexes or a representative sample of such constituents of the Underlying Index. Consistent with the relief requested from section 17(a), the Affiliated Accounts will not engage in Creation Unit transactions with a Fund.

[8] *See, e.g.,* Rule 17j–1 under the Act and Section 204A of the Advisers Act and Rules 204A–1 and 206(4)–7 under the Advisers Act.

[9] The Adviser has also adopted or will adopt a code of ethics pursuant to Rule 17j–1 under the Act and Rule 204A–1 under the Advisers Act, which contains provisions reasonably necessary to prevent Access Persons (as defined in Rule 17j–1) from engaging in any conduct prohibited in Rule 17j–1 (''Code of Ethics'').

[10] The instruments and cash that the purchaser is required to deliver in exchange for the Creation Units it is purchasing are referred to as the ''Portfolio Deposit.''

[11] In the event that an Adviser or Sub-Adviser serves as the Affiliated Index Provider for a Self-Indexing Fund, the terms ''Affiliated Index Provider'' or ''Index Provider,'' with respect to that

Continued

include under Item 10.C of Part 2 of its Form ADV a discussion of its relationship to any Affiliated Index Provider and any material conflicts of interest resulting therefrom, regardless of whether the Affiliated Index Provider is a type of affiliate specified in Item 10.

14. To the extent the Self-Indexing Funds transact with an Affiliated Person of the Adviser or Sub-Adviser, such transactions will comply with the Act, the rules thereunder and the terms and conditions of the requested order. In this regard, each Self-Indexing Fund's board of directors or trustees (''Board'') will periodically review the Self-Indexing Fund's use of an Affiliated Index Provider. Subject to the approval of the Self-Indexing Fund's Board, the Adviser, Affiliated Persons of the Adviser (''Adviser Affiliates'') and Affiliated Persons of any Sub-Adviser (''Sub-Adviser Affiliates'') may be authorized to provide custody, fund accounting and administration and transfer agency services to the Self-Indexing Funds. Any services provided by the Adviser, Adviser Affiliates, Sub-Adviser and Sub-Adviser Affiliates will be performed in accordance with the provisions of the Act, the rules under the Act and any relevant guidelines from the staff of the Commission. Applications for prior orders granted to Self-Indexing Funds have received relief to operate such funds on the basis discussed above.[12]

15. The Shares of each Fund will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified below, purchasers will be required to purchase Creation Units by making an in-kind deposit of specified instruments (''Deposit Instruments''), and shareholders redeeming their Shares will receive an in-kind transfer of specified instruments (''Redemption Instruments'').[13] On any given Business Day, the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, unless the Fund is Rebalancing (as defined below). In addition, the Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions)[14] except: (a) In the case of bonds, for minor differences when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement; (b) for minor differences when rounding is necessary to eliminate fractional shares or lots that are not tradeable round lots;[15] (c) TBA Transactions, short positions, derivatives and other positions that cannot be transferred in kind[16] will be excluded from the Deposit Instruments and the Redemption Instruments;[17] (d) to the extent the Fund determines, on a given Business Day, to use a representative sampling of the Fund's portfolio;[18] or (e) for temporary periods, to effect changes in the Fund's portfolio as a result of the rebalancing of its Underlying Index (any such change, a ''Rebalancing''). If there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Deposit Instruments or Redemption Instruments exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the ''Cash Amount'').

16. Purchases and redemptions of Creation Units may be made in whole or in part on a cash basis, rather than in kind, solely under the following circumstances: (a) To the extent there is a Cash Amount; (b) if, on a given Business Day, the Fund announces before the open of trading that all purchases, all redemptions or all purchases and redemptions on that day will be made entirely in cash; (c) if, upon receiving a purchase or redemption order from an Authorized Participant, the Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash;[19] (d) if, on a given Business Day, the Fund requires all Authorized Participants purchasing or redeeming Shares on that day to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are not eligible for transfer through either the NSCC or DTC (defined below); or (ii) in the case of Foreign Funds holding non-U.S. investments, such instruments are not eligible for trading due to local trading restrictions, local restrictions on securities transfers or other similar circumstances; or (e) if the Fund permits an Authorized Participant to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are, in the case of the purchase of a Creation Unit, not available in sufficient quantity; (ii) such instruments are not eligible for trading by an Authorized Participant or the investor on whose behalf the Authorized Participant is acting; or (iii) a holder of Shares of a Foreign Fund holding non-U.S. investments would be subject to unfavorable income tax treatment if the holder receives redemption proceeds in kind.[20]

17. Creation Units will consist of specified large aggregations of Shares (*e.g.,* 25,000 Shares) as determined by the Adviser, and it is expected that the initial price of a Creation Unit will range from $1 million to $10 million.

Self-Indexing Fund, will be limited to the employees of the applicable Adviser or Sub-Adviser that are responsible for creating, compiling and maintaining the relevant Underlying Index.

[12] *See, e.g.,* FFI Advisors, LLC, et al., Investment Company Act Release No. 31669 (June 15, 2015) (notice) and 31713 (July 13, 2015) (order); Diamond Hill Capital Management, Inc., et al., Investment Company Act Release No. 31433 (Jan. 28, 2015) (notice) and 31472 (Feb. 24, 2015) (order); ETF Securities Advisors LLC, et al., Investment Company Act Release No. 31346 (Nov. 24, 2014) (notice) and 31395 (Dec. 22, 2014) (order) (collectively, ''Prior Orders'').

[13] The Funds must comply with the federal securities laws in accepting Deposit Instruments and satisfying redemptions with Redemption Instruments, including that the Deposit Instruments and Redemption Instruments are sold in transactions that would be exempt from registration under the Securities Act of 1933 (''Securities Act''). In accepting Deposit Instruments and satisfying redemptions with Redemption Instruments that are restricted securities eligible for resale pursuant to rule 144A under the Securities Act, the Funds will comply with the conditions of rule 144A.

[14] The portfolio used for this purpose will be the same portfolio used to calculate the Fund's NAV for the Business Day.

[15] A tradeable round lot for a security will be the standard unit of trading in that particular type of security in its primary market.

[16] This includes instruments that can be transferred in kind only with the consent of the original counterparty to the extent the Fund does not intend to seek such consents.

[17] Because these instruments will be excluded from the Deposit Instruments and the Redemption Instruments, their value will be reflected in the determination of the Cash Amount (as defined below).

[18] A Fund may only use sampling for this purpose if the sample: (i) Is designed to generate performance that is highly correlated to the performance of the Fund's portfolio; (ii) consists entirely of instruments that are already included in the Fund's portfolio; and (iii) is the same for all Authorized Participants on a given Business Day.

[19] In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis (whether for a given day or a given order), the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, the Adviser may be able to obtain better execution than Share purchasers because of the Adviser's size, experience and potentially stronger relationships in the fixed income markets. Purchases of Creation Units either on an all cash basis or in-kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in-kind redemption. As a result, tax consideration may warrant in-kind redemptions.

[20] A ''custom order'' is any purchase or redemption of Shares made in whole or in part on a cash basis in reliance on clause (e)(i) or (e)(ii).

All orders to purchase Creation Units must be placed with the Distributor by or through an ''Authorized Participant'' which is either (1) a ''Participating Party,'' *i.e.,* a Broker or other participant in the Continuous Net Settlement System of the NSCC, a clearing agency registered with the Commission, or (2) a participant in The Depository Trust Company (''DTC'') (''DTC Participant''), which, in either case, has signed a participant agreement with the Distributor. The Distributor will be responsible for transmitting the orders to the Funds and will furnish to those placing such orders confirmation that the orders have been accepted, but applicants state that the Distributor may reject any order which is not submitted in proper form.

18. Each Business Day, before the open of trading on the Exchange on which Shares are primarily listed (''Listing Exchange''), each Fund will cause to be published through the NSCC the names and quantities of the instruments comprising the Deposit Instruments and the Redemption Instruments, as well as the estimated Cash Amount (if any), for that day. The list of Deposit Instruments and Redemption Instruments will apply until a new list is announced on the following Business Day, and there will be no intra-day changes to the list except to correct errors in the published list. Each Listing Exchange will disseminate, every 15 seconds during regular Exchange trading hours, through the facilities of the Consolidated Tape Association, an amount for each Fund stated on a per individual Share basis representing the sum of (i) the estimated Cash Amount and (ii) the current value of the Deposit Instruments.

19. Transaction expenses, including operational processing and brokerage costs, will be incurred by a Fund when investors purchase or redeem Creation Units in-kind and such costs have the potential to dilute the interests of the Fund's existing shareholders. Each Fund will impose purchase or redemption transaction fees (''Transaction Fees'') in connection with effecting such purchases or redemptions of Creation Units. In all cases, such Transaction Fees will be limited in accordance with requirements of the Commission applicable to management investment companies offering redeemable securities. Since the Transaction Fees are intended to defray the transaction expenses as well as to prevent possible shareholder dilution resulting from the purchase or redemption of Creation Units, the Transaction Fees will be borne only by such purchasers or redeemers.[21] The Distributor will be responsible for delivering the Fund's prospectus to those persons acquiring Shares in Creation Units and for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it. In addition, the Distributor will maintain a record of the instructions given to the applicable Fund to implement the delivery of its Shares.

20. Shares of each Fund will be listed and traded individually on an Exchange. It is expected that one or more member firms of an Exchange will be designated to act as a market maker (each, a ''Market Maker'') and maintain a market for Shares trading on the Exchange. Prices of Shares trading on an Exchange will be based on the current bid/offer market. Transactions involving the sale of Shares on an Exchange will be subject to customary brokerage commissions and charges.

21. Applicants expect that purchasers of Creation Units will include institutional investors and arbitrageurs. Market Makers, acting in their roles to provide a fair and orderly secondary market for the Shares, may from time to time find it appropriate to purchase or redeem Creation Units. Applicants expect that secondary market purchasers of Shares will include both institutional and retail investors.[22] The price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help prevent Shares from trading at a material discount or premium in relation to their NAV.

22. Shares will not be individually redeemable, and owners of Shares may acquire those Shares from the Fund, or tender such Shares for redemption to the Fund, in Creation Units only. To redeem, an investor must accumulate enough Shares to constitute a Creation Unit. Redemption requests must be placed through an Authorized Participant. A redeeming investor may pay a Transaction Fee, calculated in the same manner as a Transaction Fee payable in connection with purchases of Creation Units.

23. Neither the Trust nor any Fund will be advertised or marketed or otherwise held out as a traditional open-end investment company or a ''mutual fund.'' Instead, each such Fund will be marketed as an ''ETF.'' All marketing materials that describe the features or method of obtaining, buying or selling Creation Units, or Shares traded on an Exchange, or refer to redeemability, will prominently disclose that Shares are not individually redeemable and will disclose that the owners of Shares may acquire those Shares from the Fund or tender such Shares for redemption to the Fund in Creation Units only. The Funds will provide copies of their annual and semi-annual shareholder reports to DTC Participants for distribution to beneficial owners of Shares.

Applicants' Legal Analysis

1. Applicants request an order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provisions of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an ''open-end company'' as a management company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32)

[21] Where a Fund permits an in-kind purchaser to substitute cash-in-lieu of depositing one or more of the requisite Deposit Instruments, the purchaser may be assessed a higher Transaction Fee to cover the cost of purchasing such Deposit Instruments.

[22] Shares will be registered in book-entry form only. DTC or its nominee will be the record or registered owner of all outstanding Shares. Beneficial ownership of Shares will be shown on the records of DTC or the DTC Participants.

of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the holder, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer's current net assets, or the cash equivalent. Because Shares will not be individually redeemable, applicants request an order that would permit the Funds to register as open-end management investment companies and issue individual Shares that are redeemable in Creation Units only. Applicants state that investors may purchase Shares in Creation Units and redeem Creation Units from each Fund. Applicants further state that because Creation Units may always be purchased and redeemed at NAV, the price of Shares on the secondary market should not vary materially from NAV of Creation Units.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security that is currently being offered to the public by or through an underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Thus, purchases and sales of Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing Shares. Applicants maintain that while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been intended to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers, and (c) ensure an orderly distribution of investment company shares by contract dealers by eliminating price competition from non-contract dealers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting Shares to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in Shares does not involve a Fund as a party and will not result in dilution of an investment in Shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in Shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants contend that the price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help prevent Shares from trading at a material discount or premium in relation to their NAV.

Section 22(e) of the Act

7. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants state that settlement of redemptions for Foreign Funds will be contingent not only on the settlement cycle of the United States market, but also on current delivery cycles in local markets for underlying foreign securities held by a Foreign Fund. Applicants state that the delivery cycles currently practicable for transferring Redemption Instruments to redeeming investors, coupled with local market holiday schedules, may require a delivery process of up to fourteen (14) calendar days. Accordingly, with respect to Foreign Funds only, applicants hereby request relief under section 6(c) from the requirement imposed by section 22(e) to allow Foreign Funds to pay redemption proceeds within fourteen calendar days following the tender of Creation Units for redemption.[23]

8. Applicants believe that Congress adopted section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds. Applicants propose that allowing redemption payments for Creation Units of a Foreign Fund to be made within fourteen calendar days would not be inconsistent with the spirit and intent of section 22(e). Applicants suggest that a redemption payment occurring within fourteen calendar days following a redemption request would adequately afford investor protection.

9. Applicants are not seeking relief from section 22(e) with respect to Foreign Funds that do not effect creations and redemptions of Creation Units in-kind.

Section 12(d)(1) of the Act

10. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring securities of an investment company if such securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter and any other broker-dealer from knowingly selling the investment company's shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

11. Applicants request an exemption to permit registered management investment companies and unit investment trusts (''UITs'') that are not advised or sponsored by the Adviser, and not part of the same ''group of investment companies,'' as defined in section 12(d)(1)(G)(ii) of the Act as the Funds (such management investment companies are referred to as ''Investing Management Companies,'' such UITs are referred to as ''Investing Trusts,'' and Investing Management Companies and Investing Trusts are collectively referred to as ''Funds of Funds''), to acquire Shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any Broker registered under the Exchange Act, to sell Shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act.

12. Each Investing Management Company will be advised by an investment adviser within the meaning of section 2(a)(20)(A) of the Act (the ''Fund of Funds Adviser'') and may be sub-advised by investment advisers within the meaning of section 2(a)(20)(B) of the Act (each, a ''Fund of

[23] Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations Applicants may otherwise have under rule 15c6–1 under the Exchange Act requiring that most securities transactions be settled within three business days of the trade date.

Funds Sub-Adviser''). Any investment adviser to an Investing Management Company will be registered under the Advisers Act. Each Investing Trust will be sponsored by a sponsor (''Sponsor'').

13. Applicants submit that the proposed conditions to the requested relief adequately address the concerns underlying the limits in sections 12(d)(1)(A) and (B), which include concerns about undue influence by a fund of funds over underlying funds, excessive layering of fees and overly complex fund structures. Applicants believe that the requested exemption is consistent with the public interest and the protection of investors.

14. Applicants believe that neither a Fund of Funds nor a Fund of Funds Affiliate would be able to exert undue influence over a Fund.[24] To limit the control that a Fund of Funds may have over a Fund, applicants propose a condition prohibiting a Fund of Funds Adviser or Sponsor, any person controlling, controlled by, or under common control with a Fund of Funds Adviser or Sponsor, and any investment company and any issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by a Fund of Funds Adviser or Sponsor, or any person controlling, controlled by, or under common control with a Fund of Funds Adviser or Sponsor (''Fund of Funds Advisory Group'') from controlling (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any Fund of Funds Sub-Adviser, any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Fund of Funds Sub-Adviser or any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser (''Fund of Funds Sub-Advisory Group'').

15. Applicants propose other conditions to limit the potential for undue influence over the Funds, including that no Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (''Affiliated Underwriting''). An ''Underwriting Affiliate'' is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Fund of Funds Adviser, Fund of Funds Sub-Adviser, employee or Sponsor of the Fund of Funds, or a person of which any such officer, director, member of an advisory board, Fund of Funds Adviser or Fund of Funds Sub-Adviser, employee or Sponsor is an affiliated person (except that any person whose relationship to the Fund is covered by section 10(f) of the Act is not an Underwriting Affiliate).

16. Applicants do not believe that the proposed arrangement will involve excessive layering of fees. The board of directors or trustees of any Investing Management Company, including a majority of the directors or trustees who are not ''interested persons'' within the meaning of section 2(a)(19) of the Act (''disinterested directors or trustees''), will find that the advisory fees charged under the contract are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract of any Fund in which the Investing Management Company may invest. In addition, under condition B.5., a Fund of Funds Adviser, or a Fund of Funds' trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund under rule 12b–1 under the Act) received from a Fund by the Fund of Funds Adviser, trustee or Sponsor or an affiliated person of the Fund of Funds Adviser, trustee or Sponsor, other than any advisory fees paid to the Fund of Funds Adviser, trustee or Sponsor or its affiliated person by a Fund, in connection with the investment by the Fund of Funds in the Fund. Applicants state that any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.[25]

17. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that no Fund will acquire securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund to purchase shares of other investment companies for short-term cash management purposes. To ensure a Fund of Funds is aware of the terms and conditions of the requested order, the Fund of Funds will enter into an agreement with the Fund (''FOF Participation Agreement''). The FOF Participation Agreement will include an acknowledgement from the Fund of Funds that it may rely on the order only to invest in the Funds and not in any other investment company.

18. Applicants also note that a Fund may choose to reject a direct purchase of Shares in Creation Units by a Fund of Funds. To the extent that a Fund of Funds purchases Shares in the secondary market, a Fund would still retain its ability to reject any initial investment by a Fund of Funds in excess of the limits of section 12(d)(1)(A) by declining to enter into a FOF Participation Agreement with the Fund of Funds.

Sections 17(a)(1) and (2) of the Act

19. Sections 17(a)(1) and (2) of the Act generally prohibit an affiliated person of a registered investment company, or an affiliated person of such a person, from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines ''affiliated person'' of another person to include (a) any person directly or indirectly owning, controlling or holding with power to vote 5% or more of the outstanding voting securities of the other person, (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled or held with the power to vote by the other person, and (c) any person directly or indirectly controlling, controlled by or under common control with the other person. Section 2(a)(9) of the Act defines ''control'' as the power to exercise a controlling influence over the management or policies of a company, and provides that a control relationship will be presumed where one person owns more than 25% of a company's voting securities. The Funds may be deemed to be controlled by the Adviser or an entity controlling, controlled by or under common control with the Adviser and hence affiliated persons of each other. In addition, the Funds may be deemed to be under common control with any other

[24] A ''Fund of Funds Affiliate'' is a Fund of Funds Adviser, Fund of Funds Sub-Adviser, Sponsor, promoter, and principal underwriter of a Fund of Funds, and any person controlling, controlled by, or under common control with any of those entities. A ''Fund Affiliate'' is an investment adviser, promoter, or principal underwriter of a Fund and any person controlling, controlled by or under common control with any of these entities.

[25] Any references to NASD Conduct Rule 2830 include any successor or replacement FINRA rule to NASD Conduct Rule 2830.

registered investment company (or series thereof) advised by an Adviser or an entity controlling, controlled by or under common control with an Adviser (an ''Affiliated Fund''). Any investor, including Market Makers, owning 5% or holding in excess of 25% of the Trust or such Funds, may be deemed affiliated persons of the Trust or such Funds. In addition, an investor could own 5% or more, or in excess of 25% of the outstanding shares of one or more Affiliated Funds making that investor a Second-Tier Affiliate of the Funds.

20. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act pursuant to sections 6(c) and 17(b) of the Act to permit persons that are Affiliated Persons of the Funds, or Second-Tier Affiliates of the Funds, solely by virtue of one or more of the following: (a) Holding 5% or more, or in excess of 25%, of the outstanding Shares of one or more Funds; (b) an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25%, of the shares of one or more Affiliated Funds, to effectuate purchases and redemptions ''in-kind.''

21. Applicants assert that no useful purpose would be served by prohibiting such affiliated persons from making ''in-kind'' purchases or ''in-kind'' redemptions of Shares of a Fund in Creation Units. Both the deposit procedures for ''in-kind'' purchases of Creation Units and the redemption procedures for ''in-kind'' redemptions of Creation Units will be effected in exactly the same manner for all purchases and redemptions, regardless of size or number. There will be no discrimination between purchasers or redeemers. Deposit Instruments and Redemption Instruments for each Fund will be valued in the identical manner as those Portfolio Holdings currently held by such Fund and the valuation of the Deposit Instruments and Redemption Instruments will be made in an identical manner regardless of the identity of the purchaser or redeemer. Applicants do not believe that ''in-kind'' purchases and redemptions will result in abusive self-dealing or overreaching, but rather assert that such procedures will be implemented consistently with each Fund's objectives and with the general purposes of the Act. Applicants believe that ''in-kind'' purchases and redemptions will be made on terms reasonable to Applicants and any affiliated persons because they will be valued pursuant to verifiable objective standards. The method of valuing Portfolio Holdings held by a Fund is identical to that used for calculating ''in-kind'' purchase or redemption values and therefore creates no opportunity for affiliated persons or Second-Tier Affiliates of applicants to effect a transaction detrimental to the other holders of Shares of that Fund. Similarly, applicants submit that, by using the same standards for valuing Portfolio Holdings held by a Fund as are used for calculating ''in-kind'' redemptions or purchases, the Fund will ensure that its NAV will not be adversely affected by such securities transactions. Applicants also note that the ability to take deposits and make redemptions ''in-kind'' will help each Fund to track closely its Underlying Index and therefore aid in achieving the Fund's objectives.

22. Applicants also seek relief under sections 6(c) and 17(b) from section 17(a) to permit a Fund that is an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds to sell its Shares to and redeem its Shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[26] Applicants state that the terms of the transactions are fair and reasonable and do not involve overreaching. Applicants note that any consideration paid by a Fund of Funds for the purchase or redemption of Shares directly from a Fund will be based on the NAV of the Fund.[27] Applicants believe that any proposed transactions directly between the Funds and Funds of Funds will be consistent with the policies of each Fund of Funds. The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the investment restrictions of any such Fund of Funds and will be consistent with the investment policies set forth in the Fund of Funds' registration statement. Applicants also state that the proposed transactions are consistent with the general purposes of the Act and are appropriate in the public interest.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

A. ETF Relief

1. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of index-based ETFs.

2. As long as a Fund operates in reliance on the requested order, the Shares of such Fund will be listed on an Exchange.

3. Neither the Trust nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that Shares are not individually redeemable and that owners of Shares may acquire those Shares from the Fund and tender those Shares for redemption to a Fund in Creation Units only.

4. The Web site, which is and will be publicly accessible at no charge, will contain, on a per Share basis for each Fund, the prior Business Day's NAV and the market closing price or the midpoint of the bid/ask spread at the time of the calculation of such NAV (''Bid/Ask Price''), and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

5. Each Self-Indexing Fund, Long/Short Fund and 130/30 Fund will post on the Web site on each Business Day, before commencement of trading of Shares on the Exchange, the Fund's Portfolio Holdings.

6. No Adviser or any Sub-Adviser to a Self-Indexing Fund, directly or indirectly, will cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact with the Self-Indexing Fund) to acquire any Deposit Instrument for the Self-Indexing Fund through a transaction in which the Self-Indexing Fund could not engage directly.

B. Fund of Funds Relief

1. The members of a Fund of Funds' Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of

[26] Although applicants believe that most Funds of Funds will purchase Shares in the secondary market and will not purchase Creation Units directly from a Fund, a Fund of Funds might seek to transact in Creation Units directly with a Fund that is an affiliated person of a Fund of Funds. To the extent that purchases and sales of Shares occur in the secondary market and not through principal transactions directly between a Fund of Funds and a Fund, relief from Section 17(a) would not be necessary. However, the requested relief would apply to direct sales of Shares in Creation Units by a Fund to a Fund of Funds and redemptions of those Shares. Applicants are not seeking relief from Section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an affiliated person, or an affiliated person of an affiliated person of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

[27] Applicants acknowledge that the receipt of compensation by (a) an affiliated person of a Fund of Funds, or an affiliated person of such person, for the purchase by the Fund of Funds of Shares of a Fund or (b) an affiliated person of a Fund, or an affiliated person of such person, for the sale by the Fund of its Shares to a Fund of Funds, may be prohibited by Section 17(e)(1) of the Act. The FOF Participation Agreement also will include this acknowledgment.

the Act. The members of a Fund of Funds' Sub-Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of a Fund, the Fund of Funds' Advisory Group or the Fund of Funds' Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25 percent of the outstanding voting securities of a Fund, it will vote its Shares of the Fund in the same proportion as the vote of all other holders of the Fund's Shares. This condition does not apply to the Fund of Funds' Sub-Advisory Group with respect to a Fund for which the Fund of Funds' Sub-Adviser or a person controlling, controlled by or under common control with the Fund of Funds' Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

2. No Fund of Funds or Fund of Funds Affiliate will cause any existing or potential investment by the Fund of Funds in a Fund to influence the terms of any services or transactions between the Fund of Funds or Fund of Funds Affiliate and the Fund or a Fund Affiliate.

3. The board of directors or trustees of an Investing Management Company, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to ensure that the Fund of Funds Adviser and Fund of Funds Sub-Adviser are conducting the investment program of the Investing Management Company without taking into account any consideration received by the Investing Management Company or a Fund of Funds Affiliate from a Fund or Fund Affiliate in connection with any services or transactions.

4. Once an investment by a Fund of Funds in the securities of a Fund exceeds the limits in section 12(d)(1)(A)(i) of the Act, the Board of the Fund, including a majority of the directors or trustees who are not ''interested persons'' within the meaning of Section 2(a)(19) of the Act (''non-interested Board members''), will determine that any consideration paid by the Fund to the Fund of Funds or a Fund of Funds Affiliate in connection with any services or transactions: (i) Is fair and reasonable in relation to the nature and quality of the services and benefits received by the Fund; (ii) is within the range of consideration that the Fund would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (iii) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between a Fund and its investment adviser(s), or any person controlling, controlled by or under common control with such investment adviser(s).

5. The Fund of Funds Adviser, or trustee or Sponsor of an Investing Trust, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund under rule 12b–l under the Act) received from a Fund by the Fund of Funds Adviser, or trustee or Sponsor of the Investing Trust, or an affiliated person of the Fund of Funds Adviser, or trustee or Sponsor of the Investing Trust, other than any advisory fees paid to the Fund of Funds Adviser, or trustee or Sponsor of an Investing Trust, or its affiliated person by the Fund, in connection with the investment by the Fund of Funds in the Fund. Any Fund of Funds Sub-Adviser will waive fees otherwise payable to the Fund of Funds Sub-Adviser, directly or indirectly, by the Investing Management Company in an amount at least equal to any compensation received from a Fund by the Fund of Funds Sub-Adviser, or an affiliated person of the Fund of Funds Sub-Adviser, other than any advisory fees paid to the Fund of Funds Sub-Adviser or its affiliated person by the Fund, in connection with the investment by the Investing Management Company in the Fund made at the direction of the Fund of Funds Sub-Adviser. In the event that the Fund of Funds Sub-Adviser waives fees, the benefit of the waiver will be passed through to the Investing Management Company.

6. No Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in any Affiliated Underwriting.

7. The Board of a Fund, including a majority of the non-interested Board members, will adopt procedures reasonably designed to monitor any purchases of securities by the Fund in an Affiliated Underwriting, once an investment by a Fund of Funds in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Fund of Funds in the Fund. The Board will consider, among other things: (i) Whether the purchases were consistent with the investment objectives and policies of the Fund; (ii) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (iii) whether the amount of securities purchased by the Fund in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to ensure that purchases of securities in Affiliated Underwritings are in the best interest of shareholders of the Fund.

8. Each Fund will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings once an investment by a Fund of Funds in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the terms of the purchase, and the information or materials upon which the Board's determinations were made.

9. Before investing in a Fund in excess of the limit in section 12(d)(1)(A), a Fund of Funds and the Trust will execute a FOF Participation Agreement stating, without limitation, that their respective boards of directors or trustees and their investment advisers, or trustee and Sponsor, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Shares of a Fund in excess of the limit in section 12(d)(1)(A)(i), a Fund of Funds will notify the Fund of the investment. At such time, the Fund of Funds will also transmit to the Fund a list of the names of each Fund of Funds Affiliate and Underwriting Affiliate. The Fund of Funds will notify the Fund of any changes to the list of the names as soon as reasonably practicable after a change occurs. The Fund and the Fund of Funds will maintain and preserve a

copy of the order, the FOF Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

10. Before approving any advisory contract under section 15 of the Act, the board of directors or trustees of each Investing Management Company including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Fund in which the Investing Management Company may invest. These findings and their basis will be fully recorded in the minute books of the appropriate Investing Management Company.

11. Any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

12. No Fund will acquire securities of an investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent the Fund acquires securities of another investment company pursuant to exemptive relief from the Commission permitting the Fund to acquire securities of one or more investment companies for short-term cash management purposes.

For the Commission, by the Division of Investment Management, under delegated authority.

Brent J. Fields,

Secretary.

[FR Doc. 2016–06785 Filed 3–24–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77412; File No. SR–ISEMercury–2016–06]

Self-Regulatory Organizations; ISE Mercury, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees

March 21, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 10, 2016, ISE Mercury, LLC (the ''Exchange'' or ''ISE Mercury'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change, as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

ISE Mercury proposes to amend its Schedule of Fees to count 100% of eligible traded volume preferenced to a Market Maker towards that member's volume tiers. The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On March 10, 2016, ISE Mercury filed a proposed rule change to introduce fee and rebate tiers for Market Maker[3] and Priority Customer[4] orders based on the average daily volume (''ADV'') that a member executes in Priority Customer orders.[5] Pursuant to that proposed rule change, the Exchange will assess fees and rebates for Market Maker and Priority Customer orders based on five tiers of Total Affiliated Priority Customer ADV:[6] 0–19,999 contracts (''Tier 1''), 20,000–39,999 contracts (''Tier 2''), 40,000–59,999 contracts (''Tier 3''), 60,000–79,999 contracts (''Tier 4''), and 80,000 or more contracts (''Tier 5'').[7] As is the case on ISE Mercury's affiliated exchanges—the International Securities Exchange, LLC (''ISE'') and ISE Gemini, LLC (''ISE Gemini'')—the Exchange's ADV calculation will also include volume executed by affiliated members. In particular, the Exchange will aggregate all eligible volume from affiliated members in determining applicable tiers, provided that there is at least 75% common ownership between the members as reflected on the member's Form BD, Schedule A. While this method of aggregating volume is beneficial to large firms with multiple affiliated members, the Exchange believes that it is important to give smaller firms the ability to compete for more favorable fees and rebates. The Exchange therefore proposes to adopt ADV tiers that are based on preferenced volume—*i.e.,* volume directed to a specific Market Maker as provided in Supplementary Material .03 to Rule 713.[8] In particular, the Exchange proposes to give Market Makers volume credit for 100% of eligible traded volume preferenced to that member,[9] regardless of the actual allocation that the Market Maker receives. For example, assume Market Maker ABC is quoting at the national best bid or offer (''NBBO'') and receives a Preferenced Order for 10 contracts from an unaffiliated firm for the account of a Priority Customer. If there are other Market Makers quoting at the NBBO, Market Maker ABC may receive an allocation of 4 contracts—*i.e.,* 40% of the order. Rather than counting only the 4 contracts executed towards

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term Market Makers refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively.

[4] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in ISE Mercury Rule 100(a)(37A).

[5] *See* ISE Mercury–2016–05.

[6] The Total Affiliated Priority Customer ADV category includes all Priority Customer volume executed on the Exchange in all symbols and order types, including volume executed in the PIM, Facilitation, and QCC mechanisms.

[7] The highest tier threshold attained applies retroactively in a given month to all eligible traded contracts and applies to all eligible market participants. Any day that the market is not open for the entire trading day or the Exchange instructs members in writing to route their orders to other markets may be excluded from the ADV calculation; provided that the Exchange will only remove the day for members that would have a lower ADV with the day included.

[8] An Electronic Access Member (''EAM'') may designate a ''Preferred Market Maker'' on orders it enters into the System (''Preferenced Orders''). Supplementary Material .03 to Rule 713 describes the Exchange's rules concerning Preferenced Orders.

[9] ''Eligible volume'' refers to volume that would otherwise count towards to applicable volume tier. In the case of ADV thresholds based on Total Affiliated Priority Customer ADV, as currently implemented on ISE Mercury, all Priority Customer volume would be ''eligible.'' *See* note 6 supra.

the Market Maker's volume total, the Exchange now proposes to give that Market Maker credit for the full 10 contracts preferenced to it. This is the same credit the member would receive if the 10 contracts were sent to the exchange by an affiliated member, and the Exchange believes that this will put smaller Market Makers on more equal footing with large firms that benefit from affiliated volume.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[10] in general, and Section 6(b)(4) of the Act,[11] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities. The Exchange believes that the proposed fee change is reasonable and equitable as it provides an additional way for members to increase volume used to qualify for lower fees and higher rebates. The Exchange has adopted volume based fees and rebates in another proposed rule change filed with the Commission. While volume based fees and rebates based on affiliated volume benefit Market Makers that have affiliated order routers, the Exchange believes that smaller Market Makers that attract order flow from non-affiliated firms should similarly be able to compete for more favorable fees and rebates. Preferred Market Makers attract order flow by establishing appropriate relationships with one or more EAMs that send Preferenced Orders to the Exchange. Although Preferred Market Makers may not be allocated the full volume orders preferenced to them, the Exchange believes that it is reasonable and equitable to give these Market Makers full credit for the volume of orders that they have attracted to ISE Mercury. This will put smaller Market Makers that are not affiliated with an order routing firm on more equal footing with large firms that benefit from affiliated volume today. In addition, the Exchange does not believe that it is unfairly discriminatory to provide this incentive specifically to Preferred Market Makers. As explained above, Preferred Market Makers attract order flow to the Exchange by establishing relationships with EAMs that direct Preferenced Orders to them. Moreover, all Market Makers are eligible to become Preferred Market Makers provided that they meet the quoting obligations expected of such firms.[12]

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[13] the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposed rule change will increase competition by allowing smaller Market Makers to compete for more favorable fees and rebates. As currently implemented, Market Makers that are affiliated with an order router are advantaged relative to other firms in achieving volume based fees and rebates. Although the Exchange continues to believe that counting volume across affiliated members is appropriate,[14] the Exchange also believes that Market Makers whose relationships attract Preference Orders should also receive similar benefits. As explained above, these Market Makers attract significant volume to the Exchange but currently only receive volume credit for a portion of that volume. The proposed rule change is designed to level the playing field between these members and their competitors that already benefit from affiliated volume. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. For the reasons described above, the Exchange believes that the proposed fee change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[15] and subparagraph (f)(2) of Rule 19b–4 thereunder,[16] because it establishes a due, fee, or other charge imposed by ISE Mercury.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ISEMercury–2016–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISEMercury–2016–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4).

[12] Preferred Competitive Market Makers have quoting obligations that mirror those for Primary Market Makers. *See* Supplementary Material .03(d) to Rule 713 and Rule 804(e)(2)(iii).

[13] 15 U.S.C. 78f(b)(8).

[14] *See* note 5 supra.

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISEMercury–2016–06, and should be submitted on or before April 15, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Brent J. Fields,

Secretary.

[FR Doc. 2016–06746 Filed 3–24–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77409; File No. SR–ISEMercury–2016–05]

Self-Regulatory Organizations; ISE Mercury, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees

March 21, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 10, 2016, ISE Mercury, LLC (the ''Exchange'' or ''ISE Mercury'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change, as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

ISE Mercury proposes to amend its Schedule of Fees by adopting volume-based tiered rebates and fees. These tiers are determined by a member's average daily volume of Priority Customer orders traded on the Exchange. The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

ISE Mercury is proposing to amend its Schedule of Fees to establish volume-based tiered rebates and fees (the ''Member Volume Program'' or ''MVP''). The MVP tiers are determined by a member's average daily volume (''ADV'') of Priority Customer [3] Regular Orders,[4] in Penny and Non-Penny Pilot Symbols,[5] traded on the Exchange. The Exchange will also aggregate the trading activity of affiliated members in determining this ADV.[6] ISE Mercury believes the proposed fee and rebate tiers will incentivize firms to increase Priority Customer order flow to the Exchange. The Exchange is also proposing Penny and Non-Penny Symbol fees for both Crossing Orders and Responses to Crossing Orders. Finally, the Exchange proposes to offer Market Makers [7] a per contract discount when trading against Non-Priority Customer orders.

The Member Volume Program

Currently, the fees and rebates assessed for Regular Orders in standard options that are in the Penny Pilot are: (1) $0.20 per contract for Market Maker orders,[8] (2) $0.47 per contract for Non-ISE Mercury Market Maker,[9] Firm Proprietary [10]/Broker-Dealer,[11] and Professional Customer [12] orders; and (3) ($0.18) per contract for Priority Customer orders. The transaction fees and rebates assessed for Regular Orders that are not in the Penny Pilot are: (1) $0.20 per contract for Market Maker orders; (2) $0.90 per contract for Non-ISE Mercury Market Maker, Firm Proprietary/Broker-Dealer, and Professional Customer orders; and (3) ($0.18) per contract for Priority Customer orders.

The Exchange proposes to amend the above fees and rebates so that they will be based on a member's ADV of Priority Customer orders traded in a given month and the highest tier threshold attained applies retroactively in a given month to all eligible traded contracts and applies to all eligible market participants. This Priority Customer ADV includes all Priority Customer volume executed on the Exchange in all symbols and order types, including volume executed in the Price Improvement Mechanism (''PIM'') and the Facilitation and Qualified Contingent Cross mechanisms.

Further, the Exchange will aggregate the trading activity of separate members in calculating Priority Customer ADV provided there is at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A. The Exchange believes that aggregating this volume across members that share at least 75% common ownership will allow members to continue to execute trades on the Exchange through separate broker-dealer entities for different types of

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A Priority Customer is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).

[4] A Regular Order is an order that consists of only a single option series and is not submitted with a stock leg.

[5] Under the Penny Pilot, the minimum price variation for all participating options classes, except for the Nasdaq-100 Index Tracking Stock (''QQQ''), the SPDR S&P 500 Exchange Traded Fund (''SPY'') and the iShares Russell 2000 Index Fund (''IWM''), is $0.01 for all quotations in options series that are quoted at less than $3 per contract and $0.05 for all quotations in options series that are quoted at $3 per contract or greater. The proposed fees and rebates for Penny Pilot symbols apply to all classes in the Penny Pilot, *i.e.,* to series that are quoted at less than $3 that have a minimum price variation of $0.01 and to series that are quoted at $3 or more that have an minimum price variation of $0.05. QQQ, SPY, and IWM are quoted in $0.01 increments for all options series.

[6] Aggregation is necessary and appropriate because certain members conduct customer and market maker trading activity through separate but related broker-dealers.

[7] The term Market Makers refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively. Market Maker orders sent to the Exchange by an Electronic Access Member are assessed fees at the same level as Market Maker orders.

[8] This fee applies to ISE Mercury Market Maker orders sent to the Exchange by Electronic Access Members.

[9] A Non-ISE Mercury Market Maker, or Far Away Market Maker (''FARMM''), is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended (''Exchange Act''), registered in the same options class on another options exchange.

[10] A Firm Proprietary order is an order submitted by a member for its own proprietary account.

[11] A Broker-Dealer order is an order submitted by a member for a non-member broker-dealer account.

[12] A Professional Customer is a person who is not a broker/dealer and is not a Priority Customer.

volume, while receiving rebates based on the aggregate volume being executed across such entities.

The Exchange now proposes fees and rebates based on five volume tier levels as described in the table below. These fees and rebates will be based on the highest tier that a member reaches in a given month, and these tiered rates will apply retroactively to all eligible traded contracts for all client categories.

QUALIFYING TIER THRESHOLDS

Tier	Total affiliated priority customer ADV
Tier 1	0–19,999
Tier 2	20,000–39,999
Tier 3	40,000–59,999
Tier 4	60,000–79,999
Tier 5	80,000+

Additionally, the Exchange proposes to amend the Schedule of Fees to include language related to excluding days from the ADV calculations used to determine applicable fee and rebate tiers. Specifically, the Exchange proposes to (1) exclude from its ADV calculations any trading day on which the Exchange is closed early for holiday observance; (2) exclude days where the Exchange declares a trading halt in all securities or honors a market-wide trading halt declared by another market; and (3) permit days to be excluded from its ADV calculations where the Exchange is technically open for the entire trading day, but has instructed members to route away due to a systems or other error that ultimately does not impact trading on the Exchange. The Exchange also notes, however, that if it has a systems issue in the morning before the market opens, it may instruct members to route away to other markets. If the systems issue continues into trading hours, the Exchange is permitted to exclude the day for all members that would have a lower ADV with the day included. If, however, the systems issue is resolved prior to the opening of trading, the Exchange is not permitted to exclude the day from its ADV calculations. This is the case regardless of the fact that many members would have already made arrangements to route away in accordance with the Exchange's instructions. To prevent this undesirable result, and preserve the Exchange's intent behind adopting volume-based pricing, the Exchange proposes to allow days to be excluded from its ADV calculation whenever all members are instructed, in writing, to route their orders to other markets.

Because the days the Exchange proposes to exclude from its ADV calculation generally have artificially lower trading volume, the Exchange believes that it is reasonable and equitable to not include such days in determining fee and rebate tiers. If the Exchange did not have the ability to exclude aberrant low volume days when calculating ADV for the month, as a result of the decreased trading volume, the numerator for the calculation (*e.g.,* trading volume) would be correspondingly lower, but the denominator for the threshold calculations (*e.g.,* the number of trading days) would not be decreased. This could result in an unintended cost increase. Absent the authority to exclude days that the market is not open for the entire trading day, members will experience an effective decrease in rebates. The artificially low volumes of trading on such days could reduce the trading activity of members both daily and monthly. Accordingly, excluding such days from the monthly calculation will diminish the likelihood of an effective increase in the cost of trading on the Exchange, a result that is unintended and undesirable to the Exchange and its members.

The Exchange notes that the fees charged to Non-ISE Mercury Market Maker, Firm Proprietary/Broker Dealer and Professional Customer in Penny and Non-Penny Symbols are the same as the current fees charged, regardless of the tier level reached. However, the tiered fees and rebates for both Priority Customers and Market Makers have changed. The proposed fees and rebates for each tier and participant type are as follows:

PENNY SYMBOL FEES AND REBATES

[Per contract]

Tier	Priority customer	Market maker	Firm proprietary, B/D, FarMM & professional customer
Tier 1	($0.05)	$0.25	$0.47
Tier 2	($0.10)	$0.22	$0.47
Tier 3	($0.15)	$0.18	$0.47
Tier 4	($0.21)	$0.15	$0.47
Tier 5	($0.24)	$0.10	$0.47

NON-PENNY SYMBOL FEES AND REBATES

[Per contract]

Tier	Priority customer	Market maker	Firm proprietary, B/D, FarMM & professional customer
Tier 1	($0.05)	$0.25	$0.90
Tier 2	($0.10)	$0.22	$0.90
Tier 3	($0.15)	$0.18	$0.90
Tier 4	($0.21)	$0.15	$0.90
Tier 5	($0.24)	$0.10	$0.90

Crossing Orders

The Exchange proposes Penny and Non-Penny Symbol fees for Crossing Orders. The Exchange currently charges a fee of $0.20 per contract for Crossing Orders [13] in all symbols traded on the Exchange for all market participants, except Priority Customers who are charged $0.00 per contract for Crossing Orders. A Crossing Order is an order executed in the Exchange's Facilitation Mechanism, Solicited Order Mechanism, PIM, or submitted as a Qualified Contingent Cross order. Orders executed in the Block Order Mechanism are also considered Crossing Orders. The fees for Crossing Orders, except for PIM Orders of 500 or Fewer Contracts, in both Penny and Non-Penny Symbols have not changed from current levels.

As an exception to the fees charged for Crossing Orders, the Exchange charges a fee of $0.05 per contract for PIM Orders of 500 or Fewer Contracts in all symbols traded on the Exchange for all market participants, except that Priority Customer orders on the originating side of a PIM auction receive a rebate of ($0.13) per contract. Priority Customer orders on the contra-side of a PIM auction pay no fee and receive no rebate. PIM orders greater than 500 contracts pay the Crossing Order fee, described above. The Exchange now proposes to offer tiered fees and rebates based on Priority Customer volume, as described above, for PIM Orders of 500 or Fewer Contracts. The Exchange notes that the fees for Non-Priority Customer orders have not changed from current levels, but the fees for Priority Customer orders have changed as described in the table, below.

ALL SYMBOLS FEE/REBATE FOR PIM ORDERS OF 500 OR FEWER CONTRACTS

Tier	Priority customer	Market maker	Firm proprietary, B/D, FarMM & professional customer
Tier 1	($0.11)	$0.05	$0.05
Tier 2	($0.11)	$0.05	$0.05
Tier 3	($0.13)	$0.05	$0.05
Tier 4	($0.13)	$0.05	$0.05
Tier 5	($0.13)	$0.05	$0.05

Responses to Crossing Orders

The Exchange proposes Penny and Non-Penny Symbol fees for Responses to Crossing Orders. A Response to a Crossing Order is any contra-side interest (*i.e.,* orders and quotes) submitted after the commencement of an auction in the Exchange's Facilitation Mechanism, Solicited Order Mechanism, Block Order Mechanism, or PIM. Currently, the Exchange charges a fee of (1) $0.20 per contract for Market Maker orders and (2) $0.50 per contract for Non-ISE Mercury Market Maker, Firm Proprietary/Broker-Dealer, Professional Customer, and Priority Customer orders in all symbols. For Responses to Crossing Orders in Penny Symbols, the Exchange proposes to charge Market Makers the corresponding tiered fees in the chart titled Penny Symbol Fees and Rebates, above. For Non-ISE Mercury Market Maker, Firm Proprietary/Broker-Dealer, Professional Customer, and Priority Customer orders in Penny Symbols, the fees have not changed from current levels. For Responses to Crossing Orders in Non-Penny Symbols, the Exchange proposes to charge Market Makers the corresponding tiered fees in the chart titled Non-Penny Symbol Fees and Rebates, above. For Non-ISE Mercury Market Maker, Firm Proprietary/Broker-Dealer, Professional Customer, and Priority Customer orders in Non-Penny Symbols, the Exchange proposes to charge a fee of $0.95 per contract.

With respect to the proposed MVP, described above, the Exchange notes that the fees and rebates currently being paid on ISE Mercury are in the range of fees and rebates in the new structure. During the initial rollout of symbols on ISE Mercury, the Exchange did not adopt the proposed tiered structure due to the difficulty of calculating appropriate ADV thresholds for each tier when symbols were being listed on the Exchange each week. The Exchange, therefore, opted to provide attractive introductory rates and Priority Customer order rebates in order to attract Priority Customer orders to the Exchange during the initial rollout phase. By adopting the proposed tiered structure now, the Exchange seeks to incentivize members to send additional order flow to the Exchange in order to qualify for lower fees and higher rebates.

Market Maker Discount

The Exchange is also proposing a $0.05 per contract discount to Market Maker fees when the Market Maker trades against Non-Priority Customer orders. We believe this will incentivize Market Makers to provide competitive markets. This discount does not apply to Crossing Orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[14] in general, and Section 6(b)(4) of the Act,[15] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

The Exchange believes the fees proposed for transactions on ISE Mercury are reasonable. ISE Mercury will operate within a highly competitive market in which market participants can readily send order flow to any of the thirteen other competing venues if they deem fees at a particular venue to be excessive. The proposed MVP is intended to attract order flow to ISE Mercury by offering certain market participants incentives to submit their orders to ISE Mercury.

Member Volume Program

The Exchange believes the proposed fees and rebates in the MVP are reasonable and equitably allocated because ISE Mercury has already established fees for members trading on the Exchange, and is merely proposing to adopt volume-based tiers designed to incentivize members to send additional Priority Customer order flow to the Exchange. Further, the language permitting aggregation of volume amongst corporate affiliates for purposes

[13] These fees apply to both originating and contra orders.

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(4).

of the ADV calculation is intended to avoid disparate treatment of firms that have divided their various business activities between separate corporate entities as compared to firms that operate those business activities within a single corporate entity. For example, many firms that are members of the Exchange operate several different business lines within the same corporate entity. In contrast, other firms may be part of a corporate structure that separates those business lines into different corporate affiliates, either for business, compliance, or historical reasons. Those corporate affiliates, in turn, are required to maintain separate memberships with the Exchange in order to access the Exchange. The Exchange believes that corporate affiliates should continue to be aggregated and is clarifying when members will be considered affiliated. The Exchange notes that the proposed definition of ''affiliate'' to be used to aggregate affiliated member ADV is consistent with definitions used by other options exchanges, including MIAX.[16]

The Exchange believes that it is equitable and reasonable to permit the Exchange to eliminate from the calculation days on which the market is not open the entire trading day, either due to a holiday or trading halt, because it preserves the Exchange's intent behind adopting volume-based pricing. The proposed change is non-discriminatory because it applies equally to all members and to all volume tiers. Additionally, the Exchange believes that it is reasonable and equitable to exclude a day from its ADV calculations when members are instructed to route their orders to other markets as this preserves the Exchange's intent behind adopting volume-based pricing, and avoids penalizing members that follow this instruction. Without this change, members that route away in accordance with the Exchange's instructions may be negatively impacted, resulting in an effective cost increase for those members. The Exchange further believes that the proposed rule change is not unfairly discriminatory because it applies equally to all members and ADV calculations. As is the Exchange's current practice, the Exchange will inform members of any day to be excluded from its ADV calculations by sending members a notice and posting such notice on the Exchange's Web site.

The Exchange further believes that its proposal to provide rebates for Priority Customer orders is reasonable and equitable because the proposed rebates are competitive with the rebates offered by other exchanges employing similar tiered rebate structures based on Priority Customer volume. For example, MIAX Options Exchange (''MIAX'') and NASDAQ OMX PHLX (''PHLX'') have Priority Customer, tiered rebate programs.[17] MIAX offers a per contract rebate of $0.00 for its base tier and a per contract rebate of $0.24 for its highest rebate tier in select symbols. Similarly, PHLX offers a per contract rebate of $0.00 for its base tier and a per contract rebate of $0.21 for its highest tier in customer simple orders.[18] As proposed, ISE Mercury's Priority Customer order rebates are not unfairly discriminatory because they would apply uniformly to all similarly situated market participants and they are competitive with the rebates offered by MIAX's and PHLX's Priority Customer rebate programs.

The Exchange believes that providing higher rebates for Priority Customer orders, and creating ADV thresholds specifically for members that send such orders to ISE Mercury, attracts that order flow to the Exchange and thereby creates liquidity to the benefit of all market participants who trade on the Exchange. Further, the Exchange believes that it is equitable and not unfairly discriminatory to provide higher rebates to Priority Customer orders than to Professional Customer orders. A Priority Customer is by definition not a broker or dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). This limitation does not apply to participants on the Exchange whose behavior is substantially similar to that of market professionals, including Professional Customers, who will generally submit a higher number of orders (many of which do not result in executions) than Priority Customers. Further, Professional Customers engage in trading activity similar to that conducted by Market Makers and proprietary traders.

The Exchange believes that its proposal to assess a per contract fee for Market Maker orders is reasonable and equitable because the proposed fees are within the range of fees assessed by other exchanges employing similar tiered rebate structures such as MIAX, which offers tiered fees for Market Makers. In Penny Symbols, MIAX generally charges Market Makers a per contract fee as high as $0.25 for its base tier and a per contract fee of $0.05 for its highest tier.[19] In Non-Penny Symbols, MIAX charges a per contract fee of $0.29 for its base tier and a per contract fee of $0.09 for its highest tier.[20] Thus, MIAX's tiered Market Maker fees are competitive with ISE Mercury's fees. The Exchange believes that the price differentiation between Market Makers and other Non-Priority Customers is appropriate and not unfairly discriminatory because Market Makers have different requirements and obligations to the Exchange that other market participants do not (such as quoting requirements). The Exchange believes that it is equitable and not unfairly discriminatory to provide lower fees to Market Makers because they would apply uniformly to similarly situated market participants.

Crossing Orders

The Exchange believes the proposed rebates for PIM Orders of 500 or Fewer Contracts[21] are reasonable and equitably allocated because the proposed fees are within the range of fees assessed by other exchanges such as MIAX, which offers a rebate for PRIME Agency orders.[22] For example, MIAX offers a per contract rebate of $0.10 for each Priority Customer order and also offers an additional per contract rebate of $0.02 for members that qualify for MIAX's Priority Customer Rebate Program's volume tiers 3 and 4.[23] While ISE Mercury's tiered rebate is specifically targeted towards Priority Customer orders, the Exchange does not believe that this is unfairly discriminatory. As discussed above,

[16] *See* MIAX Fee Schedule, (1) Transaction Fees, (a) Exchange Fees, (iii) Priority Customer Rebate Program at *https://www.miaxoptions.com/sites/default/files/MIAX_Options_Fee_Schedule_02012016B.pdf.*

[17] *See* MIAX Fee Schedule, (1) Transaction Fees, (a) Exchange Fees, (iii) Priority Customer Rebate Program at *https://www.miaxoptions.com/sites/default/files/MIAX_Options_Fee_Schedule_03012016.pdf* and PHLX Fee Schedule, B. Customer Rebate Program at *http://www.nasdaqtrader.com/Micro.aspx?id=phlxpricing.*

[18] PHLX Fee Schedule, B. Customer Rebate Program, Category A at *http://www.nasdaqtrader.com/Micro.aspx?id=phlxpricing.*

[19] *See* MIAX Fee Schedule, (1) Transaction Fees, (a) Exchange Fees, (i) Market Maker Transaction Fees, Market Maker Sliding Scale at *https://www.miaxoptions.com/sites/default/files/MIAX_Options_Fee_Schedule_03012016.pdf.*

[20] *Id.*

[21] The level is set at 500 or fewer contracts because Priority Customer orders are typically less than 500 contracts.

[22] *See* MIAX Fee Schedule, (1) Transaction Fees, (a) Exchange Fees, (iii) Priority Customer Rebate Program at *https://www.miaxoptions.com/sites/default/files/MIAX_Options_Fee_Schedule_03012016.pdf.*

[23] *Id.*

Priority Customer orders on the Exchange are generally entitled to lower fees and higher rebates, and the Exchange believes that attracting more liquidity from Priority Customers will benefit all market participants that trade on ISE Mercury. Further, the Exchange believes that it is equitable and not unfairly discriminatory to provide lower fees to Priority Customers because they would apply uniformly to similarly situated market participants.

Responses to Crossing Orders

The Exchange's proposal to assess Penny and Non-Penny Symbol fees for Responses to Crossing Orders is reasonable and equitably allocated because they are within the range of fees assessed by other exchanges. Specifically, the Exchange proposes to keep fees for Responses to Crossing Orders in Penny Symbols the same and to increase fees for Responses to Crossing Orders in Non-Penny Symbols so that these fees are competitive with similar fees charged on other exchanges. For example, ISE Gemini's Fees for Responses to Crossing Orders [24] in both Penny and Non-Penny Symbols are competitive with those proposed by ISE Mercury. Further, the Exchange believes the proposed Fees for Responses to Crossing Orders are not unfairly discriminatory because they would uniformly apply to all similarly situated market participants.

With respect to the Responses to Crossing Orders' tiered fees for Market Maker orders, the Exchange believes that the proposed fees are fair, equitable, and not unfairly discriminatory because the proposed fees are consistent with the fees charged at other exchanges. For example, ISE Gemini charges Market Makers a Fee for Responses to Crossing Orders of $0.49 per contract in Penny Symbols and $0.89 per contract in Non-Penny Symbols. Similarly, ISE Mercury's proposal would charge per contract fees ranging from $0.50 (Tier 1 fee plus Marketing Fee) to $0.35 (Tier 5 fee plus Marketing Fee) in Penny Symbols and per contract fees ranging from $0.95 (Tier 1 fee plus Marketing Fee) to $0.80 (Tier 5 fee plus marketing fee) in Non-Penny Symbols. As discussed above, the Exchange believes that the price differentiation between Market Makers and the other market participants is appropriate and not unfairly discriminatory because they have requirements and obligations to the Exchange that the other market participants do not. Market Makers also incur Marketing Fees, which the other market participants do not. Thus, the Exchange believes that it is equitable and not unfairly discriminatory to assess a higher fee to certain market participants that do not have such requirements and obligations that Exchange Market Makers do.

Market Maker Discount

The Exchange believes the proposed Market Maker discount is reasonable, equitable, and not unfairly discriminatory because Market Makers have different requirements and obligations to the Exchange that other market participants do not and they incur Marketing Fees. The Exchange notes that when trading against a Priority Customer the exchange pays a rebate for Priority Customer orders, but the Exchange charges a fee for executions of Non-Priority Customer orders. The Exchange believes that offering a discount on the fees charged to Market Makers will encourage Market Maker to make better markets and execute more trades. Furthermore, charging Market Makers lower fees for trading against a Non-Priority Customer order is not a new concept in the industry. For example, BOX Options Exchange, in Non-Penny Pilot Symbols, charges Market Makers a maker fee of $0.85 per contract for trading against a Priority Customer order and a maker fee of $0.00 for trading against a Professional Customer/Broker Dealer order.[25] Finally, [sic]

The Exchange notes that the proposed rule filing is intended to further establish ISE Mercury as an attractive venue for market participants to direct their order flow as the proposed fees and rebates are competitive with those established by other exchanges. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to another exchange if they deem rebates at a particular exchange to be too low. For the reasons noted above, the Exchange believes that the proposed rebates are fair, equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[26] the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The tiered rebate structure that the Exchange proposes to adopt is similar to those currently in effect on other options exchanges such as MIAX and PHLX, and will increase competition between ISE Mercury and these markets.

In establishing the MVP, the Exchange is not imposing any burden on competition. The established volume tiers are transparent and offer members a simple way to reach different levels of fees and rebates on the exchange, similar to levels and differentials these same participants are familiar with on several other exchanges. Volume tiers are not new to the options industry and generally reward members for submitting additional volume to the Exchange, with ISE Mercury now seeking to introduce a similar structure. The Exchange also notes that other exchanges have substantially similar requirements for aggregating affiliated member ADV in determining applicable tiered rebates.

Finally, in establishing a Market Maker discount for Market Makers trading against Non-Priority Customer orders, the Exchange is not imposing any burden on competition not necessary or appropriate in furtherance of the purposes of the Act because other exchanges offer lower fees to Market Makers trading against Non-Priority Customers. Additionally, the Exchange notes that when trading against a Priority Customer the exchange pays a rebate for Priority Customer orders, but the Exchange charges a fee for executions of Non-Priority Customer orders. The Exchange believes that offering a discount on the fees charged to Market Makers will encourage Market Maker to make better markets and execute more trades.

The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any

[24] *See* ISE Gemini Fee Schedule, I. Regular Order Fees and Rebates, Fee for Crossing Orders at *http://www.ise.com/assets/gemini/documents/OptionsExchange/legal/fee/Gemini_Fee_Schedule.pdf.*

[25] *See* BOX Options Exchange Fee Schedule, Section I. Exchange Fees, A. Non-Auction Transactions at *http://boxexchange.com/assets/BOX-Exchange-Fee-Schedule-as-of-February-26-2016.pdf.*

[26] 15 U.S.C. 78f(b)(8).

unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[27] and subparagraph (f)(2) of Rule 19b–4 thereunder,[28] because it establishes a due, fee, or other charge imposed by ISE Mercury.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISEMercury–2016–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISEMercury–2016–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISEMercury–2016–05, and should be submitted on or before April 15, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Brent J. Fields,

Secretary.

[FR Doc. 2016–06744 Filed 3–24–16; 8:45 am]

BILLING CODE 8011–01–P

[27] 15 U.S.C. 78s(b)(3)(A)(ii).

[28] 17 CFR 240.19b–4(f)(2).

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77413; File No. SR–ICC–2016–003]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change To Revise the ICC Operational Risk Management Framework

March 21, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder[2] notice is hereby given that on March 10, 2016, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to update ICC's Operational Risk Management Framework. These revisions do not require any changes to the ICC Clearing Rules.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of these statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

ICC proposes updates to the ICC Operational Risk Management Framework. ICC believes such revisions will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. The proposed revisions are described in detail as follows.

The ICC Operational Risk Management Framework details ICC's dynamic and independent program of risk assessment and oversight, managed by the Operational Risk Manager (''ORM''), which aims to reduce operational incidents, encourage process and control improvement, bring transparency to operational performance standard monitoring, and fulfill regulatory obligations. ICC proposes organizational changes to its Operational Risk Management Framework related to its operational risk management processes.

ICC has revised the Operational Risk Management Framework to frame its existing operational risk program and processes around an operational risk lifecycle, designed to highlight certain aspects of the processes and present the processes in a more efficient manner. The operational risk lifecycle utilized by ICC has five components: Identify, assess, monitor, mitigate and report. Each of these lifecycle components are first defined generally in the document then applied to each of ICC's two operational risk processes: Risk assessment; and performance objectives setting and monitoring. Specifically, the content for each risk process has been reorganized to fall into each of the operational risk lifecycle components (*i.e.,* identify, assess, monitor, mitigate, and report). For completion purposes,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

ICC added information regarding the 'assess' and 'report' component of the risk assessment process. Specifically, ICC assesses each of its risk scenarios to determine the inherent risk rating associated with the occurrence of an event or incident, as well as assess the effectiveness of any relevant risk controls. Further, in the 'report' component, ICC clarified that the ORM presents operational risk reporting to an internal committee which includes members of senior management. The responsibilities of the ORM, which were previously listed out in the document, were incorporated into the risk lifecycles. The ORM will continue to provide management and staff with advice and guidance related to the development of controls designed to increase performance and reduce processing risk, as part of the 'mitigate' risk lifecycle component. Similarly, the responsibilities of senior management, which were previously listed out in the document, were incorporated into the risk lifecycles.

ICC has categorized those aspects of the operational risk management program which do not fall within this lifecycle as ''Operational Risk Focus Areas.'' These risk focus areas include: Business continuity planning and disaster recovery; vendor assessment; new products and initiatives; information security; and technology control functions. ICC has reorganized the order of these risk focus areas to better distinguish which functions may, with oversight by the ORM, be outsourced to Intercontinental Exchange, Inc. (''ICE, Inc.'') or performed by departments dedicated to that particular risk area.

ICC has made several clarifying and organizational enhancements to the various risk focus area descriptions. Further, specific details contained within other ICC policies and procedures were removed and described more generally within the Operational Risk Management Framework, in an effort to reduce redundancy amongst ICC policies and procedures. ICC continues to maintain business continuity planning and disaster recovery as two separate programs with separate and distinct components; however, ICC has grouped the description of these programs together for purposes of the Operational Risk Management Framework. ICC enhanced the ''Vendor Assessment'' risk focus area description to note that the ORM is responsible for conducting a service provider risk assessment for critical vendors, and to list the specific steps taken as part of such risk assessment. ICC also enhanced the ''Information Security'' risk focus area description to note that the ICE, Inc. Information Security Department conducts its own risk assessments related to information security and physical security/environmental controls, pursuant to internal policies which are maintained by an ICE, Inc. internal committee. Information regarding the Firm Wide Incident Management Program was included in the new 'Technology Controls Section.' ICC enhanced the 'Technology Control Functions' risk focus area description to note that the ICC Systems Operations team is responsible for executing daily clearing functions within established service expectations and performing incident management. ICC described this incident management process generally within the framework, and removed more detailed aspects of the program which are contained in specific program documentation.

General information regarding the development and enforcement of a firm-wide operational risk framework was removed, as the revised framework more clearly lays out in each particular section who is responsible for the development and enforcement of that component of the operational risk management framework. Information regarding the human resource reporting line of the ORM and specific references to titles of documents utilized as part of the risk assessment process were removed. As the Vendor Risk Management policy was retired and encompassed within the Operational Risk Management Framework, reference to the policy was removed from the document. ICC removed internal audit responsibilities from the Operational Risk Management Framework as such responsibilities are contained within internal audit documentation.

The overall governance of the Operational Risk Framework has been updated to reflect current practices. Specifically, material amendments are reviewed by the Risk Committee, and approved by the Board. The Board reviews the Operational Risk Management Framework at least annually.

Other non-material changes were made to the framework to enhance readability. Previously, ICC included regulatory requirements and industry guidance information within the framework; this information has been moved to a separate appendix to the framework. Further, information regarding Regulation Systems, Compliance, and Integrity has been added for completeness. Certain information regarding governance and governing committees has been resituated to the reporting section of the relevant operational risk lifecycle. Similarly, information regarding the roles and responsibilities of the ORM and senior management has been resituated to the appropriate section the operational risk lifecycle.

Section 17A(b)(3)(F) of the Act [3] requires, among other things, that the rules of a clearing agency be designed to protect investors and the public interest and to comply with the provisions of the Act and the rules and regulations thereunder. ICC believes that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to ICC, in particular, to Section 17(A)(b)(3)(F),[4] because ICC believes that the proposed rule changes will protect investors and the public interest, as the reorganization of ICC's existing operational risk processes around the operational risk lifecycle promotes readability and efficiency, and alleviates potential confusion throughout the Operational Risk Management Framework. In addition, the proposed revisions are consistent with the relevant requirements of Rule 17Ad–22.[5] The changes to the ICC Operational Risk Management Framework further ensure that ICC, through its operational risk program, is able to identify sources of operational risk and minimize them through the development of appropriate systems, control, and procedures. Thus, the changes are reasonably designed to meet the operational risk requirements of Rule 17Ad–22(d)(4).[6] As such, the proposed changes are designed to promote the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions within the meaning of Section 17A(b)(3)(F) [7] of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

ICC does not believe the proposed rule changes would have any impact, or impose any burden, on competition. The ICC Operational Risk Management Framework applies uniformly across all market participants. Therefore, ICC does not believe the proposed rule changes impose any burden on competition that is inappropriate in furtherance of the purposes of the Act.

[3] 15 U.S.C. 78q–1(b)(3)(F).

[4] Id.

[5] 17 CFR 240.17Ad–22.

[6] 17 CFR 240.17Ad–22(d)(4).

[7] Id.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2016–003 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number *SR–ICC–2016–003*. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's Web site at *https://www.theice.com/clear-credit/regulation*.

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2016–003 and should be submitted on or before April 15, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Brent J. Fields,

Secretary.

[FR Doc. 2016–06747 Filed 3–24–16; 8:45 am]

BILLING CODE 8011–01–P

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32032; 812–14285]

Northern Lights Fund Trust and Princeton Fund Advisors, LLC; Notice of Application

March 21, 2016.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under Section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from Section 15(a) of the Act and Rule 18f–2 under the Act, as well as from certain disclosure requirements in Rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and Sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements''). The requested exemption would permit an investment adviser to hire and replace certain sub-advisers without shareholder approval and grant relief from the Disclosure Requirements as they relate to fees paid to the sub-advisers.

APPLICANTS: Northern Lights Fund Trust (the ''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series, and Princeton Fund Advisors LLC, a Delaware limited liability company registered as an investment adviser under the Investment Advisers Act of 1940 (''the ''Adviser,'' and, collectively with the Trust, the ''Applicants'').

FILING DATES: The application was filed March 6, 2014, and amended on August 21, 2014, November 10, 2014, November 25, 2015, February 19, 2016, February 22, 2016, and March 16, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 18, 2016, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: Trust: James P. Ash, Esq., Gemini Fund Services LLC, 80 Arkay Drive, Suite 110, Hauppage, NY 11788 and Adviser: Princeton Fund Advisors, LLC, 1125 17th Street, Suite 1400, Denver, CO 80202.

FOR FURTHER INFORMATION CONTACT: Jean E. Minarick, Senior Counsel, at (202) 551–6811, or Daniele Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. The Adviser will serve as the investment adviser to the Funds pursuant to an investment advisory agreement with the Trust (the ''Advisory

Agreement'').[1] The Adviser will provide the Funds with continuous and comprehensive investment management services subject to the supervision of, and policies established by, each Fund's board of trustees (''Board''). The Advisory Agreement permits the Adviser, subject to the approval of the Board, to delegate to one or more sub-advisers (each, a ''Sub-Adviser'' and collectively, the ''Sub-Advisers'') the responsibility to provide the day-to-day portfolio investment management of each Fund, subject to the supervision and direction of the Adviser. The primary responsibility for managing the Funds will remain vested in the Adviser. The Adviser will hire, evaluate, allocate assets to and oversee the Sub-Advisers, including determining whether a Sub-Adviser should be terminated, at all times subject to the authority of the Board.

2. Applicants request an exemption to permit the Adviser, subject to Board approval, to hire certain Sub-Advisers pursuant to Sub-Advisory Agreements and materially amend existing Sub-Advisory Agreements without obtaining the shareholder approval required under Section 15(a) of the Act and Rule 18f–2 under the Act.[2] Applicants also seek an exemption from the Disclosure Requirements to permit a Fund to disclose (as both a dollar amount and a percentage of the Fund's net assets): (a) The aggregate fees paid to the Adviser; and (b) the aggregate fees paid to Sub-Advisers other than Affiliated Sub-Advisers; and (c) the fee paid to each Affiliated Sub-Adviser (collectively, ''Aggregate Fee Disclosure'').

3. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the Application. Such terms and conditions provide for, among other safeguards, appropriate disclosure to Fund shareholders and notification about sub-advisory changes and enhanced Board oversight to protect the interests of the Funds' shareholders.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or any rule thereunder, if such relief is necessary or appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard because, as further explained in the Application, the Advisory Agreements will remain subject to shareholder approval, while the role of the Sub-Advisers is substantially similar to that of individual portfolio managers, so that requiring shareholder approval of Sub-Advisory Agreements would impose unnecessary delays and expenses on the Funds. Applicants believe that the requested relief from the Disclosure Requirements meets this standard because it will improve the Adviser's ability to negotiate fees paid to the Sub-Advisers that are more advantageous for the Funds.

For the Commission, by the Division of Investment Management, under delegated authority.

Brent J. Fields,

Secretary.

[FR Doc. 2016–06748 Filed 3–24–16; 8:45 am]

BILLING CODE 8011–01–P

[1] Applicants request relief with respect to any existing and any future series of the Trust and any other registered open-end management company or series thereof that: (a) Is advised by the Adviser or its successor or by a person controlling, controlled by, or under common control with the Adviser or its successor (each, also an ''Adviser''); (b) uses the manager of managers structure described in the application; and (c) complies with the terms and conditions of the application (any such series, a ''Fund'' and collectively, the ''Funds''). For purposes of the requested order, ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] The requested relief will not extend to any Sub-Adviser that is an affiliated person, as defined in Section 2(a)(3) of the Act, of a Fund or the Adviser, other than by reason of serving as a sub-adviser to one or more of the Funds, or as an investment adviser or subadviser to any fund of the Trust other than a Fund (''Affiliated Sub-Adviser'').

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77410; File No. SR–ISE–2016–07]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Eliminate the Strict Concentration Limits on Primary Market Makers

March 21, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 15, 2016, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

ISE proposes to eliminate the 30% strict cap on the number of Primary Market Maker (''PMM'') memberships that the ISE's Board of Directors (the ''Board'') can approve for an ISE member to operate. The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposal is to eliminate the 30% strict cap on the number of PMM memberships that the Board can approve for an ISE member to operate.[3] ISE Rule 303(b) currently requires the Board show ''good cause'' to approve any PMM membership that would result in the PMM operating trading privileges associated with more than one PMM membership. The Board may waive the limitations contained in this rule if it determines that good cause has been shown and such action is, in its judgment, in the best interests of the Exchange.[4] The Board is not permitted,

[3] A PMM serves a function similar to that of a specialist on other exchanges. Among other things, a PMM must provide continuous quotations in all assigned options classes. *See* Rule 804(e)(1); Supplementary Material .01 to Rule 804. There are currently 10 outstanding PMM memberships authorized and issued by the Exchange under its Third Amended and Restated LLC Agreement (the ''LLC Agreement''). *See* LLC Agreement, Section 6.1(a).

[4] When making its determination whether good cause has been shown to waive the limitations contained in this rule, the Board must consider whether an operational, business or regulatory need

however, to grant this approval if the member and its affiliates would, as a result, be approved to exercise trading privileges associated with more than 30% of all outstanding PMM memberships.[5] Section 6.5(b) of ISE's Third Amended and Restated Limited Liability Company Agreement (the ''LLC Agreement'') contains the same 30% strict cap as Rule 303(b). This limitation on exercising PMM trading privileges is in addition to ownership and voting limitations in the LLC Agreement and in the Exchange's rules that prohibit any member from owning (or voting the shares representing) more than 20% of any class of membership.[6]

Due to the continued concentration and specialization in the options market making community, and the decreasing number of market makers available to operate these memberships, the Exchange is proposing to eliminate the 30% cap on the number of PMM memberships that the Board can approve for a member to operate.

As the number of market makers decreases, the Exchange is concerned that there may not be a sufficient number of members qualified to be PMMs if the Exchange retains the current 30% cap (thus limiting a member to operating three PMM memberships). The options markets are highly competitive, and each exchange actively seeks to attract order flow by disseminating tight and liquid markets and by providing a high level of customer satisfaction. Ensuring that the Exchange has high quality PMMs is critical in this competitive battle.

The Exchange believes that the proposed approach is consistent with treatment on other markets that do not have strict market maker concentration limits, and will enable the Board to approve members to operate multiple PMM memberships after the Board determines that good cause has been shown and if doing so would be in the best interest of the Exchange.

The Commission has previously approved rule changes that eliminated mandatory caps on the number of issues that may be allocated to market makers on other markets, such as on Pacific Exchange, Inc. (''PCX'') (n/k/a ''NYSE Arca''), where the Commission approved a rule change by PCX to eliminate its Lead Market Maker (''LMM'') concentration limit of 15% of the issues traded on the PCX options floor.[7] There, the Commission noted that PCX's concentration limits served the purpose of minimizing the disturbance to a fair and orderly market that may otherwise result from the failure of an LMM. However, the Commission also noted that other exchanges did not impose specified mandatory limits on the number of options that may be allocated to specialists, citing to the rules of the Chicago Board Options Exchange (''CBOE'').[8] In addition, the Commission has previously granted registration to new exchanges that do not have similar concentration limits.[9]

The Exchange recognizes that increasing the number of PMM memberships a member can operate could raise issues regarding concentration of market making expertise. In this regard, the proposed rule change is only an enabling rule. With the proposed change, the Board will still be required to show good cause to approve any member to operate more than one PMM membership, and could consider the number of memberships already by the member in determining whether or not there is good cause shown. Thus, the Board will need to weigh each potential application on its own merits, balancing the potential benefits of allowing a member to exercise more than one PMM membership against any potential concentration concerns. The Board would not be prohibited under the rules and under the LLC Agreement, however, from approving PMMs to operate more than a specified percentage of outstanding memberships.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[10] In particular, the proposal is consistent with Section 6(b)(5) of the Act,[11] because it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The options industry continues to experience a consolidation and decrease in the number of market makers and therefore, the Exchange is proposing a rule change that would eliminate the 30% PMM cap and would allow the Board the flexibility to approve or deny each potential PMM application based upon its determination of whether good cause had been shown and if doing so would be in the best interest of the Exchange. Also as noted above, the Commission has previously approved rule changes eliminating mandatory caps on the number of issues that may be allocated to market makers on other markets, and has granted registration to new exchanges that do not have similar concentration limits. The Exchange therefore believes that the proposed rule change is designed to remove impediments to and perfect the mechanisms of a free and open market and a national market system. Furthermore, this proposed rule change would not amend the current prohibitions in the LLC Agreement and in the Exchange's rules against a member owning or voting more than 20% of any class of membership. Thus, the only way a member could operate more than 30% of all outstanding PMM memberships would be to lease such membership, with the lease providing that the lessor retains all voting rights.[12]

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[13] the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposed rule change will increase competition among market makers to be approved as a PMM on the Exchange, thus allowing the Exchange to choose the most qualified PMM that will provide the Exchange with strong market making capabilities. Also as noted above, other markets do not have

to exceed the limits has been demonstrated, and in those cases where such a need is demonstrated, the Board must also consider any operational, business or regulatory concerns may be raised if such a waiver were granted. *See* Supplementary Material .01 to Rule 303.

[5] In 2006, the Commission approved an ISE proposal to increase the maximum number of PMM memberships that an ISE member may operate from two to three PMM memberships. *See* Securities Exchange Act Release No. 53271 (February 10, 2006), 71 FR 8625 (February 17, 2006) (SR–ISE–2005–46) (Approval Order).

[6] *See* LLC Agreement, Section 6.5(a); Supplementary Material .02 to Rule 303. The Exchange is not proposing any changes to the ownership and voting limitations.

[7] *See* Securities Exchange Act Release Nos. 47795 (May 5, 2003), 68 FR 25074 (May 9, 2003) (Notice); 48029 (June 13, 2003), 68 FR 37187 (June 23, 2003) (SR–PCX–2002–25) (Approval Order).

[8] *See* CBOE Rule 8.84 (Rule 8.84 does not impose a mandatory cap on the number of issues that may be allocated to a Designated Primary Market-Maker (''DPM'').

[9] *See* MIAX Options Exchange (''MIAX'') Rules.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *See* ISE Second A&R Constitution, Section 12.4; Supplementary Material .02 to Rule 303.

[13] 15 U.S.C. 78f(b)(8).

comparable mandatory caps or concentration limits, so eliminating the 30% PMM cap will bring the Exchange's rules in line with its competitors.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[16] As noted above, the Exchange states that waiver of this requirement will allow the Exchange to immediately remove the 30% cap and align its rules with other competing options markets that do not have comparable restrictions. The Exchange also notes that the proposed rule change preserves existing ownership and voting limitations in the LLC Agreement.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2016–07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2016–07. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2016–07 and should be submitted on or before April 15, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Brent J. Fields,

Secretary.

[FR Doc. 2016–06745 Filed 3–24–16; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

Public Notice; 30-Day Notice of Proposed Information Collection: Smart Traveler Enrollment Program

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to April 25, 2016.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Derek Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/PMO), who may be reached on 202–485–6332 or at *RiversDA@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Smart Traveler Enrollment Program
- *OMB Control Number:* 1405–0152
- *Type of Request:* Revision of a Currently Approved Collection
- *Originating Office:* Bureau of Consular Affairs, CA/OCS/PMO

- *Form Number:* DS–4024, DS–4024e
- *Respondents:* United States Citizens and Nationals
- *Estimated Number of Respondents:* 1,010,389
- *Estimated Number of Responses:* 1,010,389
- *Average Time per Response:* 20 minutes
- *Total Estimated Burden Time:* 336,796 hours
- *Frequency:* On Occasion
- *Obligation To Respond:* Voluntary

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Smart Traveler Enrollment Program (STEP) makes it possible for U.S. nationals to register on-line from anywhere in the world. In the event of a family emergency, natural disaster or international crisis, U.S. embassies and consulates rely on this registration information to provide critical information and assistance to them. 22 U.S.C. 2715 is one of the main legal authorities that deem the usage of this form necessary.

Methodology

99% of responses are received via electronic submission on the Internet. The service is available on the Department of State, Bureau of Consular Affairs Web site *http://travel.state.gov* at *https://step.state.gov/step/.* The paper version of the collection permits respondents who do not have Internet access to provide the information to the U.S. embassy or consulate by fax, mail or in person.

Dated: March 11, 2016.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Overseas Citizen Services, Department of State.

[FR Doc. 2016–06693 Filed 3–24–16; 8:45 am]

BILLING CODE 4710–06–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36009]

Gulf & Ohio Railways, Inc., H. Peter Claussen and Linda C. Claussen—Continuance in Control Exemption—North Carolina & Atlantic Railroad Co., Inc.

Gulf & Ohio Railways, Inc. (G&O), and H. Peter Claussen and Linda C. Claussen (the Claussens) (collectively, Applicants) have jointly filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of North Carolina & Atlantic Railroad Co., Inc. (NCAR), upon NCAR's becoming a Class III rail carrier.

This transaction is related to a concurrently filed verified notice of exemption in *North Carolina & Atlantic Railroad Co., Inc.—Lease & Operation Exemption—North Carolina Department of Transportation,* Docket No. FD 36008, wherein NCAR seeks Board approval under 49 CFR 1150.31 to lease from the North Carolina Department of Transportation, and to operate, approximately 5.7 miles of rail line, referred to as the Global Transpark rail corridor, between milepost GTP–0.0 (connection to the North Carolina Railroad Company track) and milepost GTP–5.7 (at the NC Global Transpark) at Kinston, in Lenoir County, NC.

Applicants expect to consummate the proposed transaction on or after April 8, 2016, the effective date of the exemption (30 days after the verified notice of exemption was filed).

According to Applicants, the Claussens own a controlling share of voting stock of G&O. G&O, in turn, wholly owns four Class III rail carriers operating in three states: (a) Knoxville & Holston River Railroad Co., Inc., operating in Tennessee; (b) Lancaster & Chester Railroad, LLC, operating in South Carolina; (c) Laurinburg & Southern Railroad Co., Inc., operating in North Carolina; and (d) Piedmont & Atlantic Railroad Co., Inc., d/b/a Yadkin Valley Railroad, operating in North Carolina.

Applicants certify that: (1) The rail lines to be operated by NCAR do not connect with any other railroads operated by the carriers in the Applicants' corporate family; (2) the continuance in control is not part of a series of anticipated transactions that would connect the rail lines to be operated by NCAR with any other railroad in Applicants' corporate family; and (3) the transaction does not involve a Class I rail carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Stay petitions must be filed no later than April 1, 2016 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36009, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Applicants' representative, Rose-Michele Nardi, Transport Counsel PC, 1701 Pennsylvania Ave. NW., Suite 300, Washington, DC 20006.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV.*''

Decided: March 21, 2016.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–06782 Filed 3–24–16; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36008]

North Carolina & Atlantic Railroad Co., Inc.—Lease and Operation Exemption—North Carolina Department of Transportation

North Carolina & Atlantic Railroad Co., Inc. (NCAR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to lease from the North

Carolina Department of Transportation (NCDOT), and to operate, approximately 5.7 miles of rail line, referred to as the Global Transpark rail corridor, between milepost GTP–0.0 (connection to the North Carolina Railroad Company track) and milepost GTP–5.7 (at the NC Global Transpark) at Kinston, in Lenoir County, N.C., pursuant to an executed lease and operating agreement.

This transaction is related to a concurrently filed verified notice of exemption in *Gulf & Ohio Railways, Inc.—Continuance in Control Exemption—North Carolina & Atlantic Railroad Co., Inc.,* Docket No. FD 36009, in which Gulf & Ohio Railways, Inc., H. Peter Claussen and Linda C. Claussen seek Board approval to continue in control of NCAR under 49 CFR 1180.2(d)(2), upon NCAR's becoming a Class III rail carrier.

NCAR certifies that the projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class II rail carrier and states that its projected annual revenue is expected not to exceed $5 million. NCAR states that the agreement regarding the subject line does not involve an interchange commitment.

The transaction may be consummated on April 8, 2016, the effective date of the exemption (30 days after the verified notice of exemption was filed). If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed by April 1, 2016 (at least seven days prior to the date the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36008 must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on applicant's representative, Rose-Michele Nardi, Transport Counsel PC, 1701 Pennsylvania Ave. NW., Suite 300, Washington, DC 20006.

According to NCAR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV*.''

Decided: March 21, 2016.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–06784 Filed 3–24–16; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36001]

BNSF Railway Company—Trackage Rights Exemption—State of Washington, Department of Transportation

The State of Washington, Department of Transportation (WDOT), pursuant to a trackage rights agreement being negotiated between WDOT and BNSF Railway Company (BNSF),[1] has agreed to grant BNSF restricted local trackage rights over approximately 5.3 miles of rail line between milepost 1.0 at Cheney, Wa., and milepost 6.30 near Four Lakes, Wa. (the Line). The trackage rights are intended to permit BNSF to move unit trains of 75 to 120 cars of grain or grain products or empty cars originating or terminating at the Highline Grain facility at milepost 6.30, and to perform overhead movements over the Line.

The transaction may be consummated on or after April 10, 2016, the effective date of the exemption (30 days after the verified notice of exemption was filed).

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed by April 1, 2016 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36001, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Karl Morell, Karl Morell & Associates, 655 15th Street NW., Suite 225, Washington, DC 20005.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: March 21, 2016.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–06783 Filed 3–24–16; 8:45 am]

BILLING CODE 4915–01–P

[1] WDOT and BNSF state that a copy of the agreement will be filed with the Board within 10 days of the agreement's execution. Also, WDOT states that Eastern Washington Gateway Railroad Company, which leases the Line for which BNSF seeks restricted local trackage rights, will be a party to the trackage rights agreement.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 35996]

San Jacinto Transportation Company, Inc.—Operation Exemption—SJRE-Railroad Series

San Jacinto Transportation Company, Inc. (SJTC), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to operate approximately 6.0 miles of rail line owned by SJRE-Railroad Series (SJRE), pursuant to an operating agreement with SJRE,[1] in Harris County, Tex. (the Line). The Line is located within the San Jacinto River and Rail Park and will connect with Union Pacific Railroad Company (UP) and BNSF Railway Company (BNSF) near mileposts 344–346 on the Lafayette Subdivision.

The transaction may be consummated on or after April 9, 2016, the effective date of the exemption (30 days after the exemption was filed).

SJTC certifies that, as a result of this transaction, its projected revenues will not result in the creation of a Class II or Class I rail carrier and will not exceed $5 million.

SJTC states that the operating agreement does not involve a provision or agreement which may limit future interchange with a third party connecting carrier. SJTC further states that, once the exemption becomes effective, it anticipates that UP and BNSF will enter into an interchange or switching agreement for SJTC to serve customers on the Line.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be

[1] SJRE is an entity within San Jacinto Real Estate, a series of LLCs' formed under the laws of Texas.

filed no later than April 1, 2016 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35996, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy must be served on John K. Fiorilla, Capehart & Scatchard, P.A., 8000 Midlantic Drive, Suite 300S, Mount Laurel, NJ 08054.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: March 21, 2016.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2016–06788 Filed 3–24–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting on Transport Airplane and Engine Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee (ARAC) Transport Airplane and Engine (TAE) Subcommittee to discuss TAE issues.

DATES: The meeting is scheduled for Wednesday, June 22, 2016, starting at 9:00 a.m. Eastern Time. Arrange for oral presentations by June 1, 2016.

ADDRESSES: Aerospace Industries Association, 1000 Wilson Blvd., Suite 1700, Arlington, VA 22209.

FOR FURTHER INFORMATION CONTACT: Ralen Gao, Office of Rulemaking, ARM–209, FAA, 800 Independence Avenue SW., Washington, DC 20591, Telephone (202) 267–3168, Fax (202) 267–5075, or email at *ralen.gao@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. III), notice is given of an ARAC meeting to be held on June 22, 2016.

The agenda for the meeting is as follows:

- Opening Remarks, Review Agenda and Minutes
- FAA Report
- ARAC Report
- Transport Canada Report
- EASA Report
- Engine HWG Report
- Airworthiness Assurance HWG Report
- Flight Test HWG Report
- Metallic and Composite Structures WG Report
- Crashworthiness and Ditching WG Report
- Any Other Business
- Action Item Review

Participation is open to the public, but will be limited to the availability of teleconference lines.

To participate, please contact the person listed in **FOR FURTHER INFORMATION CONTACT** by email or phone for the teleconference call-in number and passcode. Please provide the following information: Full legal name, country of citizenship, and name of your industry association, or applicable affiliation. If you are participating as a public citizen, please indicate so. Participants are responsible for any telephone, data usage or other similar expenses related to this meeting.

The public must make arrangements by June 1, 2016, to present oral or written statements at the meeting. Written statements may be presented to the Subcommittee by providing a copy to the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Copies of the documents to be presented to the Subcommittee may be made available by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

If you need assistance or require a reasonable accommodation for the meeting or meeting documents, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Issued in Washington, DC, on March 10, 2016.

Lirio Liu,

Designated Fedral Officer, Aviation Rulemaking Advisory Committee.

[FR Doc. 2016–06757 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–40]

Petition for Exemption; Summary of Petition Received; Wittman Regional Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before April 14, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–4042 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Taiya Carter (202) 267–2979, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on March 18, 2016.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–4042.
Petitioner: Wittman Regional Airport.
Section(s) of 14 CFR Affected: § 139.101.
Description of Relief Sought: Wittman Regional Airport is requesting an exemption to allow certain unscheduled Air Carrier operations at Wittman Regional Airport (KOSH) at limited times during Experimental Aircraft Association (EAA) Airventure 2016.

[FR Doc. 2016–06756 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2016–0003]

Surface Transportation Project Delivery Program; TxDOT Audit Report

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice, request for comment.

SUMMARY: The Surface Transportation Project Delivery Program (23 U.S.C. 327) allows a State to assume FHWA's environmental responsibilities for review, consultation, and compliance for Federal-aid highway projects. When a State assumes these Federal responsibilities, the State becomes solely responsible and liable for carrying out the responsibilities it has assumed, in lieu of FHWA. Prior to the Fixing America's Surface Transportation (FAST) Act of 2015, the program required semiannual audits during each of the first 2 years of State participation to ensure compliance by each State participating in the program. This notice announces and solicits comments on the second audit report for the Texas Department of Transportation's (TxDOT) participation in accordance to these pre-FAST Act requirements.

DATES: Comments must be received on or before April 25, 2016.

ADDRESSES: Mail or hand deliver comments to Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590. You may also submit comments electronically at *www.regulations.gov.* All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. Anyone is able to search the electronic form of all comments in any one of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, or labor union). The DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Dr. Owen Lindauer, Office of Project Development and Environmental Review, (202) 366–2655, *owen.lindauer@dot.gov,* or Mr. Jomar Maldonado, Office of the Chief Counsel, (202) 366–1373, *jomar.maldonado@dot.gov,* Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this notice may be downloaded from the specific docket page at *www.regulations.gov.*

Background

The Surface Transportation Project Delivery Program (or NEPA Assignment Program) allows a State to assume FHWA's environmental responsibilities for review, consultation, and compliance for Federal-aid highway projects. This provision has been codified at 23 U.S.C. 327. When a State assumes these Federal responsibilities, the State becomes solely responsible and liable for carrying out the responsibilities it has assumed, in lieu of FHWA. The TxDOT published its application for assumption under the National Environmental Policy Act (NEPA) Assignment Program on March 14, 2014, at Texas Register 39(11): 1992, and made it available for public comment for 30 days. After considering public comments, TxDOT submitted its application to FHWA on May 29, 2014. The application served as the basis for developing the Memorandum of Understanding (MOU) that identifies the responsibilities and obligations TxDOT would assume. The FHWA published a notice of the draft of the MOU in the **Federal Register** on October 10, 2014, at 79 FR 61370 with a 30-day comment period to solicit the views of the public and Federal agencies. After the close of the comment period FHWA and TxDOT considered comments and proceeded to execute the MOU. Since December 16, 2014, TxDOT has assumed FHWA's responsibilities under NEPA, and the responsibilities for the NEPA-related Federal environmental laws.

Prior to December 4, 2015, 23 U.S.C. 327(g) required the Secretary to conduct semiannual audits during each of the first 2 years of State participation, and annual audits during each subsequent year of State participation to ensure compliance by each State participating in the program. The results of each audit were required to be presented in the form of an audit report and be made available for public comment. On December 4, 2015, the President signed into law the FAST Act (Pub. L. 114–94, 129 Stat. 1312 (2015)). Section 1308 of the FAST Act amended the audit provisions by limiting the number of audits to one audit each year during the first 4 years of a State's participation. However, FHWA had already conducted the second audit for TxDOT's participation. This notice announces the availability of the report for second audit for TxDOT conducted prior to the FAST Act and solicits public comment on same.

Authority: Section 1313 of Public Law 112–141; Section 6005 of Public Law 109–59; 23 U.S.C. 327; 49 CFR 1.48.

Issued on: March 18, 2016

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

Draft

Surface Transportation Project Delivery Program FHWA Audit #2 of the Texas Department of Transportation June 16, 2015 Through December 16, 2015

Executive Summary

This report summarizes the results of Audit #2 of the performance by the Texas Department of Transportation (TxDOT) regarding its assumption of responsibilities and obligations, as assigned by Federal Highway Administration (FHWA) under a memorandum of understanding (MOU) whose term began on December 16, 2014. From that date, TxDOT assumed FHWA National Environmental Policy Act (NEPA) responsibilities and liabilities for the environmental review and compliance for highway projects

that require a Federal action in Texas (NEPA Assignment Program). The FHWA's role in the NEPA Assignment Program in Texas includes program review through audits, as specified in 23 U.S.C. 327 and in the MOU. The status of the Audit #1 observations (including any implemented corrective actions) is detailed at the end of this report.

The FHWA Audit #2 team (team) was formed in June 2015 and met regularly to prepare for the on-site portion of the audit. Prior to the on-site visit, the team: (1) Performed reviews of TxDOT project file NEPA documentation in TxDOT's Environmental Compliance Oversight System (ECOS), (2) examined the TxDOT pre-Audit #2 information request responses, and (3) developed interview questions. The on-site portion of this audit, comprised of TxDOT and other agency interviews, was conducted September 8–9, 2015, and September 20–25, 2015.

The TxDOT continues to make progress developing, revising, and implementing procedures and processes required to implement the NEPA Assignment Program. Overall, the team found evidence that TxDOT is committed to establishing a successful program. This report summarizes the team's assessment of the current status of several aspects of the NEPA Assignment Program, including successful practices and 17 total observations that represent opportunities for TxDOT to improve its program. The team identified three non-compliance observations that TxDOT will need to address as corrective actions in its next self-assessment and subsequent report.

While TxDOT has continued to make progress toward meeting all the responsibilities it has assumed in accordance with the MOU, the recurring non-compliance observations require TxDOT corrective action. By taking corrective action and considering changes based on the observations in this report, TxDOT will continue to move the program toward success.

Background

The Surface Transportation Project Delivery Program allows a State to assume FHWA's environmental responsibilities for review, consultation, and compliance for Federal highway projects. This program is codified at 23 U.S.C. 327. When a State assumes these Federal responsibilities, the State becomes solely responsible and liable for carrying out the obligations it has assumed, in lieu of FHWA.

The State of Texas was assigned the responsibility for making project NEPA and other related environmental decisions for highway projects on December 16, 2014. In enacting Texas Transportation Code, § 201.6035, the State has waived its sovereign immunity under the 11th Amendment of the U.S. Constitution and consents to defend any actions brought by its citizens for NEPA decisions it has made in Federal court.

The FHWA responsibilities assigned to TxDOT are varied and tied to project level decisionmaking. These laws include, but are not limited to, the Endangered Species Act (ESA), Section 7 consultations with the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration National Marine Fisheries Service, and Section 106 consultations regarding impacts to historic properties. Two Federal responsibilities were not assigned to TxDOT and remain with FHWA: (1) Making project-level conformity determinations under the Federal Clean Air Act and (2) conducting government-to-government consultation with federally recognized Indian tribes.

Prior to December 4, 2015, FHWA was required to conduct semiannual audits during each of the first 2 years of State participation in the program and audits annually for 2 subsequent years as part of FHWA's oversight responsibility for the NEPA Assignment Program. The reviews assess a State's compliance with the provisions of the MOU and all applicable Federal laws and policies. They also are used to evaluate a State's progress toward achieving its performance measures as specified in the MOU; to evaluate the success of the NEPA Assignment Program; and to inform the administration of the NEPA Assignment Program. On December 4, 2015, the President signed into law the Fixing America's Surface Transportation (FAST) Act of 2015, which amended the audit provisions of the program by changing the frequency to one audit per year during the first 4 years of the State's participation. However, this audit was conducted prior to the passage of the FAST Act, and this report is being prepared and made available under the audit provisions as they existed prior to the passage of the FAST Act. This report summarizes the results of the second audit, and updates the reader on the status or corrective actions for the results of the first audit.

Scope and Methodology

The overall scope of this audit review is defined both in statute (23 U.S.C. 327) and the MOU (Part 11). An audit generally is defined as an official and careful examination and verification of accounts and records, especially of financial accounts, by an independent unbiased body. With regard to accounts or financial records, audits may follow a prescribed process or methodology, and be conducted by ''auditors'' who have special training in those processes or methods. The FHWA considers this review to meet the definition of an audit because it is an unbiased, independent, official, and careful examination and verification of records and information about TxDOT's assumption of environmental responsibilities. The team that conducted this audit has completed special training in audit processes and methods.

The diverse composition of the team, the process of developing the review report, and publishing it in the **Federal Register** help maintain an unbiased audit and establish the audit as an official action taken by FHWA. The team for Audit #2 included NEPA subject matter experts from the FHWA Texas Division Office and FHWA offices in Washington, DC, Atlanta, GA, Columbus, OH, and Salt Lake City, UT. In addition to the NEPA experts, the team included an FHWA Professional Development Program trainee from the Texas Division office and one individual from FHWA's Program Management Improvement Team who provided technical assistance in conducting reviews.

Audits, as stated in the MOU (Parts 11.1.1 and 11.1.5), are the primary mechanism used by FHWA to oversee TxDOT's compliance with the MOU, ensure compliance with applicable Federal laws and policies, evaluate TxDOT's progress toward achieving the performance measures identified in the MOU (Part 10.2), and collect information needed for the Secretary's annual report to Congress. These audits also must be designed and conducted to evaluate TxDOT's technical competency and organizational capacity, adequacy of the financial resources committed by TxDOT to administer the responsibilities assumed, quality assurance/quality control (QA/QC) process, attainment of performance measures, compliance with the MOU requirements, and compliance with applicable laws and policies in administering the responsibilities assumed. The four performance measures identified in the MOU are: (1) Compliance with NEPA and other Federal environmental statutes and regulations, (2) quality control and QA for NEPA decisions, (3) relationships with agencies and the general public, and (4) increased efficiency, timeliness, and completion of the NEPA process.

The scope of this audit included reviewing the processes and procedures used by TxDOT to reach and document

project decisions. The team conducted a careful examination of highway project files and verified information on the TxDOT NEPA Assignment Program through inspection of other records and through interviews of TxDOT and other staff. The team gathered information that served as the basis for this audit from three primary sources: (1) TxDOT's response to a pre-Audit #2 information request, (2) a review of a random sample of project files with approval dates subsequent to the execution of the MOU, and (3) interviews with TxDOT, the U.S. Army Corps of Engineers (USACE), and the U.S. Coast Guard (USCG) staff. The TxDOT provided information in response to FHWA questions and requests for all relevant reference material. That material covered the following six topics: (1) Program management, (2) documentation and records management, (3) QA/QC, (4) legal sufficiency review, (5) performance measurement, and (6) training. The team subdivided into working groups that focused on each of the six topics.

The intent of the review was to check that TxDOT has the proper procedures in place to implement the MOU responsibilities assumed, ensure that the staff is aware of those procedures, and that staff implement the procedures appropriately to achieve NEPA compliance. The review is not intended to evaluate project-specific decisions, or to second guess those decisions, as these decisions are the sole responsibility of TxDOT.

The team defined the timeframe for highway project environmental approvals subject to this second audit to be between March 2015 and June 2015. The focus on the second review included the 3 to 4 months after FHWAs audit #1 highway project file review concluded. The second audit intended to: (1) Evaluate whether TxDOT's NEPA decisionmaking and other actions comply with all the responsibilities it assumed in the MOU, and (2) determine the current status of observations in the Audit #1 report and required corrective actions (see summary at end of this report). The team established a population of 598 projects subject to review based on lists of NEPA approvals (certified compliant by TxDOT as required in MOU Part 8.7.1) reported monthly by TxDOT. The NEPA approvals included categorical exclusion (CE) determinations, 47 other types of environmental approvals including approvals to circulate an environmental assessment (EA), findings of no significant impacts (FONSI), re-evaluations of EAs, Section 4(f) decisions, approvals of a draft environmental impact statement (EIS), and a record of decision (ROD). In order to attain a sample with a 95 percent confidence interval, the team randomly selected 83 CE projects. In addition, the team reviewed project files for all 47 approvals that were not CEs. The sample reviewed by the team was 130 approval actions.

The interviews conducted by the team focused on TxDOT's leadership and staff at Environmental Affairs Division (ENV) Headquarters in Austin and nine TxDOT Districts. To complete the interviews of District staff, the team divided into three groups of four to conduct face-to-face interviews at TxDOT Districts in Dallas, Paris, Tyler, Lubbock, Childress, Amarillo, Houston, Beaumont, and Bryan. With these interviews completed, FHWA has interviewed staff from 60 percent (15 of 25) of the TxDOT District offices. The FHWA anticipates interviewing staff from the remaining TxDOT District offices over the next year.

Overall Audit Opinion

The team recognizes that TxDOT is still implementing changes to address and improve its NEPA Assignment Program and that its programs, policies, and procedures may need revision. The TxDOT's efforts are appropriately focused on establishing and refining policies and procedures (especially in regards to the non-compliance observations made by FHWA), training staff, assigning and clarifying changed roles and responsibilities, and monitoring its compliance with assumed responsibilities. The team has determined that TxDOT continues to make reasonable progress despite some noted delays (pending ECOS upgrades) as the program matures beyond the start-up phase of NEPA Assignment operations. In addition, the team believes TxDOT is committed to establishing a successful program. The team's analysis of project file documentation and interview information identified several non-compliance observations, and several other observations including evidence of good practice. One non-compliance observation is recurrent from Audit#1, relating to ''conditional clearances,'' that appears to reflect a misunderstanding on the part of TxDOT on when and whether information at hand is sufficient to support a NEPA decision that complies with the requirements of the MOU. This is a point of concern for FHWA and if necessary, this issue will be a focus of future audits.

The TxDOT staff and management have engaged FHWA and have received constructive feedback from the team to revise TxDOT's standard operating procedures. By considering and acting upon the observations contained in this report, TxDOT should continue to improve upon carrying out its assigned responsibilities and ensure the success of its NEPA Assignment Program.

Non-Compliance Observations

AUDIT #2

Non-compliance observations are instances where the team found the State was out of compliance or deficient with regard to a Federal regulation, statute, guidance, policy, or the terms of the MOU (including State procedures for compliance with the NEPA process). Such observations may also include instances where the State has failed to maintain adequate personnel and/or financial resources to carry out the responsibilities assumed. Other observations that suggest a persistent failure to adequately consult, coordinate, or take into account the concerns of other Federal, State, tribal, or local agencies with oversight, consultation, or coordination responsibilities could be non-compliant. The FHWA expects TxDOT to develop and implement corrective actions to address all non-compliance observations as soon as possible. The TxDOT has already informed the team it is implementing some recommendations made by FHWA to address non-compliance and other observations. The FHWA will conduct follow up reviews of the non-compliance observations as part of Audit #3, and if necessary, future audits.

The MOU (Part 3.1.1) states ''pursuant to 23 U.S.C. 327(a)(2)(A), on the Effective Date, FHWA assigns, and TxDOT assumes, subject to the terms and conditions set forth in 23 U.S.C. 327 and this MOU, all of the USDOT Secretary's responsibilities for compliance with the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.* with respect to the highway projects specified under subpart 3.3. This includes statutory provisions, regulations, policies, and guidance related to the implementation of NEPA for Federal highway projects such as 23 U.S.C. 139, 40 CFR parts 1500–1508, DOT Order 5610.1C, and 23 CFR part 771 as applicable.'' Also, the performance measure in MOU Part 10.2.1(A) for compliance with NEPA and other Federal environmental statutes and regulations commits TxDOT to maintaining *documented compliance* with requirements of all

applicable statutes, regulations, procedures, and processes set forth in the MOU. The following non-compliance observations were found by the team based on documentation (or lack thereof) in project files and other documentation.

Audit #2 Non-Compliance Observation #1

Non-compliance Observation #1 is an instance (1 out of 130 actions reviewed) where TxDOT made a CE determination for a project before all regulatory criteria for CE determination were met. The TxDOT followed a State procedure relating to the NEPA approval subject to ''conditional clearances'' that allowed the project to proceed to construction. Audit #1 Non-compliance Observation #2 also was an instance where a CE determination was made by TxDOT staff before all environmental requirements had been satisfied (*i.e.,* project level air quality conformity and listing in the Statewide Transportation Improvement Program (STIP)) following the same TxDOT procedure. Discovery of this second instance of non-compliance tied to conditional clearance approvals triggered additional requests for information by the team and gathering information through informal interviews.

The Non-compliance Observation was that an ECOS project record showed that a TxDOT decisionmaker made a CE determination decision before the consultation for the project was completed. The completion of the consultation would have confirmed that a required constraint for the CE was met. This instance involved the determination of whether a project qualified for CE (c)(26). The FHWA's regulation at 23 CFR 771.117(c)(26) restricts the use of the CE to projects that meet all the constraints in 23 CFR 771.117(e). The constraint in 23 CFR 771.117(e)(3) prohibits the use of the CE if it involves a finding of ''adverse effect'' to a historic property or the use of a resource protected under Section 4(f), except for actions resulting in de minimis impacts. The ECOS record shows that at the time of the CE determination, these impacts were presumed, but consultation was not yet initiated in writing nor documented as completed such that the application of that CE could be justified. Later in time, after the CE determination was used to allow the project to proceed to a point where TxDOT made a request to FHWA to proceed to construction with Federal funding, the project record contained Texas Historical Commission (THC) concurrence that the effect was not adverse, and that a de minimis impact determination was supported. The TxDOT should not have applied a CE to a project before confirming that all conditions and constraints for use of that CE were met. By proceeding in this manner, TxDOT has not complied with the requirements for use of that CE, as specified in regulation. Also, the actions taken by TxDOT that lead to the ''conditional clearance'' do not comply with FHWA's Section 4(f) regulation, 23 CFR 774, where the CE determination was made when outcome of the Section 4(f) impact was not determined.

At the team's request for additional information on projects processed with ''conditional clearances,'' TxDOT provided a list of 18 projects that included the non-compliant project identified in Audit #1 and described above. Eight project files showed documentation that a CE determination was made before the period for tribal consultation was complete. The TxDOT, FHWA, and Indian Tribes with an interest in Texas have executed programmatic agreements that define for which projects TxDOT would consult and manner of consultation. Those agreements commit TxDOT to send information to a Tribe and allow for a 30-day period for the Tribe to respond. If the Tribe does not respond after the 30 days, TxDOT may proceed to the next step of the process. These agreements commit TxDOT and FHWA to a manner of consultation that was not followed for eight projects. The TxDOT's assumption of FHWA's NEPA responsibilities does not permit TxDOT to disregard commitments it has made (along with FHWA) to complete tribal consultation before moving to the next step (making a CE determination). These actions are a violation of MOU Part 5.1.1 where TxDOT is subject to the same procedural and substantive requirements in interagency agreements such as programmatic agreements. Additionally, TxDOT's completion of NEPA decisionmaking prior to completing tribal consultation violates MOU Part 7.2.1 where TxDOT has committed to ensure that it has processes and procedures in place that provide for proactive and timely consultation to carry out responsibilities assumed under the MOU.

The TxDOT has a Standard Operating Procedure (SOP) for issuing a Letter of Authority (LOA) dated April 1, 2015, that enables the project to proceed to the next step in project development after a decisionmaker has made a NEPA decision based on incomplete information. Issuance of a LOA allows a project to proceed to the bidding process. For the 18 projects in the list provided, TxDOT certified to FHWA that the project's NEPA requirements were satisfied. The TxDOT has noted in the project record that the project was ''conditionally cleared'' for letting. Upon review, the team identified 11 projects of the 18 reviewed that did violate MOU Part 8.7.1 because the NEPA certification included projects that either did not conform to required conditions to apply CEs or did not complete required consultation requirements. Also, TxDOT's SOP for issuing a LOA does not comply with MOU Part 5.2.1 in that TxDOT's procedures did not result in compliance with Federal regulations. The remaining seven projects on the list of 18 ''conditional clearance'' projects advanced by TxDOT did not indicate an instance of an unjustified NEPA approval, but rather were for actions that occured post-NEPA approval (*e.g.,* 404 permit issuance, Interstate Access Justification and right-of-way (ROW) purchase).

As a result, FHWA has asked that TxDOT immediately refrain from issuing LOAs based on ''conditional clearances.'' The TxDOT has begun the process of revising the subject SOP. The FHWA will review the SOP to ensure that it satisfactorily complies with FHWA policy and the MOU. In addition, FHWA has requested that TxDOT report any projects that use the revised SOP to FHWA in advance of FHWA project authorization until further notice.

Audit #2 Non-Compliance Observation #2

Two projects reviewed by the team were in error regarding NEPA decision reporting. The MOU Part 8.2.6 requires the listing of any approvals and decisions made. One CE determination was reported to FHWA as an action that would utilize less than $5 million of Federal funds (CE (c)(23)) where the project file listed the CE determination for an action that would take place entirely within the existing operational ROW (CE (c)(22)). A second project was correctly reported on the monthly list, but a review of the project file lacked documentation for this determination. Even though these may result from data entry errors, TxDOT should make every effort to ensure the decisions it reports monthly are accurate and project files are complete.

Audit #2 Non-Compliance Observation #3

Twelve project file records were missing information that appeared to be out of compliance with TxDOT's procedures or documentation policy. One project's CE Determination Form

did not identify the approver's title. Another project file lacked the Public Involvement summary. Nine project files lacked records, or included forms that lacked signatures where TxDOT procedures indicated that signatures were required. These included signatures on a Biological Evaluation form, Project Coordination Request form, and a Public Hearing Certification. One project file where a public involvement event lacked documentation on what was presented. The implication of the TxDOT procedure is that the signature or information on the form is part of the review and approval of the report or form. Project files with missing information may suggest that a NEPA decision was based on incomplete or ambiguous information. The TxDOT has informed FHWA that it will review the files for these projects and take corrective action.

Observations and Successful Practices

This section summarizes the team's observations about issues or practices that TxDOT may want to consider as areas to improve and practices the team believes are successful that TxDOT may want to continue or expand in some manner. Further information on these observations and practices is contained in the following subsections that address the six topic areas identified in FHWA's team charter and work plan to perform this audit.

Throughout the following subsections, the team lists 14 remaining observations that FHWA urges TxDOT to act upon in order to make improvements. The FHWA's suggested methods of action include: corrective action, targeted training, revising procedures, continued self-assessment, or some other means. The team acknowledges that, by sharing this draft audit report with TxDOT, TxDOT has the opportunity to begin the process of implementing actions to address the observations to improve its program prior to the publication of this report. The FHWA will consider the status of these observations as part of the scope of Audit #3. The team will also include a summary discussion that describes progress since the last audit in the Audit #3 report.

1. Program Management

The team recognized four successful program management practices. First, it was evident through interviews that TxDOT has employed many highly qualified staff for its program. Second, the team saw evidence of strong communication between TxDOT's ENV and District staff with regard to explaining roles and responsibilities associated with implementation of the MOU for NEPA Assignment. Third, based on the response to the pre-Audit #2 information request and interview questions, the team recognized TxDOT ENV's efforts to develop and update procedures, guidance, and tools as necessary or required to assist Districts in meeting requirements of the MOU. Finally, District staff understands and takes pride in and ownership of their CE determinations. The ENV likewise takes pride in the responsibility for EA and EIS decisionmaking and oversight for the NEPA Assignment Program.

In addition, the team found evidence of six successful program management practices through information provided by TxDOT and through interviews. The team recognizes the TxDOT project Core Team concept, which provides joint ENV and District peer reviews for EAs and EISs as a good example of TxDOT utilizing its existing staff to analyze NEPA documents and correct compliance issues on higher level of NEPA documentation and procedures before project approval. Many Districts appreciate the efforts of and results from the project Core Team and credit them for assuring their projects are compliant.

The ''NEPA Chat'' continues to be a notable example of TxDOT's effort to achieve a compliant NEPA Assignment Program with enhanced communication among TxDOT environmental staff statewide. The NEPA Chat, led by ENV, provides a platform for complex issues to be discussed openly, and for Districts to learn about statewide NEPA Assignment Program issues, and new policies and procedures. To date, the NEPA Chat has proven to be an effective vehicle to disseminate relevant NEPA information quickly and selectively to the TxDOT District Environmental Coordinators.

Also, based on interviews and the response to the pre-audit information request, almost all of the ENV and District staff feel there is sufficient staff to deliver a successful NEPA Assignment Program at the ENV and District level. This is further supported by ENV's willingness to shift responsibilities to better align with the needs of the NEPA Assignment Program. After interviewing the various Districts, they indicated that ENV is available to assist the Districts whenever they need help.

The ENV Self-Assessment Branch (SAB) fosters regular and productive communication with District staff after environmental decisions are made. The SAB staff prepares and transmits a summary of the results of their reviews of project documentation, both positive and negative, and follows up with the District Environmental Coordinator responsible for the project via telephone. They provided this feedback within 2 weeks of their review, which resulted in early awareness of issues and corrective action, where necessary, and positive feedback.

The refinement of the pilot ''Risk Assessment'' tool (a ''smart pdf form'') for environmental documents is a successful, but optional, procedure that may become part of ECOS during the scheduled upgrades. Based on the team's interviews, when District staff use the form, they are better able to understand the resources to be considered, what resources should receive further analysis, and the resulting output serves as documentation for District decisions. Even though this tool is not yet currently integrated within ECOS, it can be uploaded when used.

The TxDOT noted that it had recently developed a QA/QC Procedures for Environmental Documents Handbook (March 2015), and it is used by the project Core Team to develop EA and EIS documents. Through TxDOT's response to pre-Audit #2 questions and through interviews with various staff, TxDOT has continued to demonstrate that it has provided a good base of tools, guidance, and procedures with associated and timely updates to assist in meeting the terms of the MOU and still takes pride in exercising its assumed responsibilities.

The team considers three observations sufficiently important to note below. The FHWA urges TxDOT to consider ongoing and/or additional improvements or corrective actions to project management in its NEPA Assignment Program to address these observations.

AUDIT #2 Observations

Audit #2 Observation #1

Based on interviews with the USACE and USCG, FHWA would like to draw TxDOT's attention to several items. The team found that USCG had multiple ENV and District points of contact and preferred to deal with only one ENV point of contact at TxDOT. A single point of contact was the practice prior to the NEPA Assignment Program when issues needed to be elevated. The TxDOT has indicated that it identified a point of contact for USCG in August of this year, but will follow up in writing. The USACE noted that with the final rule the USACE opinion may change with regard to how it conducts its own regulatory process. This may prove to be problematic for applicants

like TxDOT. Furthermore, interviews with TxDOT staff noted that the relationship with THC may warrant additional attention due to changes in the coordination process for a Section 404 nationwide permit and preconstruction notification for Federal projects. Generally, it is important for TxDOT to maintain and strengthen relationships with Federal agencies including the State Historic Preservation Officer that processes Section 106 actions. This may be considered critical under NEPA Assignment as TxDOT is acting as a Federal agency.

Audit #2 Observation #2

The team found in a legacy project (*i.e.,* a project that began with FHWA as the lead agency and was transferred to be TxDOT-led after NEPA Program Assignment) that an ESA ''no effect'' determination was made by TxDOT to support a FONSI. Previously, when acting as the lead agency, FHWA had requested that TxDOT resolve issues identified in the USFWS correspondence for the project. In this instance, the project record initially reflects a ''may affect'' determination by FHWA that later changed to a ''no effect'' determination by TxDOT. The team was unable to find documentation in the project file to justify why such a change occurred. The team is currently working with TxDOT to review the process by which TxDOT makes ''no effect'' determinations for ESA. If concerns remain after this collaboration, FHWA may invite our USFWS liaison to review this issue in more depth as part of Audit #3.

Audit #2 Observation #3

One project file contained information about an 8-mile detour categorized as not a ''major traffic disruption.'' An interviewee at a different District identified what they considered a different standard (*i.e.,* 2-mile detour) for a ''major traffic disruption.'' These observations suggest TxDOT's approach to defining 23 CFR 771.117(e)(4) for major traffic disruption may be inconsistent. The FHWA recognizes that the context of when a disruption is considered to be ''major'' is important and may depend on local conditions. The FHWA urges TxDOT to develop guidance and a set of examples for rural, urban, and metropolitan Districts to align when major traffic disruption occurs.

2. Documentation and Records Management

The team relied on information in ECOS, TxDOT's official file of record, to evaluate project documentation and records management. The ECOS is a tool for information records, management, and disclosure within TxDOT District Offices, between Districts and ENV, and between TxDOT and the public. The strength of ECOS is its potential for adaptability and flexibility. The challenge for TxDOT is to maintain and update the ECOS operating protocols (for consistency of use and document/data location) and to educate its users on updates in a timely manner.

Successful Practices

A number of best practices demonstrated by TxDOT were evident as a result of the documentation and records management review. The ECOS has demonstrated system-wide improvements in usage by Districts since Audit #1, most notably in the areas of download speed and interface. The ECOS has improved in areas of connectivity and speed, and technical support for ECOS is rated as being very high and responsive. The team recognizes the need for continuous update and maintenance for the ECOS system and ENV's upcoming plans for additional NEPA compliance and documentation related improvements in five phases. The team also recognized that TxDOT Districts are making good use of the Project Risk Assessment Forms to Develop Project Scope and help guide the environmental process.

Based on examination of the 130 sample files reviewed, the team identified five general observations that are mostly issues where record keeping and documentation could be improved or clarified. The team used a documentation checklist to verify the presence of information required by regulation and review the files of the 130 sampled projects.

Audit #2 Observation #4

One project shows a NEPA clearance date that occurs after the LOA clearance date. The TxDOT has indicated that this was a data entry error that was preserved ''in order to understand the progression of project development.'' The NEPA clearance must occur before a date of LOA clearance according to TxDOT process.

During the interviews, the team learned that ECOS files may be deleted by their author and leave no trace of that deletion in ECOS. In addition, the team learned through interviews that deleted files may not be recovered. The FHWA is concerned and urges TxDOT to consider that if decisional information can be deleted, especially if the deletion occurs after the NEPA decision document is signed, the project record would not support the decisions made.

Audit #2 Observation #5

The team reviewed files for one project where the NEPA decision may be an example of a potential inconsistency in NEPA document content for a single project. The scope in the EA document described both a road widening with bridge replacement and widening without bridge replacement. The FONSI document project scope was described as roadway widening, the file documentation was unclear as to the status of the intent to replace the bridge. The team urges TxDOT to carefully compare the project description in an EA and any resulting FONSI and to explain in the FONSI any project description changes from the EA.

The team found there were 15 out of 83 project files where criteria for a specific CE category remained either undocumented or unclear for certain CEs (c(26)–(28)). Examples included a project that may not conform to 23 CFR 771.117(e)(4) due to major traffic disruption, a c(22) operational ROW project stated both ''rehab lanes'' and ''widen lanes,'' and c(23) projects not to exceed $5 million in Federal funds.

Audit #2 Observation #6

The FHWA is generally interested in how TxDOT fulfills its environmental commitments, which TxDOT records through an Environmental Permits, Issues and Commitments (EPIC) sheet. Such sheets become part of both the project record and often, the project bid package. In reviewing project files, the ECOS commitment tab defaults to the following note ''No EPICs exist for this project'' while the same file contained uploaded EPIC sheets in the ECOS documentation tab. Since the EPIC sheet is the way TxDOT implements its environmental commitments, the team would like to draw TxDOT's attention to occasional contradictory information on EPICs in its project files. The team acknowledges that TxDOT has recognized this issue and created a joint District and ENV team to address this issue to address this problem.

Audit #2 Observation #7

The team found two examples of a single project that had multiple CE approvals. Each decision document had a different approval date, however the project was unchanged. The approval documents (with different dates) otherwise appeared to be identical, with the exception of minor editorial changes, such as adding a position title or utilizing an updated form. After interviews with SAB staff, the team learned that this practice was used to

correct editorial mistakes or when new forms were released. The team could not determine the appropriate NEPA approval date. If a decision document (CE, FONSI, or ROD) needs to be revisited, FHWA regulations require a re-evaluation. A re-evaluation does not create a new NEPA approval date, it just analyzes if the original decision remains valid in light of the new information. The TxDOT might clarify its project files by including a journal entry in ECOS to explain the correction of errors on forms.

Audit #2 Observation #8

One type of decision reviewed by the team was a sequence of re-evaluations on the same project change that occurred after a NEPA approval has been made. The team found one project that had three partial re-evaluations in succession for the same design change (a sidewalk relocation) for adjacent parcels and a construction easement in each separate re-evaluation consultation checklist. The TxDOT indicated in its comment on this observation that the project was proceeding under a design-build contract that led to a number of changes. The FHWA is concerned that this TxDOT activity could possibly lead to segmenting the review of new impacts if this practice were to continue.

Audit #2 Observation #9

In general the team views the continuing delay in implementing needed substantive ECOS upgrades (*i.e.,* outdated CE terminology and EPIC documentation contradiction, since CE MOU approval on February 12, 2014) and the current schedule to implement upgrades over 5 years to be too long a timeframe as recurring errors may result. The team urges TxDOT to implement the upgrades with the timeframe of FHWA audits, as it has continued to make recurring observations on project recordkeeping during audits.

3. Quality Assurance/Quality Control

The team considers the QA/QC program to be generally in compliance with the provisions of TxDOT's QA/QC Plan. The team was pleased to see that many of the positive items mentioned and observed in Audit #1 appear to be continuing to occur.

Successful Practices

The team observed four areas of successful practices currently in place that align with TxDOT's QA/QC Control Procedures for Environmental Documents. First, during the team site visits to the TxDOT Districts it learned that one District (Houston) has one person dedicated to reviewing the NEPA documents in order to review documentation for quality and completeness (QC as it occurs before the decision is made), and heard in an interview from another District (Dallas) they are planning to do the same.

Second, the team learned that the Core Team concept (QC) appears to be working and is well received by the District offices visited during the audit. The opportunity of District Environmental Coordinators to work with an ENV person early in the process to identify potential issues should result in efficient document preparation, an expectation of a quality document, complete project file, and improved project delivery.

Third, the team received a lot of positive comments from the Districts visited regarding the SAB of TxDOT. The District staffs stated that the SAB feedback (QA that occurs after the decision is made) was quick and resulted in a great training tool to improve documentation on future projects. The team urges TxDOT to continue this practice and encourages TxDOT to consider more focused and timely input at the pre-decision stage of project development process during QC. It is possible that the non-compliance observations cited in this report could have been identified and corrected if an enhanced pre-decisional (QC) process related check were implemented.

Fourth, since the beginning of 2015, TxDOT has created over 31 tool kits, guidance, forms, handbooks, and procedures to improve consistency and compliance of its NEPA documents and decisions. Feedback during interviews indicated that the TxDOT staff appreciated the effort from ENV to create user friendly forms and procedures to ensure compliance and reduce errors in their documentation.

As a result of the team's file reviews and interviews, it considers three observations as sufficiently important to urge TxDOT to consider improvements or corrective actions in its approach to QA/QC.

Audit #2 Observation #10

During the audit file reviews, the team occasionally found difficulty locating information in project files and could not determine whether environmental requirements were addressed but not documented. Based on what the team found in ECOS records, TxDOT appears to lack a statewide standard or guidance on ECOS naming conventions or ECOS file management. The FHWA reviewers found file names that were not intuitive for conducting efficient or comprehensive reviews. During interviews with the Districts visited, TxDOT staff at times also had trouble locating information in ECOS and was uncertain of the details of projects when questioned. This lack of consistency statewide is an issue that TxDOT acknowledged in a closeout meeting with the team and stated that it was working toward resolving the issue internally. The team will continue to monitor this issue in Audit #3.

Audit #2 Observation #11

Based on the recurring non-compliance observations from Audits #1 and #2, the team urges TxDOT to focus effort on its QA/QC actions. In a few instances, the team found documentation in the project files that was the result of QC, especially when a form was in error and had to be redone. But generally, the team found no entries in project files that showed projects had been reviewed for QC. The team could not determine for the project files reviewed for this audit whether TxDOT's actions effectively implemented QA/QC actions that were agreed to in MOU Part 8.2.4. The FHWA will focus efforts in Audit #3 on how TxDOT applies QC and implementing QA strategies to individual projects.

4. Legal Sufficiency Review

From interviews the team learned there are two attorneys in TxDOT's Office of General Counsel (OGC) who provide legal services on environmental issues. The OGC has an ongoing process to fill the third environmental attorney position in OGC. In addition, OGC has had an outside contract attorney providing legal assistance on environmental issues for a number of years. The OGC recently completed its biannual procurement of outside legal services for environmental issues, and has now obtained legal services from a total of three law firms. Legal counsel (both OGC staff and outside counsel) are primarily dedicated to serve as a resource providing legal assistance in project development, review of environment documents, and legal sufficiency reviews.

Assistance from OGC (who assisted in developing the sections) is guided by ENVs Project Delivery Manual Sections 303.080 through 303.086. These sections provide guidance on requesting legal sufficiency, legal sufficiency review of FHWA projects, and review of publishing a Notice of Intent (NOI) to prepare an EIS and Notice of Availability in the **Federal Register**. Per the guidance, legal sufficiency is required prior to approval of:

(1) NOI to prepare an EIS

(2) Final Environmental Impact Statement (FEIS)
(3) Individual 4(f) Statement (programmatic or de minimis 4(f) evaluations do not require legal sufficiency review)
(4) Notice that a permit, license, or approval is final under 34 U.S.C. 139(1).

The OGC is available as a resource to ENV and the Districts to answer questions on NEPA issues and specific questions on projects. Requests for assistance are made through ENV and the vehicle for communication is primarily email. The guidance states that communications between OGC and ENV for the purpose of rendering legal services or advice are protected by the attorney-client privilege.

Based on a report provided by OGC, since January 1, 2015, it has reviewed or has been involved in providing legal review for 15 project actions. These included five 139(l) notices, an FEIS/ROD, three RODs, one NOI, an EA, a public hearing and response report, an FEIS, and an FEIS errata sheet. The OGC provided legal sufficiency reviews for all 139(l) reviews, the FEIS errata sheet, and the FEIS.

Currently, ENV project managers request the review of documents and/or materials by OGC. The lead attorney in OGC assigns the project to staff based on workload and issues. He works with the project managers to agree upon an acceptable review timeframe. Per OGC, reviews are only done after the technical reports have been reviewed and approved by ENV. Comments from the attorney are provided in the usual comment/response matrix to ENV, which incorporates them into the overall comment/response matrix that is sent to the project Core Team to address. Once any comments are adequately addressed, the attorney will issue a legal sufficiency statement. The OGC does not maintain a separate project file as it completes review of a project.

In reviewing the document for legal sufficiency the OGC attorneys rely on Federal regulations and guidance, TxDOT toolkits and manuals, and discussions with project delivery managers. The OGC relies on the subject matter experts to ensure the technical reports are adequate, and only does an in-depth review of a technical report if warranted. In general, the attorneys are looking for consistent, well written documents that are reader friendly and clearly document the NEPA decision. After reviewing the document, there is a consultation between the lead attorney and staff attorney concerning the review results before a legal sufficiency finding is issued. Copies of emails providing comments on Federal and State register notices, the legal sufficiency reviews of several Section 139(l) notices, and an FEIS were provided to the team.

The lead attorney for OGC has 11 years of transportation experience with TxDOT but until NEPA assignment process began, only limited NEPA experience. The other OGC attorney's NEPA experience also began with the NEPA Assignment process. The contract attorney has had approximately 12 years of experience working NEPA issues and lawsuits in Texas. The OGC may hire outside law firms to provide assistance on an as-needed basis. All such firms have extensive transportation and NEPA experience.

The OGC indicated that there has been some early involvement in project familiarization and information gathering so that it is aware of potential issues, impacts, and timeframes during project initiation and scoping. The OGC is making a concerted effort also to attend public hearings and other project meetings as the project development process progresses. The OGC wants to be considered a resource for the ENV and TxDOT Districts from early on in project development as opposed to only being contacted when there are major issues.

Based on the team interviews and review of documentation, the requirements for legal sufficiency under the MOU are being adequately fulfilled. In FHWA's experience, legal staff can expand their role by inserting themselves into the project development process and promoting their availability as a resource to TxDOT staff.

Audit #2 Observation #12

Neither in the project delivery manual nor elsewhere does OGC provide an expectation for the time frame necessary for a legal review. The team urges TxDOT to establish a review time frame for legal sufficiency, develop some education and outreach to the TxDOT Districts regarding the OGC role, especially as a resource, and suggested additions to the legal sufficiency documentation.

5. Performance Measurement

Part 10 of the MOU identifies performance measures to be reported by TxDOT that FHWA would consider in conducting audits. The FHWA did not independently verify the measures reported by TxDOT. The TxDOT's first Self-Assessment Summary Report (since implementing NEPA Assignment) discusses progress made toward meeting the four performance measures. These measures provide an overall indication of TxDOT's discharge of its MOU responsibilities. In addition, in collecting data related to the reporting on the performance measures, TxDOT monitors its overall progress in meeting the targets of those measures and includes this data in self-assessments provided under the MOU (Part 8.2.5). The four performance measures are: (1) Compliance with NEPA and other Federal environmental statutes and regulations, (2) QA/QC for NEPA decisions, (3) relationships with agencies and the general public, and (4) increased efficiency and timeliness in completion of the NEPA process.

The TxDOT reports three measures of compliance with NEPA and other Federal laws and regulations: (1) Percent of complete NEPA Assignment Program Compliance Review Reports submitted to FHWA on schedule, (2) percent of identified corrective actions that are implemented, and (3) percent of final environmental documents that contain evidence of compliance with requirements of Section 7, Section 106, and Section 4(f). The measured results range between 97 percent and 100 percent complete.

The TxDOT considered QA/QC for NEPA decisions with three measures: (1) Percent of FEISs and individual Section 4(f) determinations with legal sufficiency determinations that pre-date environment document approval, (2) percent of EAs and EISs with completed environmental review checklists in the file, and (3) percent of sampled environmental project files determined to be complete and adequate for each self-assessment period. These measured results range between 94.3 percent and 100 percent.

The TxDOT is still in the process of assessing its measure of relationships with agencies and the general public. Since the completion of Audit #1, TxDOT has prepared and distributed a survey to agencies it interacts with as part of NEPA. The survey asked agency staff to respond to TxDOT's capabilities, responsiveness, efficiency, communications, and quality. The TxDOT proposes to poll agencies each year and report comparisons in future self-assessments. The TxDOT's measure of its relationship with the public is to compare the number of complaints received year to year. The TxDOT reports no complaints from the public received since assuming NEPA Assignment. A second measure for public relationship is the percent of signed final EA or EIS projects where a public meeting or hearing was conducted and the associated documentation was in the file. The TX DOT reports a measure of 92.3 percent because one EA file had a missing signed public hearing certification page. A third measure of relationships

considered by TxDOT is the time between beginning a formal conflict resolution process and the date of resolution. The TxDOT reports there was no conflict resolution process initiated during the team's review period.

The TxDOT provided its initial measures of increased efficiency and timeliness in completion of the NEPA process in the Self-Assessment Summary Report. Its first of three measures is to compare the median time to complete CEs, EAs, and EISs before and after assignment. The TxDOT reports that it needs more time to compile post-NEPA assignment data. The TxDOT reports that the pre-NEPA assignment median time frame to complete an EA is 1060 days (35.33 months) and 3,351 days (111.7 months) to complete an EIS. The second measure is the median time frame from submittal of biological assessment to receipt of biological opinion. The TxDOT reports that the pre-NEPA Assignment median time frame for completing a biological opinion is 43 days, and 16 days to complete informal consultation. The TxDOT reported a time frame of 65 days for a single biological opinion since NEPA Assignment. The 10 informal consultations since assignment had a median time frame of 28 days (12 days longer).

In interviews, the team learned of several best practices from the TxDOT CE Self-Assessment Report. The TxDOT's QA/QC process generates measures of error rates that provide useful information to improve the overall program management and efficiency. The TxDOT has used performance measures to evaluate the effectiveness of the SAB Feedback Program, and has demonstrated reduced error rates over its limited review time frames. Also, some of the measures closely correlated with follow up training which demonstrated its utility. One individual stated in an interview that the initial rate was initially in the high single digit percentiles (c.f., if CE determinations were signed or not). The team then considered three periods of data corresponding to rough quarter yearly time frames. In the initial quarter, people who made mistakes and were then mentored through a phone call showed a drop in number of errors over time. The same people were, for the most part, no longer making the same errors after the third quarter.

Another practice the team learned about through interviews was that TxDOT had collected and considered many measures of its performance in addition to the ones in the Self-Assessment Report Summary. The team requested more information about these additional measures from TxDOT and has received some details (TxDOT's CE Self-Assessment Report). The team hopes to see more. The team encourages TxDOT to generate performance measures in addition to the ones reported and to share those measures with the team as part of FHWA's overall review of NEPA assignment.

Audit #2 Observation #13

The team continues to be concerned that the measure for the TxDOT relationship with the public may be too limited by focusing on the number of complaints, and urges TxDOT to continue thoughtful consideration of the development of this measure. The team learned through interviews that the CSTAR database is where complaints get recorded and distributed to different parts of TxDOT, but that it apparently was not consulted to compute a baseline measure to use for comparison. Also, public complaints, according to District staff, come into individual District offices which may not be tabulated in CSTAR. The team urges TxDOT to consider the measure of public relationship in more refined detail than agency-wide scale to distinguish concerns that are tied to a particular project and those tied to program management and decisionmaking. The FHWA acknowledges that public comments and complaints were and will continue to be an important consideration in project level decisionmaking. The performance measure for public relationship should address TxDOT's consideration of project specific concerns (not just the number of complaints) and concerns about the environmental program.

6. Training Program

The team recognizes the following successful practices. The team learned of resource sharing within the Houston District of Subject Matter Resource (SMR) staff who serve as in-house sources of knowledge and expertise. The SMR staff also commit to attend formal training and perform self-study in their resource areas, which allows them to provide training and mentor other staff on subjects within or related to the resource area.

A second best practice described to the team was that TxDOT conducted a survey of its staff in the summer of 2015 to determine needs and issues related to training. The TxDOT provided the survey results, and the team found these data to be both detailed and informative. The TxDOT reported during the pre-Audit #2 that this information was used to identify training needed by ENV staff to professionally develop Division staff and maintain expertise in their respective subject areas. The survey results from District staff identified training needed for District environmental staff to perform job duties. The team looks forward to reviewing TxDOT's progressive training plan and the updated training plan based on the new data.

A third best practice the team learned through interviews is that the TxDOT tool kit (available to consultants, local government staff, and the public) provides training opportunities for documentation and record keeping. When a consultant raises a question or concern in response to a TxDOT document review comment, staff can refer to the tool kit in order to support the TxDOT position. Finally, the ENV Director said in his interview that the tool kits contribute to increased consistency throughout the process (*e.g.,* comments on documents, format, and content), resulting in a more predictable project development process. That consistency is appreciated across the board in Districts and LPAs.

Audit #2 Observation #14

The FHWA recognizes that TxDOT's annual environmental conference is its primary outreach to LPAs and consultants to address a wide array of environmental topics that reinforce existing and new environmental policies and procedures. However, the 2015 conference was not well attended by LPA staff, a fact acknowledged by the Director of ENV in his interview. He also indicated that he was thinking of reaching out to large metropolitan planning organizations and the Association of Texas Metropolitan Planning Organizations in a meaningful way in coordination with TxDOT's training coordinator. The team also learned through interviews that some, especially rural District local government staff, were uninformed of the changes with TxDOT NEPA Assignment. The team encourages the Director of ENV and the training coordinator to implement ways to train local government staff.

Status of Observations since the Last Audit (December 2015)

Non-Compliant Observations

Audit #1 identified two non-compliance observations. One was related to the application of a CE action that related to a program that TxDOT did not have. The TxDOT acknowledges this non-compliance observation and has taken corrective action to prevent future non-compliance. Accordingly, a

stand-alone noise wall project using 23 CFR 771.117(c)(6) is no longer a possible selection of CE actions that any TxDOT District can make. The other was an instance where a CE determination was made (called a conditional NEPA approval or ''conditional clearance'') before all environmental requirements had been satisfied. Since Audit #1, TxDOT has continued to make NEPA approvals ''conditionally,'' and those actions have been identified as non-compliant in this report. The TxDOT drafted an update of an SOP to address this issue. The FHWA expects TxDOT to prepare a corrective action so that its program would comply with the MOU. The FHWA will review the corrective action and indicate to TxDOT whether it satisfactorily addresses this concern. Also, FHWA requested that TxDOT take additional steps to prevent any future non-compliance in this regard.

Observations

1. Updates to ECOS, the TxDOT File of Record

The TxDOT ran into further delays in implementing its ECOS upgrade contract. The TxDOT has a plan in place that outlines five phases of work to be performed to upgrade ECOS over many years. Substantive ECOS upgrades are still pending as of the development of this draft report. This is leading to continued observations by FHWA, and inconsistencies within ECOS by TxDOT users. A lack of mandatory filing and naming conventions by ENV contributes to this issue. Of concern to FHWA is the ability for TxDOT users to potentially delete files and approvals in ECOS without an archive of such actions. This could be problematic as it differs from the FHWA's previous understanding of ECOS security measures in place from Audit #1.

2. Addressing Conflicts and Disputes

Since Audit #1, TxDOT has implemented conflict resolution training for its ENV and District staff. This training has been well received and should help prepare staff to recognize when conflicts may occur and to take steps to address issues before they develop into disputes. Interviews conducted for Audit #2 suggest that TxDOT and resource agency staff may need to focus on improving communication in order to foster and nurture relationships.

3. Local Public Agency Project Reviews

This observation continues as is. The Local Public Agencys (LPA) were invited to the TxDOT Environmental Coordinators Conference (ECC), but TxDOT ENV confirmed that few LPAs attended. It was further noted by TxDOT that perhaps the ECC may not be the best training venue for LPAs that need more than introductory information or refreshers on NEPA related topics. Furthermore, some rural Districts indicated that they remain Department Delegate on local projects when LPAs can or should be project sponsors, because LPAs in the rural areas are sometimes unaware of what to do to develop their projects. The situation seems to be different in metropolitan areas where LPAs are more sophisticated and can perform well as project sponsors.

4. Recording and Implementing Environmental Commitments

The team continued to find issues with the EPIC sheet and commitments in Audit #2. A total of 21 instances were found where inconsistencies in EPIC reporting were noted. Primarily, there was the fundamental problem of EPICs being required (and sometimes uploaded under the documentation tab) for a project but a notice stating ''No EPICs Exist for this project'' under the EPIC tab in ECOS was frequently found. The TxDOT has formed an internal team to address this issue.

5. Inadequate Project Description

The TxDOT has begun to address the issue of inadequate project descriptions by providing training on expectations for what should be in a project description in its 2015 environmental conference. The training instructors included individuals from FHWA and TxDOT. The team continued to find project descriptions that were unclear or may not have supported the decisions made in project files. The team suggests that TxDOT apply QA/QC to this issue. The TxDOT acknowledges this is a continuing issue and has indicated that it will continue to address it in NEPA chats and training.

6. Project File Organization and Completeness Issues

The team continued to find outdated terms in project files (*e.g.,* BCE/PCE) and occasional difficulty in finding information in project files with no consistent file labeling protocol or expectations for where to find specific information. For example, resource agency coordination letters were sometimes found as individual documents in a file and other times they were appended to a NEPA document. The TxDOT indicated that it formed a workgroup in the summer of 2015 that meets to address inconsistencies regarding filing and naming conventions.

7. Public Disclosure of ECOS Project Records

The TxDOT has not taken any actions on this item other than to make information available upon request or at public meetings/hearings for a project.

8. No EAs or EIS Being Reviewed by the SAB Team

The team learned that SAB only performs post decision (QA) reviews and provides feedback to both the Districts directly and the Corrective Action Team at ENV to consider if any process or procedural changes are needed. The FHWA believes there is a function that SAB or others could serve before the decision is made that would add value to the upfront QC process for both document content and procedural compliance. The FHWA understands the expected benefits of Core Team reviews but believes something more is needed and would be helpful to Districts.

9. Sampling Approach for QA/QC

The team learned in Audit #2 that there is a risk-based sampling method applied to choosing projects types that are selected for more detailed reviews, and that the number of staff available for the reviews dictates the number of reviews that are completed. The review sample is based on a computer generated model that chooses some of the projects randomly. There is no established sampling methodology for self-assessing the effectiveness of TxDOT's standards or guidance. The FHWA would like to see more clarification from TxDOT on the effectiveness of its current practice and be provided data to verify TxDOT claims of compliance.

10. Confusion in Understanding Quality Control, Quality Assurance, and Self-Assessment

Most of the confusion within TxDOT regarding these terms has been cleared up. The FHWA believes that additional internal (QC) review (beyond the Core Team concept for project documentation) for NEPA process related checks by TxDOT before the decisions were made would add value to the process, help ensure NEPA compliance, and assist with FHWA's requirement to make informed and fully compliant project authorization decisions.

11. Narrow Definition of the QA/QC Performance Measure

The team's Observation #11 was that the QA/QC measure for NEPA decisions focused only on EA and EIS projects. The team urges TxDOT to consider evaluating a broader range of NEPA related decisions (including, but not limited to CEs, re-evaluations, Section 4(f), and STIP/Transportation Improvement Program (TIP) consistency). Note that the recurring non-compliance observations occurred on CEs with either STIP/TIP or Section 4(f) items that were not ready for a decision to be made. In recent interviews with TxDOT staff, the team learned that TxDOT will examine other measures on an ongoing basis for internal use. The team believes that if the QA/QC refocuses attention not only on the documentation, but also on the required sequential NEPA process related items, that improved efficiencies related to TxDOT's NEPA decision and FHWA project authorization could result. The team believes that a more relevant focus on process could potentially help avoid non-compliance actions by TxDOT under the MOU and FHWA non-compliance observations in future audits.

12. Performance Measure Utility

Observation #12 was that the utility of several of the performance measures was difficult to determine. Also, the team was concerned that the measure for the TxDOT relationship with the public may be too limited by focusing on the number of complaints. Through recent interviews, the team learned that TxDOT staff agree with FHWA's concerns about utility. Quantifying changes in relationships with the public or agencies is possible, but the number is hard to interpret. Regarding the survey of agencies, TxDOT staff indicated that they did not know if agencies have higher expectations of TxDOT compared with other agencies. Considering the TxDOT relationship with the public, staff told the team that, during the preparation of their application, they considered various sorts of surveys and social media outreach. Given the cost of these approaches, TxDOT was not convinced of their utility and so decided not to use any of them. This leaves the performance measure difficult to address for TxDOT and may be a recurring FHWA observation until it is resolved.

13. TxDOT Reliance on the California Department of Transportation (Caltrans) Training Plan

The team's Observation #13 was that the Caltrans training plan, which served as a basis for the TxDOT training plan, may not adequately meet the needs of TxDOT. The team urged TxDOT to consider other State DOT approaches to training. The TxDOT staff said in a recent interview that they had reviewed training plans from Virginia, Ohio, Alaska, and Florida. They also indicated that prior to Audit #2, TxDOT had completed a survey of staff in District offices and at ENV to assess training needs. The team was told that the surveys would be used to update the training plan in the spring of 2016.

14. Adequacy of Training for Non-TxDOT Staff

Observation #14 urged TxDOT to assess whether the proposed training approach for non-TxDOT staff (relying heavily upon the annual ECC) is adequate and responsive enough to address a need to quickly disseminate newly developed procedures and policy. Through interviews, the team learned that TxDOT does not prioritize training classes specifically for non-TxDOT staff. The Director of ENV acknowledged that the training session at the recent ENV conference for LPA staff was not well attended and was thinking of reaching out to large planning organizations. The TxDOT concluded that its priority for training is first for TxDOT staff internally (ENV and District staff), second for consultants that TxDOT hires for environmental work, and third for LPAs. In years three and beyond of the TxDOT NEPA Assignment, the training plan may start to focus on the second, and eventually third, priority groups of individuals.

15. What Training is Mandatory

Observation #15 resulted in a team suggestion that the progressive training plan clearly identify the training required for each job classification. The TxDOT training coordinator told the team that the progressive training plan will address training required to meet State law (16 hours of training) and job task certification. This plan will be developed at the end of 2015.

16. Training Plan, Consideration of Resource Agency Recommendations

The team learned in a recent interview that in the fall of 2015 (as in the fall of 2014), TxDOT subject matter experts planned to reach out to resource agencies to ask what training they would like to see conducted for TxDOT staff. Previously, USACE staff said that TxDOT needed 404 training. The TxDOT scheduled and completed Section 404 training in two different locations during October 2015. The TxDOT will continue to schedule Section 404 training.

Next Steps

The FHWA provided this draft audit report to TxDOT for a 14-day review and comment period. The team has considered TxDOT comments in developing this draft audit report. As the next step, FHWA will publish a notice in the **Federal Register** to make it available to the public and for a 30-day comment period review (23 U.S.C. 327(g)). No later than 60 days after the close of the comment period, FHWA will respond to all comments submitted in finalizing this draft audit report, pursuant to 23 U.S.C. 327(g)(B). Once finalized, the audit report will be published in the **Federal Register**.

[FR Doc. 2016–06819 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Notice of Unsafe Condition Involving Commercial Motor Vehicles Affected by Volvo Trucks North America's Safety Recall and Out-of-Service Declaration

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice.

SUMMARY: FMCSA has determined that commercial motor vehicles manufactured by Volvo Trucks North America (Volvo Trucks) and affected by the National Highway Traffic Safety Administration (NHTSA) Part 573 Safety Recall Report No. 16V–097000, that have not already received the interim or permanent recall remedy repair specified by Volvo in the recall, are likely to cause an accident or breakdown because of a defective steering shaft which may disconnect from the junction block without warning, causing the vehicle to be in an unsafe condition. FMCSA is notifying commercial motor vehicle operators that vehicles subject to the recall without the interim or permanent repair will be subject to an immediate out-of-service order under 49 CFR 396.9 or compatible state regulations.

DATES: This Notice is effective March 23, 2016.

FOR FURTHER INFORMATION CONTACT: Charles J. Fromm, Deputy Chief

Counsel, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, by telephone at 202–366–3551 or via email at *charles.fromm@dot.gov*. FMCSA office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: On February 16, 2016, Volvo Trucks initiated a safety recall affecting nearly 16,000 Class 8 motor vehicles in the United States. According to Volvo, a condition exists which could lead to separation of the steering shaft from the junction block. Also, the bolt connecting the upper steering shaft to the lower steering shaft may not have been properly tightened. Volvo's report to NHTSA states that either condition can lead to separation of the steering shaft and immediate loss of steering ability and control, which could lead to a crash. Volvo Trucks issued a Safety Recall Alert on March 10, which directed all owners of the affected vehicles to take the vehicles out of operation as soon as possible and cautioned that the separation can occur without warning and amended its safety recall on March 15, alerting NHTSA of the more serious hazard. Volvo Trucks strongly recommends that these vehicles remain out of service until repairs are made. NHTSA is overseeing Volvo Truck's recall efforts to ensure prompt notification of the defect to vehicle owners and that vehicles are not operated in a defective condition. Volvo's Safety Recall Report is available on its Web site at: *http://www-odi.nhtsa.dot.gov/owners/SearchDetails?searchCriteria.prod_ids=1991310&searchCriteria.model_yr=2016&searchCriteria.make=VOLVO&searchCriteria.model=VNL&activeTab=0&searchType=PROD&prodType=V&targetCategory=A&cmplCount=1&rclCount=3&invCount=1&tsbCount=0*.

Additionally, to assist with notification efforts, on March 18, 2016, FMCSA posted an Inspection Bulletin on its Web site. *https://www.fmcsa.dot.gov/newsroom/urgent-inspection-bulletin-safety-recall-issued-volvo-trucks*. The Inspection Bulletin advised FMCSA inspectors and state partners under the Motor Carrier Safety Assistance Program (MCSAP) of the condition of the affected vehicles and requested inspectors to direct the operators of such vehicles to contact Volvo Customer Service before continuing in operation. The Inspection Bulletin also noted that continued operation of the affected vehicles could be considered a violation of 49 CFR 396.7, which prohibits operation of a vehicle in a condition likely to cause an accident or a breakdown. Today's notice formalizes that determination and clarifies that FMCSA and its state partners under the MCSAP program will place a vehicle out-of-service if the necessary repair or replacement has not been made, based on the identified out-of-service defect under 49 CFR 393.209(c), which requires that a steering column to be securely fastened.

The Secretary of Transportation has statutory authority to set minimum standards for commercial motor vehicle safety, including ensuring that commercial motor vehicles ''are maintained, equipped, loaded, and operated safely'' and to prescribe requirements for the ''safety of operation and equipment of, a motor carrier.'' (49 U.S.C. 31136(a)(1) and 49 U.S.C. 31502(b)). The Secretary also has broad power in carrying out motor carrier safety statutes and regulations to, among other things, ''inspect the equipment of a carrier or lessor'' and ''perform other acts the Secretary considers appropriate.'' (49 U.S.C. 504(c)(1) and 49 U.S.C. 31133(a)(10)). The Administrator of FMCSA has been delegated authority under 49 CFR 1.87(f), (i) and (j) to carry out the functions vested in the Secretary of Transportation by 49 U.S.C. chapter 311, subchapter III, 49 U.S.C. chapter 315, and 49 U.S.C. 504. This delegation of authority includes the authority to declare unsafe vehicles out-of-service under 49 CFR 396.9. Under 49 U.S.C. 31102, MCSAP State partners agree to conduct roadside inspections. In 49 CFR part 350, MCSAP state partners agree to adopt state safety laws and regulations that are compatible with 49 CFR parts 390–397.

Out-of-Service Determination

FMCSA has determined that commercial motor vehicles subject to Volvo Trucks' Safety Recall (NHTSA Part 573 Safety Recall Report No. 16V–097000), that have not already received the interim or permanent recall remedy repair specified by Volvo in the above-referenced recall, are likely to cause an accident or breakdown and are therefore in an unsafe condition. The condition of the steering column is also a violation of 49 CFR 393.209(c) which requires the steering column to be securely fastened. Because of the potential consequences associated with continued operation of these vehicles, through this notice FMCSA is declaring unsafe the operation of any unrepaired vehicle affected by the Volvo Trucks recall under NHTSA Campaign No. 16V097000 and declaring such vehicles to be in an out-of-service condition. The affected vehicles should not be operated, and the operation of an unrepaired affected vehicle will therefore subject the operator to an out-of-service order under federal or compatible state regulations.

FMCSA is directing its investigators and state partners conducting roadside inspections to perform a Level IV inspection on any unrepaired affected vehicles and to place the vehicle out of service based on the violation of 49 CFR 393.209(c). Level IV inspections, which are typically performed on a one-time basis on a particular item as a special inspection, are not included in FMCSA's Safety Measurement System (SMS), and therefore the out-of-service declaration will not affect a motor carrier's SMS score.

Placing the vehicle out-of-service under this Notice is not intended to provide a basis for further enforcement action and seeks only the immediate cessation of the operation of vehicles that have been deemed to be in an unsafe condition. Operators of vehicles declared out-of-service, however, must comply with an out-of-service order. Motor carrier operators who violate an out-of-service order will be subject to civil penalties and other enforcement as provided in the Federal Motor Carrier Safety Regulations.

Issued under the authority delegated in 49 CFR 1.87 on: March 22, 2016.

T. F. Scott Darling, III,

Acting Administrator.

[FR Doc. 2016–06880 Filed 3–23–16; 11:15 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0072]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 40 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or

greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions were granted December 15, 2015. The exemptions expire on December 15, 2017.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

On November 12, 2015, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (80 FR 70060). That notice listed 40 applicants' case histories. The 40 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 40 applications on their merits and made a determination to grant exemptions to each of them.

III. Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 40 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, aphakia, chronic optic neuropathy, complete loss of vision, corneal scar, macular scar, macular toxoplasmosis, optic atrophy, optic nerve atrophy, phthisical cornea, prosthetic eye, refractive amblyopia, retinal detachment, and strabismic amblyopia. In most cases, their eye conditions were not recently developed. Thirty of the applicants were either born with their vision impairments or have had them since childhood.

The 10 individuals that sustained their vision conditions as adults have had it for a range of 6 to 41 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 40 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision in careers ranging for 3 to 51 years. In the past three years, 1 driver was involved in a crash, and 1 driver was convicted of a moving violation in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the November 12, 2015 notice (80 FR 70060).

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

FMCSA believes it can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers

demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 40 applicants, 1 driver was involved in a crash, and 1 driver was convicted of a moving violation in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 40 applicants listed in the notice of November 12, 2015 (80 FR 70060).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 40 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

V. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based upon its evaluation of the 40 exemption applications, FMCSA exempts the following drivers from the vision requirement in 49 CFR 391.41(b)(10):

John W. Adams (TN)
David R. Alford (UT)
Randy S. Asher (NE)
Steven W. Barrows (OR)
Steven A. Blinco (MT)
Charles W. Bradley (SC)
Ricky A. Bray (AR)
Ryan M. Coelho (RI)
Travis R. Cook (KS)
Larry P. Davis (MO)
Donald S. Fries (PA)
Kerrie K. Furbish (ME)
Jerry W. Gibson (TX)
Trevor H. Hilton (IL)
Michael D. Judy (KS)
Karen L. Kelly (DE)
Joel H. Kohagen (IA)
Kelly K. Kremer (OR)
Edward R. Lockhart (MS)
Joshua L. Marasek (TX)
Rodolfo Martinez, Jr. (TX)
Arthur J. McClintic (MI)
Dale A. McCoy (ME)
Gregory G. Miller (OH)
Zack E. Minielly (GA)
Tobias G. Olsen (NY)
Elroy Perkins (MS)
Roy C. Rogers (WV)
Michael P. Rydzinski (MI)
Dale L. Schneider (IA)
Keith R. Seabaugh (MO)
Robert G. Seils (NY)
Randall C. Stephens (TN)
Dale L. Stewart (MI)
Warren S. Supulski (NC)
Paul J. Vines (AL)
Hany A. Wagieh (NJ)
Charles W. Williamson (OK)
Gregory A. Woodward (OR)
Alton R. Young III (MS)

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: March 16, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–06794 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0002; Notice 1]

Cooper Tire & Rubber Company, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Cooper Tire & Rubber Company (Cooper), has determined that certain Cooper tires do not fully comply with paragraph S5.5.1(b) of Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New pneumatic radial tires for light vehicles.* Cooper filed a report dated January 8, 2016, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Cooper then petitioned NHTSA under 49 CFR part 556 requesting a decision that the subject noncompliance is inconsequential to motor vehicle safety.

DATES: The closing date for comments on the petition is April 25, 2016.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and be submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Deliver:* Deliver comments by hand to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

The petition, supporting materials, and all comments received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All documents submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. The docket ID number for this petition is shown at the heading of this notice.

DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview: Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Cooper submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Cooper's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Tires Involved: Affected are approximately 338 Cooper Discoverer A/T3 size 265/70R18 Standard Load Tubeless Radial tires that were manufactured between September 27, 2015 and October 3, 2015.

III. Noncompliance: Cooper explains that the DOT serial week and year appears upside down and backwards in the tire identification number (TIN) molded into the outboard sidewalls of the subject tires and those tires therefore do not meet the requirements specified in paragraph S5.5.1 of FMVSS No. 139.

IV. Rule Text: Paragraph S5.5.1 of FMVSS No. 139 requires in pertinent part:

S5.5.1 *Tire Identification Number.*

. . .

(b) *Tires manufactured on or after September 1, 2009.* Each tire must be labeled with the tire identification number required by 49 CFR part 574 on the intended outboard sidewall of the tire. Except for retreaded tires, either the tire identification number or a partial tire identification number, containing all characters in the tire identification number, except for the date code and, at the discretion of the manufacturer, any optional code, must be labeled on the other sidewall of the tire. Except for retreaded tires, if a tire does not have an intended outboard sidewall, the tire must be labeled with the tire identification number required by 49 CFR part 574 on one sidewall and with either the tire identification number or a partial tire identification number, containing all characters in the tire identification number except for the date code and, at the discretion of the manufacturer, any optional code, on the other side wall.

V. Summary of Cooper's Petition: Cooper believes that this noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Cooper submitted the following information and analysis of the subject noncompliance:

1. Cooper cited paragraph S5.5.1(b) of FMVSS No. 139, which requires tires manufactured on or after September 1, 2009 to be labeled with the TIN required by 49 CFR part 574 on the intended outboard sidewall of the tire.

2. Cooper also noted that 49 CFR 574.5 states that ''[e]ach tire manufacturer shall conspicuously label on one sidewall of each tire it manufactures . . . a tire identification number containing the information set forth in paragraphs (a) through (d) of this section.'' The company further noted that 49 CFR 574.5(d) specifies that ''[t]he fourth grouping, consisting of four numerical symbols, must identify the week and year of manufacture,'' with the first two symbols identifying the week and the last two identifying the year.

3. Cooper stated that the subject tires, on the outboard side only, were molded with an upside down and backwards DOT serial week and year. The serial number stamping should read: ''DOT UPH4 1A6 3915.'' The outboard side, which includes the date code, was molded with the date code information oriented incorrectly upside down and backwards, which resulted in the characters being out of proper sequence.

4. Cooper explained that the existence of the stamping error was determined by visual examination of a subject tire on October 21, 2015 by warehouse personnel in Grand Prairie, TX. Upon further investigation, it was determined that only tires cured in one press

location (E10L) during one production week (3915) were affected. Tires with the same SKU code were also curing in another press (Z11L), but these tires were stamped correctly. Cooper stated that sorting of its internal inventories revealed that for curing press E10L, during DOT serial week 3915, there was a total net cure of 518 tires, of which 180 tires have been accounted for in its warehouse. There were 338 tires distributed. Cooper made the final determination that a noncompliance exists as to those 338 tires on January 6, 2015.

5. Cooper states that the 338 subject tires do meet and/or exceed all performance requirements and all other labeling and marking requirements of FMVSS No. 139.

Furthermore, Cooper is not aware of any crashes, injuries, customer complaints, or field reports associated with the subject tires.

Cooper has informed NHTSA that the subject tires located in its inventory count reconciliation have been returned to the company's Findlay, OH plant, where they will be corrected prior to being released for sale.

In summation, Cooper believes that the described noncompliance is inconsequential to motor vehicle safety, and that its petition, to exempt Cooper from providing recall notification of the noncompliance, as required by 49 U.S.C. 30118, and remedying the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject tires that Cooper no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after Cooper notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2016–06730 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0003; Notice 1]

Continental Tire the Americas, LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Continental Tire the Americas, LLC (CTA), has determined that certain CTA tires do not fully comply with paragraph S5.5(f) of Federal Motor Vehicle Safety Standard (FMVSS) No. 139 *New Pneumatic Radial Tires for Light Vehicles.* CTA filed a report dated December 11, 2015, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* CTA then petitioned NHTSA under 49 CFR part 556 requesting a decision that the subject noncompliance is inconsequential to motor vehicle safety.

DATES: The closing date for comments on the petition is April 25, 2016.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments regarding this petition. Comments must refer to the docket and notice number cited in the title of this notice and be submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Deliver:* Deliver comments by hand to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

The petition, supporting materials, and all comments received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All documents submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview: Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing regulations at 49 CFR part 556), CTA submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of CTA's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Tires Involved: Affected are approximately 1,800 General Tire brand Grabber size LT265/75R16 112/109 Q LRC tires that were manufactured between December 10, 2010 and September 9, 2013.

III. Noncompliance: CTA explains that due to a mold error, the number of tread plies indicated on the sidewall of the subject tires does not match the actual number of plies in the tire construction. The tires are marked ''PLIES: TREAD: 2 POLYESTER + 2 STEEL + 2 POLYAMIDE'' whereas the correct marking should be: ''PLIES: TREAD: 2 POLYESTER + 2 STEEL + 1 POLYAMIDE.'' As a consequence, these tires do not meet requirements specified in paragraph S5.5(f) of FMVSS No. 139.

IV. Rule Text: Paragraph S5.5(f) of FMVSS No. 139 states, in pertinent part:

S5.5 *Tire Markings.* Except as specified in paragraph (a) through (i) of S5.5, each tire must be marked on each sidewall with the information specified in S5.5(a) through (d) and on one sidewall with the information specified in S5.5(e) through (i) according to the phase-in schedule specified in S7 of this standard. . .

(f) The actual number of plies in the sidewall, and the actual number of plies in the tread area, if different.

V. Summary of CTA's Petition: CTA described the subject noncompliance and stated its belief that the noncompliance is inconsequential to motor vehicle safety.

In support of its petition, CTA submitted the following information pertaining to the subject noncompliance:

(a) CTA stated that the tires covered by this petition are labeled with incorrect information regarding the number of tread plies. The company noted that while the number of polyester and steel plies indicated on the sidewall is accurate, the number of polyamide plies indicated is incorrect. The company contended, however, that this mislabeling has no impact on the operational performance of these tires or on the safety of vehicles on which these tires are mounted. The company asserted that the tires meet or exceed all of the performance requirements of FMVSS No. 139.

(b) CTA noted that NHTSA has concluded in response to numerous other petitions that this type of noncompliance is inconsequential to motor vehicle safety. CTA referenced notices that NHTSA has published in the **Federal Register** granting the following inconsequentiality petitions:

- Petition of Hankook Tire America Corp., 79 FR 30688 (May 28, 2014);
- Petition of Bridgestone Americas Tire Operations, LLC, 78 FR 47049 (August 2, 2013);
- Petition of Cooper Tire & Rubber Company, 78 FR 47050 (August 2, 2013).

(C) CTA states that all tires covered by its petition meet or exceed the performance requirements of FMVSS No. 139, as well as the other labeling requirements of the standard.

(d) CTA also states that it is not aware of any crashes, injuries, customer complaints, or field reports associated with the subject noncompliance.

CTA additionally informed NHTSA that it has quarantined all existing inventory of the tires that contain the noncompliant tire sidewall labeling and has corrected the molds at the manufacturing plant so that no additional tires will be manufactured with the noncompliance.

In summation, CTA believes that the described noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and to remedy the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject tires that CTA no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve equipment distributors and dealers from the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after CTA notified them that the subject noncompliance exists.

Authority: 49 U.S.C. 30118, 30120: Delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2016–06731 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0039]

NHTSA Enforcement Guidance Bulletin 2016–01; Guidance on Submission and Treatment of Manufacturer Communications to Dealers, Owners, or Purchasers About a Defect or Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) is issuing this notice to make manufacturers aware of the statutory requirement to index their communications to dealers, owners, or purchasers about a defect or noncompliance, and to provide recommendations for complying with the index requirement. Additionally, a change in the law requires NHTSA to publicly post all such communications on its Web site and it is therefore providing notice of its intention to do so. NHTSA will also publicly post on its Web site the manufacturers' indexes to their communications as they are received.

FOR FURTHER INFORMATION CONTACT: For legal issues: Kerry Kolodziej, Office of the Chief Counsel, NCC–100, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590 (telephone: 202–366–5263).

For submission of documents pursuant to 49 CFR 579.5: *tsb@dot.gov.*

For submission of documents pursuant to 49 CFR 573.6(c)(10): Recalls Portal Help Desk, 1–888–719–9220; *recalls.helpdesk@dot.gov.*

SUPPLEMENTARY INFORMATION: The National Highway Traffic Safety Administration (NHTSA or Agency) is issuing this notice of its intent to enforce and implement the requirements of 49 U.S.C. 30166(f), as amended by the Moving Ahead for Progress in the 21st Century Act (MAP–21).

I. Legal and Policy Background

A. Manufacturers Are Required To Submit Copies to NHTSA of Communications to Their Dealers, Owners, or Purchasers About a Defect or Noncompliance

The National Traffic and Motor Vehicle Safety Act (Safety Act), as amended, requires motor vehicle and

motor vehicle equipment manufacturers to provide NHTSA with copies of communications they send to their dealers, owners, or purchasers. Specifically, the Safety Act requires manufacturers to submit ''a true or representative copy of each communication to the manufacturer's dealers or to owners or purchasers of a motor vehicle or replacement equipment produced by the manufacturer about a defect or noncompliance with a motor vehicle safety standard prescribed under this chapter in a vehicle or equipment that is sold or serviced.'' 49 U.S.C. 30166(f). This is a long-standing requirement. *See* Motor Vehicle and Schoolbus Safety Amendments of 1974, Public Law 93–492, 158(a)(1), 88 Stat. 1470, 1475 (1974).

1. Scope of Submission Requirement

The requirement for manufacturers to submit copies of their communications to the Agency is broad and requires not only submission of manufacturers' communications to dealers,[1] owners, or purchasers about vehicle and equipment recalls, but all communications ''about a defect or noncompliance.'' 49 U.S.C. 30166(f)(1). With regard to defects, the statutory submission requirement is not limited to communications about safety-related defects. ''Defect'' is a statutorily defined term meaning ''any defect in performance, construction, a component, or material of a motor vehicle or motor vehicle equipment.'' 49 U.S.C. 30102(a)(2). The plain language of the provision requiring submission of copies of manufacturer communications to the Agency does not condition use of the word ''defect'' to ''defect related to motor vehicle safety,'' as is the case with other provisions of the Safety Act. *Compare* 49 U.S.C. 30166(f), *with* 49 U.S.C. 30112(a)(3), 30118(a).

Moreover, the Agency has long interpreted the requirement that manufacturers submit copies of their communications to dealers, owners, or purchasers as capturing all defect-related communications. *See* 49 CFR 579.5. In 1975, the Agency explained that the statute ''specifically authorizes the agency to require the submission'' of communications about a defect, whether or not safety related. Proposed Amendment, 49 FR 43227, 43228 (Sept. 19, 1975). The Agency explained that this was important because ''[i]t is the responsibility of the NHTSA, not the manufacturers, to make a final determination as to whether or not a given defect is safety-related.'' *Id.* In 1978, the Agency reiterated that the law ''specifically grants the agency [ ] authority'' to collect all communications about a defect and rejected the call from some commenters to limit the submissions to only manufacturer communications about ''safety-related defects.'' Final Rule, 43 FR 60165, 60168–69 (Dec. 28, 1978).

2. Implementing Regulations

NHTSA implements the statutory requirement that manufacturers submit representative copies of their communications to dealers, owners, or purchasers through two regulations: One specifically addressing recall communications, 49 CFR 573.6(c)(10), and the other addressing manufacturer communications more broadly, 49 CFR 579.5.

Many communications about a defect or noncompliance are communications manufacturers make to their dealers, owners, or purchasers about recalls. Some examples of these communications are letters to dealers and vehicle owners informing them about a recall and service bulletins (also known as technical service bulletins or TSBs) that provide repair instructions for trained technicians performing the recall remedy. NHTSA requires manufacturers to submit a representative copy to NHTSA of recall communications ''not later than 5 days after they are initially sent to manufacturers, distributors, dealers, or purchasers.'' 49 CFR 573.6(c)(10). This applies to ''all notices, bulletins, and other communications that relate directly to the defect or noncompliance [that is the subject of a recall] and are sent to more than one manufacturer, distributor, dealer or purchaser.'' *Id.*

The second regulation that implements the requirement for manufacturers to submit communications about a defect or noncompliance to the Agency is 49 CFR 579.5. That requires manufacturers to submit ''a copy of all notices, bulletins, and other communications (including those transmitted by computer, telefax, or other electronic means and including warranty and policy extension communiqués and product improvement bulletins) other than those required to be submitted pursuant to § 573.6(c)(10) of this chapter, sent to more than one manufacturer, distributor, dealer, lessor, lessee, owner, or purchaser, in the United States, regarding any defect in its vehicles or items of equipment (including any failure or malfunction beyond normal deterioration in use, or any failure of performance, or any flaw or unintended deviation from design specifications), whether or not such defect is safety-related.'' 49 CFR 579.5(a). It also requires that ''[e]ach manufacturer shall furnish to NHTSA a copy of each communication relating to a customer satisfaction campaign, consumer advisory, recall, or other safety activity involving the repair or replacement of motor vehicles or equipment, that the manufacturer issued to, or made available to, more than one dealer, distributor, lessor, lessee, other manufacturer, owner, or purchaser, in the United States.'' 49 CFR 579.5(b). Manufacturer communications required by 49 CFR 579.5 are due to the Agency ''not later than five working days after the end of the month'' in which they were issued. 49 CFR 579.5(d).

B. NHTSA's Current Treatment of Manufacturer Communications Submitted to the Agency

It is important that manufacturers fully comply with the requirement to submit copies of communications to their dealers, owners, or purchasers about a defect or noncompliance so that the Agency can effectively carry out its mission. Among other things, the Agency reviews these communications to evaluate whether a safety issue is involved, to engage in proactive communications with manufacturers where there may be a misunderstanding or misidentification of the risk of a particular issue that a manufacturer has decided to control and remedy via a field action that is less than a recall, and to ensure that recalls are carried out effectively.

NHTSA posts a great deal of information on its Web site, *www.safercar.gov*, including copies of many manufacturer communications. NHTSA's Web site has a search tool that allows a user to search for available documents and information by make, model, and model year of a vehicle, or by brand name and other identifying information for motor vehicle equipment.[2] When a user performs a search, NHTSA's Web site currently displays available documents and information in four categories: (1) Recalls, (2) Defect Investigations, (3)

[1] The Safety Act defines ''dealer'' as ''a person selling and distributing new motor vehicles or motor vehicle equipment primarily to purchasers that in good faith purchase the vehicles or equipment other the for resale.'' 49 U.S.C. 30102(a)(1). Therefore the requirement to submit communications to the Agency captures communications including both those between a motor vehicle manufacturer and its dealers and equipment suppliers and their motor vehicle manufacturer customers. *See* 49 CFR 579.5.

[2] The search tool is currently available at *http://www-odi.nhtsa.dot.gov/owners/SearchSafetyIssues.*

Complaints, and (4) Service Bulletins.[3] NHTSA plans to rename the ''Service Bulletins'' category as ''Manufacturer Communications'' to more fully reflect the available content. Each of these four categories except ''Complaints,'' which are complaints submitted to the Agency primarily by vehicle owners, may contain copies of manufacturer communications submitted to the Agency.

Where manufacturer communications involve a recall (*i.e.,* concern a safety-related defect or noncompliance), the Agency makes them available along with other recall-related documents under the ''Recalls'' section of its Web site. Other manufacturer communications that relate to an Agency defect investigation (*i.e.,* concern a potential safety-related defect) are also available under the ''Defect Investigations'' section of the Web site. Additionally, NHTSA posts manufacturer communications about customer satisfaction campaigns (*i.e.,* concerning defects that have not been determined to pose an unreasonable risk to motor vehicle safety) on the currently named ''Service Bulletins'' portion of its Web site. NHTSA also posts information about service bulletins (*i.e.,* repair instructions for trained technicians) for issues that have not been determined to be a safety-related defect or noncompliance on its Web site under the currently named ''Service Bulletin'' section of its Web site. NHTSA summarizes service bulletins and makes the summary available, along with an option to request a copy of the documents.[4]

II. New MAP–21 Requirements Regarding Manufacturer Communications Submitted to the Agency

MAP–21 amended the Safety Act to require manufacturers to submit additional information to the Agency along with copies of their communications and to require the Agency to make that additional information and the communications themselves available on the Agency's Web site.

MAP–21 required manufacturers to accompany their submissions of communications to the Agency with an index to each communication. MAP–21, Public Law 112–141, § 31303(a)(2), 126 Stat. 405, 764 (2012) (codified at 49 U.S.C. 30166(f)(2)). Specifically, communications manufacturers are required to submit to NHTSA under 49 U.S.C. 30166(f) ''shall be accompanied by an index to each communication, that—(A) identifies the make, model, and model year of the affected vehicles; [and] (B) includes a concise summary of the subject matter of the communication.'' *Id.*

While NHTSA already proactively made a substantial number of manufacturer communications available to the public on its Web site, MAP–21 also changed the law to make it mandatory for the Agency to post all manufacturer communications to dealers, owners, or purchasers about a defect or noncompliance on its Web site. *See* 49 U.S.C. 30166(f)(1). Additionally, NHTSA must post the manufacturers' indexes to their communications on its Web site in a searchable format. 49 U.S.C. 30166(f)(2).

To implement these changes in the law, NHTSA is providing guidance to manufacturers on the index requirement. This guidance is warranted because manufacturers have not been submitting compliant indexes to the Agency since the MAP–21 changes became effective on October 1, 2012. *See* MAP–21, Public Law 112–141, § 3, 126 Stat. 405, 413 (2012). In addition to putting manufacturers on notice of this index requirement and the Agency's intention to enforce it, providing guidance will also help to ensure consistency in the format and content of manufacturer indexes, thereby enabling the Agency to readily make the indexes publicly available in a searchable format on its Web site.

NHTSA is also providing notice of its intention to publicly post all manufacturer communications submitted to the Agency pursuant to 49 U.S.C. 30166(f) on its Web site. MAP–21 requires NHTSA to post all manufacturer communications to dealers, owners, or purchasers about a defect or noncompliance. Prior to MAP–21, the Agency did not post certain manufacturer communications (specifically, certain service bulletins) on its Web site, which some manufacturers claimed to be copyrighted documents. Congress in MAP–21's explicit requirement that the Agency post ''each communication to the manufacturer's dealers or to owners'' about a defect or noncompliance, has now made clear that copyright law is not a restriction on NHTSA action.

III. Guidance Regarding Index Requirement

The law now requires manufacturers to submit to NHTSA copies of their communications to dealers, owners, or purchasers about a defect or noncompliance and requires that such communications ''shall be accompanied by an index to each communication.'' 49 U.S.C. 30166(f). The index must identify the make, model, and model year of the affected vehicles and include a concise summary of the subject matter of the communication. 49 U.S.C. 30166(f)(2). This requirement has been in effect since October 1, 2012. *See* MAP–21, Public Law 112–141, 3, 126 Stat. 405, 413 (2012).

Most manufacturers comply with the long-standing requirement to submit copies to the Agency of their communications to dealers, owners, or purchasers about a defect or noncompliance.[5] However, manufacturers have not complied with the change in law requiring them to accompany their communications to the Agency with indexes to those communications.

We are providing this guidance to make manufacturers aware of their legal obligation to index their communications. The Agency expects all manufacturers to expeditiously come into full compliance with the law and will take additional action to enforce the index requirement as necessary. The index requirement is subject to daily civil penalties. *See* 49 U.S.C. 30165(a)(3).

We are also providing this guidance to communicate to manufacturers the content requirements for the index. We are providing recommendations for preparing and submitting the index to help ensure consistency across manufacturers and to enable the Agency to readily make the indexes publicly available in a searchable format on its Web site.

A. Which manufacturers must submit indexed communications to the Agency?

Every manufacturer of motor vehicles or motor vehicle equipment is responsible both for submitting copies of communications to dealers, owners, or purchasers and to provide an

[3] NHTSA presently provides summary information, but does not post copies of service bulletins under the currently named ''Service Bulletin'' portion of its Web site.

[4] NHTSA's Web site does not currently include summary information on all service bulletins generated by a manufacturer. Service bulletins for safety recalls in general are not included, and also service bulletins which do not pertain to a safety issue may not be included in the summaries provided.

[5] Where manufacturers have failed to comply with this requirement, the Agency has taken enforcement action. *See* August 28, 2015 Consent Order, In re: AQ15–001, Triumph Motorcycles (America), Ltd.; July 8, 2015 Consent Order, In re: AQ14–001, Forest River, Inc.; July 8, 2015 Consent Order, In re: TQ14–003, Spartan Motors, Inc. The Agency has also has and continues to take steps to educate the industry about the communication submission requirement so that the Agency receives this critical information.

accompanying index of those communications to the Agency. 49 U.S.C. 30166(f). The Safety Act defines ''manufacturer'' broadly to mean ''a person—(A) manufacturing or assembling motor vehicles or motor vehicle equipment; or (B) importing motor vehicles or motor vehicle equipment for resale.'' 49 U.S.C. 30102(a)(5).

B. What types of communications must a manufacturer index going forward?

As discussed in this notice, NHTSA implemented the requirement to submit copies of communications to dealers, owners, or purchasers about a defect or noncompliance through regulations at 49 CFR 573.6(c)(10) and 49 CFR 579.5. Therefore, a manufacturer must accompany its future submissions of all communications pursuant to these provisions with an index that meets the statutory requirements.

C. How does a manufacturer come into compliance with the index requirement for prior submissions?

The index requirement became effective as of October 1, 2012. *See* MAP–21, Public Law 112–141, 3, 126 Stat. 405, 413 (2012). No manufacturer to date has submitted compliant indexes. Some manufacturers have submitted incomplete indexes to their communications that do not satisfy the statutory requirements. To come into full compliance with the law, a manufacturer must submit complete indexes to the communications it previously submitted to the Agency pursuant to 49 CFR 579.5 between October 1, 2012 and the present, along with copies of all communications listed in the index.

A compliant submission requires both a complete index and copies of the indexed communications. *See* 49 U.S.C. 30166(f). A manufacturer may not supplement its earlier submission of communications pursuant to 49 CFR 579.5 by providing an index only. While we understand that this may necessitate, in many cases, manufacturers to resubmit a large quantity of communications to the Agency, this is what the law requires. The Agency must receive a full and complete submission of communications accompanied by an index so that it may fulfill its statutory obligation to make the communications and index available on its Web site.[6]

While a manufacturer must accompany future submissions of communications pursuant to 49 CFR 573.6(c)(10) (*i.e.,* recall communications) with an index, we are exercising our enforcement discretion to deem prior submissions of these communications compliant with this requirement. These are recall communications, such as letters to owners or dealers informing them of the recall and service bulletins regarding the recall repair. Manufacturers need not resubmit copies of recall communications or an accompanying index.[7]

The Agency has long had a practice of posting recall communications on its Web site along with a great deal of information about the recall. As safety critical information, the Agency wants to avoid any disruption that could occur by making changes to the recall portion of its Web site. Moreover, changes are unnecessary. Recall communications are already indexed and available on the Agency's Web site. Recall communications are readily accessible through a searchable interface that is familiar to public users of the Agency's Web site.

D. When are indexed communications due to the Agency?

The law requires that communications submitted to the Agency ''shall be accompanied by an index.'' 49 U.S.C. 30166(f)(2). Therefore, manufacturers should submit an index at the same time as they submit communications to the Agency. As discussed above, 49 CFR 573.6(c)(10) requires submission of recall communications ''not later than 5 days after they are initially sent to manufacturers, distributors, dealers, or purchasers.'' Manufacturer communications required by 49 CFR 579.5 are due to the Agency ''not later than five working days after the end of the month'' in which they were issued. 49 CFR 579.5(d).

1. Current and Prospective Submissions of Communications

The Agency expects manufacturers to make a good faith effort to expeditiously comply with the requirement to provide an index to accompany the communications they submit to the Agency. However, the Agency recognizes that manufacturers will need to educate staff and may need to change internal policies and procedures to begin complying with this requirement. While the Agency is not excusing noncompliance with the law, the Agency recognizes that the entire industry has been out of compliance with the index requirement and intends to exercise its enforcement discretion to allow manufacturers a reasonable period of time from the date of this notice to come into compliance with the index requirement on a going forward basis. However, manufacturers should not delay providing communications to the Agency.

2. Retroactive Resubmissions of Indexed Communications

The Agency will not excuse manufacturers from providing indexes for communications submitted to the Agency pursuant to 49 CFR 579.5 on or after October 1, 2012. For any communications previously submitted to the Agency pursuant to 49 CFR 579.5 that were not accompanied by a fully compliant index at the time of submission, manufacturers must submit indexed communications to the Agency. As discussed above, this requires an index along with resubmission of all communications listed in the index. This is necessary to allow the Agency to fulfill its statutory obligations.

The Agency intends to exercise enforcement discretion to allow manufacturers a reasonable period of time to resubmit indexed communications required by 49 CFR 579.5. The Agency recognizes that, in many cases, the volume of communications submitted to the Agency since October 1, 2012 is significant. The Agency will take the volume of communications into account in considering what constitutes a reasonable period of time for a given manufacturer. In general, we expect that a manufacturer will resubmit indexed communications on a rolling basis until it achieves full compliance.

In sum, the Agency is not specifying a deadline for compliance with the index requirement before it expects to take enforcement action. All manufacturers must begin immediately making a reasonable good faith effort to take steps to comply expeditiously for both retroactive and future submissions. The Agency will take any such actions into account in evaluating whether a given manufacturer came into compliance with the law within a reasonable period of time.

E. What are the penalties for not complying with the index requirement?

Indexes are required by 49 U.S.C. 30166(f), therefore, failure to provide indexes, or failure to provide timely or complete indexes, is subject to civil

[6] An index must enable a user to locate the indexed communications. NHTSA will provide each communication with a unique identifier, linked to the manufacturer-provided index. NHTSA will provide instructions on its Web site for using the unique identifier to search for and retrieve the communication.

[7] This is not intended to limit the Agency's authority to make future requests for documents or information. *See* 49 CFR 30166(b), (e), (g).

penalties under current law of up to $21,000 per violation per day and up to a maximum penalty of $105 million for a related series of daily violations. 49 U.S.C. 30165(a)(3); *see* Civil Penalty Factors, 81 FR 10520 (Mar. 1, 2016) (issuing final rule).

F. What information must the index contain?

At a minimum, an index must identify the make, model, and model year of the affected vehicles and must include a concise summary of the subject matter of the communication. These are statutory requirements. 49 U.S.C. 30166(f)(2). This is mandatory information when applicable.

However, the Agency recognizes that for communications submitted by motor vehicle equipment manufacturers, in many cases, there are no specific affected vehicles. This is also true for a limited number of generalized communications by motor vehicle manufacturers. In such cases, the manufacturer should include other identifying information for the affected motor vehicles or motor vehicle equipment in lieu of make, model, and model year information for specific affected vehicles.[8]

To help ensure consistency across manufacturers, the Agency is also providing recommendations on the specific format and content of the indexes. In addition to the recommendations provided in this notice, the Agency may provide more detailed recommendations on a forthcoming Web page at *http://www-odi.nhtsa.dot.gov/mc/*. The Agency will make available a template index for download and will provide examples of completed index entries on its Web site. The Agency encourages manufacturers to continue to visit this Web page as the Agency may refine its recommendations over time as it evaluates manufacturers' index submissions. While we are providing guidance and recommendations at this time, the Agency will evaluate the content and consistency of index submissions across manufacturers to determine whether a future rulemaking is warranted.

1. Recommended Format for Index

NHTSA strongly recommends that manufacturers submit their indexes as word searchable electronic files. While the Agency is not requiring use of any particular software, to ensure compatibility, the Agency requests that manufacturers submit indexes as searchable Microsoft Excel files.

The Agency recommends that a manufacturer list each communication on a separate row in its index and include separate columns for each item of discrete information included. For example, the index should include separate columns for make, of the affected vehicles, model of the affected vehicles, and model year of the affected vehicles. We recommend including a separate row for each make, model, or model year of vehicle affected by a single communication. In other words, a single communication may populate multiple rows on an index. We also recommend including a column for manufacturer communication identifier number, if one is used.

The Agency's Web site and template index available for download will provide more specific recommendations and information on the Agency's preferred format for manufacturer indexes. *See http://www-odi.nhtsa.dot.gov/mc/* (forthcoming).

2. Recommendations for Preparing the Concise Summary

At a minimum, NHTSA recommends that a concise summary of the subject matter of a manufacturer's communication should identify the defect or noncompliance, describe the effect of the defect or noncompliance, and describe the purpose or type of the communication. In many cases, simply repeating the subject line or title of a communication will be insufficient. Likewise, a generic description that does not actually summarize the communication or describes multiple communications with minimal changes, such as ''service bulletin number 123'' does not meet the statutory requirements. The Agency will post examples of concise summaries on its Web site.

G. Recommended Method of Submitting the Indexed Communications to the Agency

NHTSA requests that manufacturers submit their indexed communications to the Agency electronically. Electronic submission will best enable the Agency to make the manufacturer communications and searchable index available to the public on the Internet as the law requires.

As discussed above, manufacturers must index recall communications that they submit to the Agency pursuant to 49 CFR 573.6(c)(10) and communications that they submit pursuant to 49 CFR 579.5. Manufacturers are required to submit recall communications through NHTSA's recalls portal and should also submit their recall communication indexes through the portal. *See* 49 CFR 573.9. For communications required by 49 CFR 579.5, NHTSA strongly recommends that manufacturers submit their indexed communications electronically to *tsb@dot.gov*. *See* 49 CFR 579.6(a).

We note that some manufacturers have had a past practice of submitting multiple communications under 49 CFR 579.5 in a consolidated format, such as a single large .pdf file. We strongly recommend that manufacturers discontinue this practice, in order to ensure that each communication listed in the manufacturer's index is a readily identifiable separate document. The Agency would prefer to receive each communication as a separate .pdf file.

IV. Notice of Intention to Publicly Post All Manufacturer Communications About a Defect or Noncompliance on NHTSA's Web Site

NHTSA has reevaluated the information that the law permits it to make publicly available on its Web site in light of the changes made by MAP–21. As a result, NHTSA is providing this notice of its intent to publicly post all manufacturer communications submitted to it pursuant to 49 U.S.C. 30166(f).

The law now affirmatively requires NHTSA to ''make available on a publicly accessible Internet Web site'' copies of communications to manufacturers' dealers, owners, or purchasers about a defect or noncompliance that manufacturers submit to the Agency.

Prior to enactment of MAP–21, the Agency did not publicly post copies of all service bulletins that it received.[9] Some manufacturers copyright their service bulletins. Service bulletins are a manufacturer's repair instructions, and repair shops or other interested individuals may purchase them from a commercial source.

Pursuant to the fair use limitation on copyright, to date NHTSA has posted on its Web site copies of service bulletins for recall repairs and service bulletins related to its defect investigations. *See* 17 U.S.C. 107; *see also* 49 U.S.C. 30167(b). NHTSA also has made a paper copy of other service bulletins available

[8] This does not excuse a motor vehicle manufacturer from providing make, model, and model year information for affected vehicles when that information is reasonably available. For example, it is not sufficient for a motor vehicle manufacturer to include vehicle platform information in its index instead of make and model.

[9] Although the law also limits the Agency's ability to disclose confidential information, 49 U.S.C. 30167, manufacturers do not treat these documents as confidential and, in the case of service bulletins, make them available to the public through commercial providers. *See* 49 CFR part 512.

to the public pursuant to the library provision of copyright law. *See* 17 U.S.C. 108.

Congress necessarily made the decision in enacting MAP–21, that copyright law does not restrict NHTSA from publicly posting copies of all manufacturer communications received by the Agency pursuant to 49 U.S.C. 30166(f) on its Web site. Indeed, 49 U.S.C. 30166(f) expressly requires the Agency to do so.

MAP–21 trumps the limited waiver of sovereign immunity for copyright infringement claims. *See* 28 U.S.C. 1498(b). Congress could not have intended to allow manufacturers to assert copyright infringement against the federal government based on the Agency's publication of service bulletins and other manufacturer communications on its Web site in light of the express statutory requirement that the Agency do so. *See Food & Drug Admin.* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 143 (2000) (''The classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute. This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand . . . . [A] specific policy embodied in a later federal statute should control our construction of the earlier statute, even though it has not been expressly amended.'') (internal quotation marks, brackets, and citations omitted).

Because the law directs the Agency to make manufacturer communications publicly available on its Web site, the Agency is acting to effectuate the law. The Agency will post on its Web site those manufacturer communications submitted to the Agency on or after the October 1, 2012 effective date of MAP–21 that are not already available on the Agency's Web site. Going forward, the Agency intends to post to its public Web site all manufacturer communications submitted pursuant to 49 U.S.C. 30166(f), including documents submitted pursuant to 49 CFR 573.6(c)(10) or 579.5. The Agency will also post manufacturer indexes for communications submitted to the Agency on or after October 1, 2012 on a rolling basis as compliant indexes are received. The Agency intends to make manufacturer indexes available in a searchable format.

Applicability/Legal Statement: This Enforcement Guidance Bulletin sets forth NHTSA's current interpretation and thinking on this topic and guiding principles and best practices to be utilized in complying with the legal requirements of 49 U.S.C. 30166(f). This Bulletin is not a final agency action and is intended as guidance only. This Bulletin is not intended, nor can it be relied upon, to create any rights enforceable by any party against NHTSA, the Department of Transportation, or the United States. Moreover, these recommended practices to not establish any defense to any violations of the statutes and regulations that NHTSA administers. This Bulletin may be revised without notice to reflect changes in NHTSA's evaluation and analysis, or to clarify and update text.

Authority: 49 U.S.C. 30101, *et seq.;* 49 U.S.C. 30165(a)(3), 30166(f); delegations of authority at 49 CFR 1.95(a), 501.2(a)(1), 501.5.

Issued on: March 21, 2016.

Paul A. Hemmersbaugh,

Chief Counsel.

[FR Doc. 2016–06759 Filed 3–24–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before April 25, 2016.

Address comments to: Record Center, Pipeline and Hazardous Materials Safety Administration U.S. Department of Transportation Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on March 10, 2016.

Donald Burger,

Chief, Office of the Special Permits and Approvals.

Application number	Docket number	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
20205–N		Tier Holdings, LLC	173.244	To authorize the one-time movement of a tank built in accordance with ASME section VIII Div. 1. 2013 containing no more than 3,500 pounds of sodium metal.
20213–N		West Cryogenics, Inc	172.203(a), 172.301(c), 180.211(c)(2)(i).	To authorize the repair of certain DOT 4L cylinders without requiring pressure testing to the internal jacket.

Application number	Docket number	Applicant	Regulation(s) affected	Nature of the special permits thereof
20214–N	.....	University of Southern California.	177.817, 177.823(a), 172.200, 172.300, 172.602(c)(1), 172.604(a)(3), 172.400.	To authorize the transportation in commerce of certain waste materials on approximately 0.4 mile of public roads without being subject to certain hazard communication requirements.
20215–N	.....	Pollux Aviation, Ltd	175.30(a)(1), 172.101(j)	To authorize the transportation in commerce of diesel and gasoline in amounts that exceed the quantity limitations for transportation by 14 CFR part 133 Rotorcraft External Load Operations transporting hazardous materials attached to or suspended from an aircraft in remote areas of the U.S. only, when no other means of transportation are available.
20217–N	.....	Nuance Medical, LLC	171.23(b), 171.8, 173.304a(a)(1), 173.306(a)(3).	To authorize the transportation in commerce of certain Division 2.1 gases in a DOT 2Q container.
20218–N	.....	Tremear, Inc	178.345–2, 178.346–2, 178.347–2(a), 178.348–2(a).	To authorize the manufacture, marking, sale, and use of DOT 400 series cargo tank motor vehicles fabricated using materials not authorized in § 178.345–2, and thicknesses not authorized in §§ 178.346–2, 178.347–2 and 178.348–2.
20219–N	.....	Coastal Helicopters, Inc	175.30(a)(1), 175.75, 172.101(j), 172.101(j)(1), 172.200(a), 172.204(c)(3), 172.300(a), 172.300(b), 173.27(b)(2).	To authorize the transportation in commerce of certain hazardous materials by 14 CFR part 133 Rotorcraft External Load Operations, transporting hazardous materials attached to or suspended from an aircraft, in remote areas of the U.S. only, without being subject to hazard communication requirements, quantity limitations and certain loading and stowage requirements.
20220–N	.....	Agility Fuel Systems, Inc	173.220(a)	To authorize the transportation in commerce of compressed natural gas fuel systems that are not part of an internal combustion engine.
20221–N	.....	Comet Technologies USA, Inc.	173.304a(a)(2)	To authorize the transportation in commerce of a Division 2.2 gas in a non-DOT specification pressure vessel.
20224–N	.....	Axalta Coating Systems, LLC.	172.504(a), 173.242, 172.101(c)(10)(ii)(F)(iii), 172.302a.	To authorize the transportation in commerce of certain waste paints and paint related materials, Class 3, in metal or plastic pails, packed in roll-off containers.

[FR Doc. 2016–05922 Filed 3–24–16; 8:45 am]
BILLING CODE 4909–60–M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Applications for Special Permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before April 25, 2016.

ADDRESSES COMMENTS TO: Record Center, Pipeline and Hazardous Materials Safety Administration U.S. Department of Transportation Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC or at *http://regulations.gov*.

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(6); 49 CFR 1.53(b)).

Issued in Washington, DC, on March 10, 2016.

Donald Burger,

Chief, Office of the Special Permits and Approvals.

Application number	Docket number	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
9393–M		ITW Sexton, Inc	178.33–8(a), 178.65(a), 178.65(c).	To modify the special permit to authorize burst testing and modify the pressure relief device (PRD) requirements.
10704–M		Boost Oxygen, LLC		To modify the special permit to authorize a lower minimum burst pressure and pressure rating.
14282–M		Innovative Technology Partnerships, LLC.	177.835(g), 172.301(c)	To modify the special permit to authorize the transportation in commerce of packages which may contain explosives and inert/benign cushioning to ensure the package is full.
16011–M		Americase, Inc		To modify the special permit to authorize a thermally insulated fiberboard packaging for transporting recalled and damaged lithium batteries and equipment powered by lithium batteries by reducing certain hazard communication requirements.
16081–M		Cabela's Incorporated	178.602, 173.22a(c)	To modify the special permit to authorize additional Division 1.4 materials and no longer require a copy of the special permit to be furnished to the carrier.
16461–M		Coastal		To modify the Hydrotesting, special permit to LLC authorize the addition of an aluminum alloy not previously authorized under the terms of the special permit.

[FR Doc. 2016–05921 Filed 3–24–16; 8:45 am]
BILLING CODE 4909–60–M

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Minimum Security Devices and Procedures, Reports of Suspicious Activities, and Bank Secrecy Act Compliance Program

AGENCY: Office of the Comptroller of the Currency (OCC), Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, ''Minimum Security Devices and Procedures, Reports of Suspicious Activities, and Bank Secrecy Act Compliance Program.''

DATES: Written comments should be received on or before May 24, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0180, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Office of the Comptroller of the Currency, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed collection of information set forth in this document.

Title: Minimum Security Devices and Procedures, Reports of Suspicious Activities, and Bank Secrecy Act Compliance Program.

OMB Control No.: 1557–0180.

Form Numbers: 8010–1/8010–9.

Abstract:

Minimum Security Devices and Procedures

Under §§ 21.2 and 21.4; and §§ 568.2 and 568.4, national banks and savings associations are required to designate a security officer who must develop and administer a written security program. The security officer shall report at least annually to the institution's board of directors on the effectiveness of the security program. The substance of the report shall be reflected in the board's minutes. These requirements ensure that the security officer is responsible for the security program and that institution management and the board of directors are aware of the content and effectiveness of the program. These requirements ensure prudent institution management and institution safety and soundness.

Suspicious Activity Report (SAR)

The Financial Crimes Enforcement Network (FinCEN) and Federal financial institution supervisory agencies [1] (bank regulators) adopted the SAR in 1996 to simplify the process through which depository institutions inform their regulators and law enforcement about suspected criminal activity. The SAR was updated in 1999, 2002, 2006, 2009 and 2013.

In 1992, the Department of the Treasury was granted broad authority to require suspicious transaction reporting under the Bank Secrecy Act (BSA). *See* 31 U.S.C. 5318(g). FinCEN, which has been delegated authority to administer the BSA, joined with the bank regulators in 1996 in requiring, on a consolidated form (the SAR form), reports of suspicious transactions. *See* 31 CFR 1020.320(a) (formerly 31 CFR 103.18(a)). The filing of SARs is necessary to prevent and detect crimes involving depository institution funds, institution insiders, criminal transactions, and money laundering. These requirements are necessary to ensure institution safety and soundness.

Banks and savings associations are required to maintain a copy of any SAR filed and the original or business record equivalent of any supporting documentation for a period of five years. The documents are necessary for criminal investigations and prosecutions.

[1] The Federal financial institution supervisory agencies are the Office of the Comptroller of the Currency (OCC), Board of Governors of the Federal Reserve System (Board), Federal Deposit Insurance Corporation (FDIC), and National Credit Union Administration (NCUA).

Procedures for Monitoring Bank Secrecy Act Compliance

Under 12 CFR 21.21, national banks and savings associations are required to develop and provide for the continued administration of a program reasonably designed to assure and monitor their compliance with the BSA and applicable Treasury regulations. The compliance program shall be in writing, approved by the board of directors and noted in the minutes. These requirements are necessary to ensure institution compliance with the BSA and applicable Treasury regulations.

Type of Review: Regular.

Affected Public: Business, for-profit institutions, and non-profit.

Estimated Number of Respondents: 1,485.

Estimated Total Annual Burden: 714,205 hours.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information shall have practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology, and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: March 21, 2016.

Mary H. Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2016–06758 Filed 3–24–16; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: FHA New Account Request, Transition Request, and Transfer Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the collections of information required to comply with the terms and conditions of FHA New Account Request, Transition Request, and Transfer Request.

DATES: Written comments should be received on or before May 24, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for further information to Bureau of the Fiscal Service, Bruce A. Sharp, 200 Third Street, A4–A, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Dwayne Boothe, Branch Manager, Special Investments Branch; 200 Third Street, Room 119, Parkersburg, WV 26106–1328, or *dwayne.boothe@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Form Numbers and Titles:

FS Form 5354—FHA Transaction Request

FS Form 5366—FHA New Account Request

FS Form 5367—FHA Debenture Transfer Request

OMB Number: 1530–0054 (Previously approved as 1535–0120 as a collection conducted by Department of the Treasury/Bureau of the Public Debt.)

Transfer of OMB Control Number: The Bureau of Public Debt (BPD) and the Financial Management Service (FMS) have consolidated to become the Bureau of the Fiscal Service (Fiscal Service). Information collection requests previously held separately by BPD and FMS will now be identified by a 1530 prefix, designating Fiscal Service.

Abstract: The information is used to (1) establish a book-entry account; (2) change information on a book-entry account; and (3) transfer ownership of a book-entry account on the HUD system, maintained by the Federal Reserve Bank of Philadelphia.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 300.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 50.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: March 11, 2016.

Bruce A. Sharp,

Bureau Clearance Officer.

[FR Doc. 2016–06807 Filed 3–24–16; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Orders 13469 and 13224

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (OFAC) is publishing updated identifying information for one individual whose property and interests in property are blocked pursuant to Executive Order (E.O.) 13469, ''Blocking Property of Additional Persons Undermining Democratic Processes or Institutions in Zimbabwe,'' and one entity whose property and interests in property are blocked pursuant to E.O. 13224, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism,'' both of which have previously been designated and added to OFAC's Specially Designated Nationals and Blocked Persons (SDN) List.

DATES: OFAC's actions described in this notice were effective on March 22, 2016, as further specified below.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202/622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490, or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202–622–0077.

Notice of OFAC Actions

On March 22, 2016, OFAC updated the identifying information for one previously designated individual whose property and interests in property are blocked pursuant to E.O. 13469 and one previously designated entity whose property and interests in property are blocked pursuant to E.O. 13224. The updated identifying information for the individual and entity is as follows:

Individual:

AL-SHANFARI, Thamer Bin Said Ahmed (a.k.a. AL SHANFARI, SHEIKH THAMER; a.k.a. AL SHANFARI, Thamer; a.k.a. AL SHANFARI, Thamer Said Ahmed; a.k.a. AL-SHANFARI, Thamer Bin Saeed; a.k.a. AL-SHANFARI, Thamer Said Ahmed; a.k.a. SHANFARI, Thamer), P.O. Box 18, Ruwi 112, Oman; DOB 03 Jan 1968; nationality Oman; citizen Oman; Passport 00000999 (Oman); alt. Passport 3253 (Oman); Chairman & Managing Director, Oryx Group and Oryx Natural Resources (individual) [ZIMBABWE].

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AL-SHANFARI, Thamer Bin Said Ahmed (a.k.a. AL SHANFARI, SHEIKH THAMER; a.k.a. AL SHANFARI, Thamer; a.k.a. AL SHANFARI, Thamer Said Ahmed; a.k.a. AL-SHANFARI, Thamer Bin Saeed; a.k.a. AL-SHANFARI, Thamer Said Ahmed; a.k.a. SHANFARI, Thamer), P.O. Box 18, Ruwi 112, Oman; DOB 03 Jan 1968; alt. nationality Oman; alt. citizen Oman; Passport 00000999 (Oman); alt. Passport 3253 (Oman) (individual) [ZIMBABWE].

Entity:

REVIVAL OF ISLAMIC HERITAGE SOCIETY (a.k.a. AFGHAN SUPPORT COMMITTEE; a.k.a. AHIYAHU TURUS; a.k.a. AHYA UL TURAS; a.k.a. AHYA UTRAS; a.k.a. AL–FORQAN AL-KHAIRYA; a.k.a. AL-FURQAN AL-KHARIYA; a.k.a. AL-FURQAN CHARITABLE FOUNDATION; a.k.a. AL-FURQAN FOUNDATION WELFARE TRUST; a.k.a. AL-FURQAN KHARIA; a.k.a. AL-FURQAN UL KHAIRA; a.k.a. AL-FURQAN WELFARE FOUNDATION; a.k.a. AL-TURAZ ORGANIZATION; a.k.a. AL-TURAZ TRUST; a.k.a. FORKHAN RELIEF ORGANIZATION; a.k.a. HAYAT UR RAS AL-FURQAN; a.k.a. HAYATURAS; a.k.a. HAYATUTRAS; a.k.a. HIYAT ORAZ AL ISLAMIYA; a.k.a. JAMIA IHYA UL TURATH; a.k.a. JAMIAT AL-HAYA AL-SARAT; a.k.a. JAMIAT AYAT-UR-RHAS AL ISLAMIA; a.k.a. JAMIAT IHIA AL-TURATH AL-ISLAMIYA; a.k.a. JAMIAT IHYA UL TURATH AL ISLAMIA; a.k.a. JAMITO AHIA TORAS AL-ISLAMI; a.k.a. LAJNAT UL MASA EIDATUL AFGHANIA; a.k.a. LAJNATUL FURQAN; a.k.a. ORGANIZATION FOR PEACE AND DEVELOPMENT PAKISTAN; a.k.a. RAIES KHILQATUL QURANIA FOUNDATION OF PAKISTAN; a.k.a. REVIVAL OF ISLAMIC SOCIETY HERITAGE ON THE AFRICAN CONTINENT; a.k.a. ''AL MOSUSTA FURQAN''; a.k.a. ''AL-FORKAN''; a.k.a. ''AL-FURKAN''; a.k.a. ''AL-MOSASATUL FURQAN''; a.k.a. ''ASC''; a.k.a. ''HITRAS''; a.k.a. ''JAMIAT AL-FURQAN''; a.k.a. ''MOASSESA AL-FURQAN''; a.k.a. ''MOSASA-TUL-FORQAN''; a.k.a. ''RIHS''; a.k.a. ''SOCIAL DEVELOPMENT FOUNDATION''), House Number 56, E. Canal Road, University Town, Peshawar, Pakistan; Afghanistan; Near old Badar Hospital in University Town, Peshawar, Pakistan; Chinar Road, University Town, Peshawar, Pakistan [SDGT].

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REVIVAL OF ISLAMIC HERITAGE SOCIETY (a.k.a. AFGHAN SUPPORT COMMITTEE; a.k.a. AHIYAHU TURUS; a.k.a. AHYA UL TURAS; a.k.a. AHYA UTRAS; a.k.a. AL FORQAN CHARITY; a.k.a. AL-FORQAN AL-KHAIRYA; a.k.a. AL-FURQAN AL-KHARIYA; a.k.a. AL-FURQAN CHARITABLE FOUNDATION; a.k.a. AL-FURQAN FOUNDATION WELFARE TRUST; a.k.a. AL-FURQAN KHARIA; a.k.a. AL-FURQAN UL KHAIRA; a.k.a. AL-FURQAN WELFARE FOUNDATION; a.k.a. AL-TURAZ ORGANIZATION; a.k.a. AL-TURAZ TRUST; a.k.a. EAST AND WEST ENTERPRISES; a.k.a. FORKHAN RELIEF ORGANIZATION; a.k.a. HAYAT UR RAS AL-FURQAN;

a.k.a. HAYATURAS; a.k.a. HAYATUTRAS; a.k.a. HIYAT ORAZ AL ISLAMIYA; a.k.a. JAMIA IHYA UL TURATH; a.k.a. JAMIAT AL-HAYA AL-SARAT; a.k.a. JAMIAT AYAT-UR-RHAS AL ISLAMIA; a.k.a. JAMIAT IHIA AL-TURATH AL-ISLAMIYA; a.k.a. JAMIAT IHYA UL TURATH AL ISLAMIA; a.k.a. JAMITO AHIA TORAS AL-ISLAMI; a.k.a. LAJNAT UL MASA EIDATUL AFGHANIA; a.k.a. LAJNATUL FURQAN; a.k.a. ORGANIZATION FOR PEACE AND DEVELOPMENT PAKISTAN; a.k.a. RAIES KHILQATUL QURANIA FOUNDATION OF PAKISTAN; a.k.a. REVIVAL OF ISLAMIC SOCIETY HERITAGE ON THE AFRICAN CONTINENT; a.k.a. ''AL MOSUSTA FURQAN''; a.k.a. ''AL-FORKAN''; a.k.a. ''AL-FURKAN''; a.k.a. ''AL-MOSASATUL FURQAN''; a.k.a. ''ASC''; a.k.a. ''HITRAS''; a.k.a. ''JAMIAT AL-FURQAN''; a.k.a. ''MOASSESA AL-FURQAN''; a.k.a. ''MOSASA-TUL–FORQAN''; a.k.a. ''RIHS''; a.k.a. ''SOCIAL DEVELOPMENT FOUNDATION''), House Number 56, E. Canal Road, University Town, Peshawar, Pakistan; Afghanistan; Near old Badar Hospital in University Town, Peshawar, Pakistan; Chinar Road, University Town, Peshawar, Pakistan; 218 Khyber View Plaza, Jamrud Road, Peshawar, Pakistan; 216 Khyber View Plaza, Jamrud Road, Peshawar, Pakistan [SDGT].

Dated: March 22, 2016.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–06804 Filed 3–24–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Financial Research Advisory Committee

AGENCY: Office of Financial Research, Treasury.

ACTION: Financial Research Advisory Committee-Solicitation of Applications for Committee Membership.

SUMMARY: The Office of Financial Research is soliciting applications for membership on its Financial Research Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Susan Stiehm, Designated Federal Officer, Office of Financial Research, Department of the Treasury, (212) 376–9808.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, (Pub. L. 92–463, 5 U.S.C. App. 2 § 1–16, as amended), the Treasury Department established a Financial Research Advisory Committee (Committee) to provide advice and recommendations to the Office of Financial Research (OFR) and to assist the OFR in carrying out its duties and authorities.

(I) Authorities of the OFR

Background

The OFR was established under Title I of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203, July 21, 2010). The purpose of the OFR is to support the Financial Stability Oversight Council (Council) in fulfilling the purposes and duties of the Council and to support the Council's member agencies by:

—Collecting data on behalf of the Council, and providing such data to the Council and member agencies;
—Standardizing the types and formats of data reported and collected;
—Performing applied research and essential long-term research;
—Developing tools for risk measurement and monitoring;
—Performing other related services;
—Making the results of the activities of the OFR available to financial regulatory agencies; and
—Assisting such member agencies in determining the types and formats of data authorized by the Dodd-Frank Act to be collected by such member agencies.

(II) Scope and Membership of the Financial Research Advisory Committee

The Financial Research Advisory Committee was established to advise the OFR on issues related to the responsibilities of the office. It may provide its advice, recommendations, analysis, and information directly to the OFR and the OFR may share the Committee's advice and recommendations with the Secretary of the Treasury or other Treasury officials. The OFR will share information with the Committee as the Director determines will be helpful in allowing the Committee to carry out its role.

The Financial Research Advisory Committee is an advisory committee that was established on April 6, 2012 and renewed its charter on March 8, 2016. The OFR is currently soliciting applications for membership in order to provide for rotation of membership, as provided in its original and renewed charter, as well as to provide for a diverse and balanced body with a variety of interests, backgrounds, and viewpoints represented. Providing for such diversity enhances the views and advice offered by the Committee.

(II) Application for Advisory Committee Appointment

Treasury seeks applications from individuals representative of a constituency within the fields of economics, financial institutions and markets, statistical analysis, financial markets analysis, econometrics, applied sciences, risk management, data management, information standards, technology, or other areas related to OFR's duties and authorities. The terms of members chosen to serve may vary. Membership on the Committee is limited to the individuals appointed and is non-transferrable. Regular attendance is essential to the effective operation of the Committee. Some members of the Committee may be required to adhere to the conflict of interest rules applicable to Special Government Employees, as such employees are defined in 18 U.S.C. 202(a). These rules include relevant provisions in 18 U.S.C. related to criminal activity, Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), and Executive Order 12674 (as modified by Executive Order 12731).

To apply, an applicant must submit an appropriately-detailed resume and a cover letter describing their interest, reasons for application, and qualifications. In accordance with Department of Treasury Directive 21–03, a clearance process includes fingerprints, tax checks, and a Federal Bureau of Investigation criminal check. Applicants must state in their application that they agree to submit to these pre-appointment checks.

The application period for interested candidates will extend to April 22, 2016. Applications should be submitted in sufficient time to be received by the close of business on the closing date and should be sent to *OFR_FRAC@ofr.treasury.gov* or by mail to: Office of Financial Research, Department of the Treasury, Attention: Susan Stiehm, 1500 Pennsylvania Avenue NW., MT–1330, Washington, DC 20220.

Dated: March 21, 2016.

Barbara Shycoff,

Chief of External Affairs.

Action Memorandum Clearance Sheet

Subject/Title: **Federal Register** Notice for third Financial Research Advisory Committee Meeting.

Drafted by: Susan Stiehm.

Contributions by: John Zitko.

	Office, Title	Name	Date
Approved[1] by:	OFR, Director	Richard Berner	3/21
Reviewed[2] by:	OFR, COO	Nicole Bynum	
	OFR, Chief of Staff	Kathleen Victorino	3/14
	OFR, Senior Attorney Advisor	John Zitko	
	OFR, CDO	Con Crowley	3/14
	OFR, CTO	John Talbot	3/14
	OFR, Deputy Director, Research and Analysis.	Stacey Schreft	
Cleared[3] by:	OFR, Chief Counsel	Matt Reed	3/15
	OFR, Chief of External Relations	Barbara Shycoff	3/11

[1] The approver is the final review before the document can be sent to the intended recipient. It is recommended that you limit the number of approvers to 1.
[2] A reviewer has read the document and provided comments on part of the document. This person has not necessarily endorsed all of the language within the document.
[3] A clearer has read the document and endorses the language in the final document relevant to the clearer's office.

Delivery Instructions

Return to policy office for delivery.
Deliver through the OFR Front Office (include specific instructions below).
Other (see below).
Specific delivery instructions:

[FR Doc. 2016–06798 Filed 3–24–16; 8:45 am]
BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

2016 Report on the Terrorism Risk Insurance Program

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice and request for comment.

SUMMARY: The Terrorism Risk Insurance Act of 2002, as amended (TRIA), requires participating insurers to make insurance available for losses resulting from acts of terrorism, and provides a federal government backstop for the insurers' resulting financial exposure. TRIA established, in the U.S. Department of the Treasury, the Terrorism Risk Insurance Program (TRIP), which is administered by the Secretary of the Treasury (Secretary), with the assistance of the Federal Insurance Office (FIO). The Terrorism Risk Insurance Program Reauthorization Act of 2015 (Reauthorization Act), which extended and amended certain provisions of TRIP, requires the Secretary to submit a report to Congress concerning, among other things, the overall effectiveness of TRIP. To assist the Secretary in formulating the report, FIO is seeking comment on the statutory factors that the report must analyze and other related matters.

DATES: Comments must be submitted not later than April 15, 2016.

ADDRESSES: Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov,* in accordance with the instructions on that site. In general, the Department will post all comments to *www.regulations.gov* without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. The Department will also make such comments available for public inspection and copying in the Treasury's Library, 1500 Pennsylvania Avenue NW., Washington, DC 20220, on official business days between the hours of 10:00 a.m. and 5:00 p.m. Eastern Time. You can make an appointment to inspect comments by telephoning (202) 622–0990. All comments, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

Electronic submissions are encouraged.

Comments may also be mailed to the Department of the Treasury, Federal Insurance Office, MT 1410, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Richard A. Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, (202) 622–2922 (this is not a toll-free number) or Kevin Meehan, Policy Advisor, Federal Insurance Office, (202) 622–7009 (not a toll free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Section 111 of the Reauthorization Act (Pub. L. 114–1) requires the Secretary to submit a report to the Committee on Financial Services of the House of Representatives and the Committee on Banking, Housing, and Urban Affairs of the Senate on, among other things, the impact and effectiveness of TRIP. The report must also include an evaluation of information that is being separately collected by Treasury, including certain data appropriate for analyzing the effectiveness of TRIP.

II. Solicitation for Comments

Collecting additional information and views on the matters that must be addressed in the report to Congress will assist the Secretary in the formulation of the report and enhance the report's accuracy and value. Treasury seeks comment from interested parties on all Section 111 elements that must be covered in the report, including comments on:

1. The overall effectiveness of the TRIP;

2. Observed changes or trends relating to matters that Treasury is collecting data about under Section 111 of the Reauthorization Act;

3. Whether any aspects of TRIP have the effect of discouraging or impeding insurers from providing commercial property casualty insurance coverage or coverage for acts of terrorism; and

4. The impact of TRIP on workers' compensation insurers.

In addition to comments on the above, Treasury also seeks comment from interested parties on:

5. The availability and affordability of terrorism risk insurance coverage, both nationally and in particular geographic areas; and

6. Other issues relating to TRIP or terrorism insurance or reinsurance more broadly that may be relevant to Treasury's assessment of the effectiveness of TRIP.

Michael T. McRaith,

Director, Federal Insurance Office.

[FR Doc. 2016–06795 Filed 3–24–16; 8:45 am]
BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

March 22, 2016

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before April 25, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Control Number: 1545–0233.

Type of Review: Reinstatement with change of a previously approved collection.

Title: Application for Automatic Extension of Time to File Certain Business Income Tax, Information, and Other Returns.

Abstract: Form 7004 is used by corporations and certain non-profit institutions to request an automatic 5-month or 6-month extension of time to file their income tax returns. The information is needed by IRS to determine whether Form 7004 was timely filed so as not to impose a late filing penalty in error and also to insure that the proper amount of tax was computed and deposited.

Estimated Total Annual Burden Hours: 44,324,250.

OMB Control Number: 1545–1834.

Type of Review: Extension without change of a currently approved collection.

Title: Revenue Procedure 2003–39, Section 1031 LKE (Like-Kind Exchanges) Auto Leasing Programs.

Abstract: Revenue Procedure 2003–39 provides safe harbors for certain aspects of the qualification under Sec. 1031 of certain exchanges of property pursuant to Like-Kind Exchange (LKE) Programs for federal income tax purposes.

Estimated Total Annual Burden Hours: 8,600.

OMB Control Number: 1545–2018.

Type of Review: Extension without change of a currently approved collection.

Title: Revenue Procedure 2006–31, Revocation of Election filed under I.R.C. 83(b).

Abstract: This revenue procedure sets forth the procedures to be followed by individuals who wish to request permission to revoke the election they made under Internal Revenue Code section 83(b).

Estimated Total Annual Burden Hours: 400.

OMB Control Number: 1545–2240.

Type of Review: Extension without change of a currently approved collection.

Title: Form 14145—IRS Applicant Contact Information.

Abstract: Form 14145 is used by the IRS Recruitment Office to collect contact information from individuals who may be interested in working for the IRS now, or at any time in the future (potential applicants).

Estimated Total Annual Burden Hours: 66,085.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–06824 Filed 3–24–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Proposed Information Collection (Alternate Signer Certification (VA Form 21–0972)); Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including new collections, and allow 60 days for public comment in response to the notice.

VA Form 21–0972 will be used to collect the alternate signer information necessary for VA to accept benefit application forms signed by individuals on behalf of Veterans and claimants. The information collected will be used to contact the alternate signer for verification purposes.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before May 24, 2016.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900—NEW (Alternate Signer Certification)'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Alternate Signer Certification (VA Form 21–0972).

OMB Control Number: 2900—NEW.

Type of Review: New collection.

Abstract: VA Form 21–0972 will be used to collect the alternate signer information necessary for VA to accept benefit application forms signed by individuals on behalf of Veterans and

claimants. The information collected will be used to contact the alternate signer for verification purposes.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,250 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 5,000.

By direction of the Secretary.

Kathleen M. Manwell,

Program Analyst, VA Privacy Service, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–06735 Filed 3–24–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0495]

Proposed Information Collection (Marital Status Questionnaire, VA Form 21P–0537); Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before May 24, 2016.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0495'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Marital Status Questionnaire, VA Form 21P–0537.

OMB Control Number: 2900–0495.

Type of Review: Revision of an approved collection.

Abstract: VA Form 21P–0537 is used to verify a surviving spouse's current marital status to determine his or her continuing entitlement to Dependency and Indemnity Compensation (DIC) benefits. The form letter is automatically generated and mailed to DIC beneficiaries. Agency action depends on the information provided by the beneficiary. If the information provided supports the beneficiary's continued entitlement to benefits, no action is taken. If the information provided by the beneficiary does not support continued entitlement to benefits, VA will take action to terminate benefit payments, based on the facts found.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,484 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 17,808.

By direction of the Secretary.

Kathleen M. Manwell,

Program Analyst, VA Privacy Service, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–06734 Filed 3–24–16; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 81 Friday,

No. 58 March 25, 2016

Book 2 of 3 Books

Pages 16285–16890

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

Occupational Exposure to Respirable Crystalline Silica; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–2010–0034]

RIN 1218–AB70

Occupational Exposure to Respirable Crystalline Silica

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is amending its existing standards for occupational exposure to respirable crystalline silica. OSHA has determined that employees exposed to respirable crystalline silica at the previous permissible exposure limits face a significant risk of material impairment to their health. The evidence in the record for this rulemaking indicates that workers exposed to respirable crystalline silica are at increased risk of developing silicosis and other non-malignant respiratory diseases, lung cancer, and kidney disease. This final rule establishes a new permissible exposure limit of 50 micrograms of respirable crystalline silica per cubic meter of air (50 μg/m^3) as an 8-hour time-weighted average in all industries covered by the rule. It also includes other provisions to protect employees, such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping.

OSHA is issuing two separate standards—one for general industry and maritime, and the other for construction—in order to tailor requirements to the circumstances found in these sectors.

DATES: The final rule is effective on June 23, 2016. Start-up dates for specific provisions are set in § 1910.1053(l) for general industry and maritime and in § 1926.1153(k) for construction.

Collections of Information

There are a number of collections of information contained in this final rule (see Section VIII, Paperwork Reduction Act). Notwithstanding the general date of applicability that applies to all other requirements contained in the final rule, affected parties do not have to comply with the collections of information until the Department of Labor publishes a separate notice in the **Federal Register** announcing the Office of Management and Budget has approved them under the Paperwork Reduction Act.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), the Agency designates Ann Rosenthal, Associate Solicitor of Labor for Occupational Safety and Health, Office of the Solicitor of Labor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, to receive petitions for review of the final rule.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Frank Meilinger, Director, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email *meilinger.francis2@dol.gov.*

For technical inquiries, contact William Perry or David O'Connor, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1950.

SUPPLEMENTARY INFORMATION: The preamble to the rule on occupational exposure to respirable crystalline silica follows this outline:

Citation Method

In the docket for the respirable crystalline silica rulemaking, found at *http://www.regulations.gov*, every submission was assigned a document identification (ID) number that consists of the docket number (OSHA–2010–0034) followed by an additional four-digit number. For example, the document ID number for OSHA's Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis is OSHA–2010–0034–1720. Some document ID numbers include one or more attachments, such as the National Institute for Occupational Safety and Health (NIOSH) prehearing submission (*see* Document ID OSHA 2010–0034–2177).

When citing exhibits in the docket, OSHA includes the term ''Document ID'' followed by the last four digits of the document ID number, the attachment number or other attachment identifier, if applicable, page numbers (designated ''p.'' or ''Tr.'' for pages from a hearing transcript), and in a limited number of cases a footnote number (designated ''Fn''). In a citation that contains two or more document ID numbers, the document ID numbers are separated by semi-colons. For example, a citation referring to the NIOSH prehearing comments and NIOSH testimony obtained from the hearing transcript would be indicated as follows: (Document ID 2177, Attachment B, pp. 2–3; 3579, Tr. 132). In some sections, such as Section V, Health Effects, author names and year of study publication are included before the document ID number in a citation, for example: (Hughes *et al.*, 2001, Document ID 1060; McDonald et al., 2001, 1091; McDonald *et al.*, 2005, 1092; Rando *et al.*, 2001, 0415).

I. Executive Summary

This final rule establishes a permissible exposure limit (PEL) for respirable crystalline silica of 50 μg/m^3 as an 8-hour time-weighted average (TWA) in all industries covered by the rule. In addition to the PEL, the rule includes provisions to protect employees such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping. OSHA is issuing two separate standards—one for general industry and maritime, and the other for construction—in order to tailor requirements to the circumstances found in these sectors. There are, however, numerous common elements in the two standards.

The final rule is based on the requirements of the Occupational Safety and Health Act (OSH Act) and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act, OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so. *See* Section II, Pertinent Legal Authority, for a full discussion of OSH Act legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. OSHA has also developed estimates of the risk of silica-related diseases, assuming exposure over a working lifetime, at the preceding PELs as well as at the revised PEL and action level. Comments received on OSHA's preliminary analysis, and the Agency's final findings, are discussed in Section V, Health Effects, and Section VI, Final Quantitative Risk Assessment and Significance of Risk. OSHA finds that employees exposed to respirable crystalline silica at the preceding PELs are at an increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also result in increased risk of death from other nonmalignant respiratory diseases including chronic obstructive pulmonary disease (COPD), and from kidney disease. OSHA further concludes that exposure to respirable crystalline silica constitutes a significant risk of material impairment to health and that the final rule will substantially lower that risk. The Agency considers the level of risk remaining at the new PEL to be significant. However, based on the evidence evaluated during the rulemaking process, OSHA has determined a PEL of 50 μg/m^3 is appropriate because it is the lowest level feasible for all affected industries.

OSHA's examination of the technological and economic feasibility of the rule is presented in the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA), and is summarized in Section VII of this preamble. OSHA concludes that the PEL of 50 μg/m^3 is technologically feasible for most operations in all affected industries, although it will be a technological challenge for several affected sectors and will require the use of respirators for a limited number of job categories and tasks.

OSHA developed quantitative estimates of the compliance costs of the rule for each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide a screening analysis of the economic feasibility of complying with the rule and an evaluation of the economic impacts. Industries with unusually high costs as a percentage of revenues or profits were further analyzed for possible economic feasibility issues. After performing these analyses, OSHA finds that compliance with the requirements of the rule is economically feasible in every affected industry sector.

The final rule includes several major changes from the proposed rule as a result of OSHA's analysis of comments and evidence received during the comment periods and public hearings. The major changes are summarized below and are fully discussed in Section XV, Summary and Explanation of the Standards.

Scope. As proposed, the standards covered all occupational exposures to respirable crystalline silica with the exception of agricultural operations covered under 29 CFR part 1928. OSHA has made a final determination to exclude exposures in general industry and maritime where the employer has objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 μg/m^3 as an 8-hour TWA under any foreseeable conditions. OSHA is also excluding exposures in construction where employee exposure to respirable crystalline silica will remain below 25 μg/m^3 as an 8-hour TWA under any foreseeable conditions. In addition, OSHA is excluding exposures that result from the processing of sorptive clays from the scope of the rule. The standard for general industry and maritime also allows employers to comply with the standard for construction in certain circumstances.

Specified Exposure Control Methods. OSHA has revised the structure of the standard for construction to emphasize the specified exposure control methods for construction tasks that are presented in Table 1 of the standard. Unlike in the proposed rule, employers who fully and properly implement the controls listed on Table 1 are not separately required to comply with the PEL, and are not subject to provisions for exposure assessment and methods of compliance. The entries on Table 1 have also been revised extensively.

Protective Clothing. The proposed rule would have required use of protective clothing in certain limited situations. The final rule does not include requirements for use of protective clothing to address exposure to respirable crystalline silica.

Housekeeping. The proposed rule would have prohibited use of compressed air, dry sweeping, and dry brushing to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL. The final rule allows for use of compressed air, dry sweeping, and dry brushing in certain limited situations.

Written Exposure Control Plan. OSHA did not propose a requirement for employers to develop a written exposure control plan. The final rule includes a requirement for employers covered by the rule to develop a written exposure control plan, and the standard for construction includes a provision for a competent person (*i.e.*, a designated individual who is capable of identifying crystalline silica hazards in the workplace and who possesses the authority to take corrective measures to address them) to implement the written exposure control plan.

Regulated Areas. OSHA proposed to provide employers covered by the rule with the alternative of either establishing a regulated area or an access control plan to limit access to areas where exposure to respirable crystalline silica exceeds the PEL. The final standard for general industry and maritime requires employers to establish a regulated area in such circumstances. The final standard for construction does not include a provision for regulated areas, but includes a requirement that the written exposure control plan include procedures used to restrict access to work areas, when necessary, to minimize the numbers of employees exposed to respirable crystalline silica and their level of exposure. The access control plan alternative is not included in the final rule.

Medical Surveillance. The proposed rule would have required employers to make medical surveillance available to employees exposed to respirable crystalline silica above the PEL for 30 or more days per year. The final standard for general industry and maritime requires that medical surveillance be made available to employees exposed to respirable crystalline silica at or above the action level of 25 μg/m^3 as an 8-hour TWA for 30 or more days per year. The final standard for construction requires that medical surveillance be made available to employees who are required by the standard to use respirators for 30 or more days per year.

The rule requires the employer to obtain a written medical opinion from physicians or other licensed health care professionals (PLHCPs) for medical

examinations provided under the rule but limits the information provided to the employer to the date of the examination, a statement that the examination has met the requirements of the standard, and any recommended limitations on the employee's use of respirators. The proposed rule would have required that such opinions contain additional information, without requiring employee authorization, such as any recommended limitations upon the employee's exposure to respirable crystalline silica, and any referral to a specialist. In the final rule, the written opinion provided to the employer will only include recommended limitations on the employee's exposure to respirable crystalline silica and referral to a specialist if the employee provides written authorization. The final rule requires a separate written medical report provided to the employee to include this additional information, as well as detailed information related to the employee's health.

Dates. OSHA proposed identical requirements for both standards: an effective date 60 days after publication of the rule; a date for compliance with all provisions except engineering controls and laboratory requirements of 180 days after the effective date; a date for compliance with engineering controls requirements, which was one year after the effective date; and a date for compliance with laboratory requirements of two years after the effective date.

OSHA has revised the proposed compliance dates in both standards. The final rule is effective 90 days after publication. For general industry and maritime, all obligations for compliance commence two years after the effective date, with two exceptions: The obligation for engineering controls commences five years after the effective date for hydraulic fracturing operations in the oil and gas industry; and the obligation for employers in general industry and maritime to offer medical surveillance commences two years after the effective date for employees exposed above the PEL, and four years after the effective date for employees exposed at or above the action level. For construction, all obligations for compliance commence one year after the effective date, with the exception that certain requirements for laboratory analysis commence two years after the effective date.

Under the OSH Act's legal standard directing OSHA to set health standards based on findings of significant risk of material impairment and technological and economic feasibility, OSHA does not use cost-benefit analysis to determine the PEL or other aspects of the rule. It does, however, determine and analyze costs and benefits for its own informational purposes and to meet certain Executive Order requirements, as discussed in Section VII. Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis and in the FEA. Table I–1—which is derived from material presented in Section VII of this preamble—provides a summary of OSHA's best estimate of the costs and benefits of the rule using a discount rate of 3 percent. As shown, the rule is estimated to prevent 642 fatalities and 918 moderate-to-severe silicosis cases annually once it is fully effective, and the estimated cost of the rule is $1,030 million annually. Also as shown in Table I–1, the discounted monetized benefits of the rule are estimated to be $8.7 billion annually, and the rule is estimated to generate net benefits of approximately $7.7 billion annually.

Table I-1: Annualized Benefits, Costs and Net Benefits of OSHA's Final Silica Rule

Discount Rate		**3%**
Annualized Costs		
Engineering Controls (includes Abrasive Blasting)		$661,457,000
Respirators		$32,884,000
Exposure Assessment		$96,241,000
Medical Surveillance		$96,354,000
Familiarization and Training		$95,936,000
Regulated Area		$2,637,000
Written Exposure Control Plan		$44,273,000
Total Annualized Costs (point estimate)		**$1,029,782,000**
Annual Benefits: Number of Cases Prevented*		
Fatal Lung Cancers (midpoint estimate)	124	
Fatal Silicosis & other Non-Malignant Respiratory Diseases	325	
Fatal Renal Disease	193	
Silica-Related Mortality	642	$6,398,160,000
Silicosis Morbidity	918	$2,288,753,000
Monetized Annual Benefits (midpoint estimate)*		**$8,686,913,000**
Net Benefits*		**$7,657,131,000**

*Results are estimates based on assumptions outlined in in Section VII.G, Benefits and Net Benefits.

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Standards and Guidance

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act (29 U.S.C. 651 et seq.) (''the Act'' or ''the OSH Act''), is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources'' (29 U.S.C. 651(b)). To achieve this goal Congress authorized the Secretary of Labor (''the Secretary'') ''to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce'' (29 U.S.C. 651(b)(3); *see* 29 U.S.C. 654(a) (requiring employers to comply with OSHA standards), 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of the Act's enactment), and 655(b) (authorizing promulgation, modification or revocation of standards pursuant to notice and comment)). The primary statutory provision relied upon by the Agency in promulgating health standards is section 6(b)(5) of the Act; other sections of the OSH Act, however, authorize the Occupational Safety and Health Administration (OSHA) to require labeling and other appropriate forms of warning, exposure assessment, medical examinations, and recordkeeping in its standards (29 U.S.C. 655(b)(5), 655(b)(7), 657(c)).

The Act provides that in promulgating standards dealing with toxic materials or harmful physical agents, such as respirable crystalline silica, the Secretary shall set the standard which ''most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health . . . even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life'' (29 U.S.C. 655(b)(5)). Thus, ''[w]hen Congress passed the Occupational Safety and Health Act in 1970, it chose to place pre-eminent value on assuring employees a safe and healthful working environment, limited only by the feasibility of achieving such an environment'' (*American Textile Mfrs. Institute, Inc.* v. *Donovan,* 452 US 490, 541 (1981) (*''Cotton Dust''*)).

OSHA proposed this new standard for respirable crystalline silica and conducted its rulemaking pursuant to

section 6(b)(5) of the Act ((29 U.S.C. 655(b)(5)). The preceding silica standard, however, was adopted under the Secretary's authority in section 6(a) of the OSH Act (29 U.S.C. 655(a)), to adopt national consensus and established Federal standards within two years of the Act's enactment (see 29 CFR 1910.1000 Table Z–1). Any rule that ''differs substantially from an existing national consensus standard'' must ''better effectuate the purposes of this Act than the national consensus standard'' (29 U.S.C. 655(b)(8)). Several additional legal requirements arise from the statutory language in sections 3(8) and 6(b)(5) of the Act (29 U.S.C. 652(8), 655(b)(5)). The remainder of this section discusses these requirements, which OSHA must consider and meet before it may promulgate this occupational health standard regulating exposure to respirable crystalline silica.

Material Impairment of Health

Subject to the limitations discussed below, when setting standards regulating exposure to toxic materials or harmful physical agents, the Secretary is required to set health standards that ensure that ''no employee will suffer material impairment of health or functional capacity . . .'' (29 U.S.C. 655(b)(5)). OSHA has, under this section, considered medical conditions such as irritation of the skin, eyes, and respiratory system, asthma, and cancer to be material impairments of health. What constitutes material impairment in any given case is a policy determination on which OSHA is given substantial leeway. ''OSHA is not required to state with scientific certainty or precision the exact point at which each type of [harm] becomes a material impairment'' (*AFL–CIO* v. *OSHA,* 965 F.2d 962, 975 (11th Cir. 1992)). Courts have also noted that OSHA should consider all forms and degrees of material impairment—not just death or serious physical harm (*AFL–CIO,* 965 F.2d at 975). Thus the Agency has taken the position that ''subclinical'' health effects, which may be precursors to more serious disease, can be material impairments of health that OSHA should address when feasible (43 FR 52952, 52954 (11/14/78) (Preamble to the Lead Standard)).

Significant Risk

Section 3(8) of the Act requires that workplace safety and health standards be ''reasonably necessary or appropriate to provide safe or healthful employment'' (29 U.S.C. 652(8)). The Supreme Court, in its decision on OSHA's benzene standard, interpreted section 3(8) to mean that ''before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe'' (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.*, 448 U.S. 607, 642 (1980) (plurality opinion) (*''Benzene''*)). The Court further described OSHA's obligation as requiring it to evaluate ''whether significant risks are present and can be eliminated or lessened by a change in practices'' (*Benzene,* 448 U.S. at 642). The Court's holding is consistent with evidence in the legislative record, with regard to section 6(b)(5) of the Act (29 U.S.C. 655(b)(5)), that Congress intended the Agency to regulate unacceptably severe occupational hazards, and not ''to establish a utopia free from any hazards'' or to address risks comparable to those that exist in virtually any occupation or workplace (116 Cong. Rec. 37614 (1970), Leg. Hist. 480–82). It is also consistent with Section 6(g) of the OSH Act, which states that, in determining regulatory priorities, ''the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments'' (29 U.S.C. 655(g)).

The Supreme Court in *Benzene* clarified that OSHA has considerable latitude in defining significant risk and in determining the significance of any particular risk. The Court did not specify a means to distinguish significant from insignificant risks, but rather instructed OSHA to develop a reasonable approach to making its significant risk determination. The Court stated that ''[i]t is the Agency's responsibility to determine, in the first instance, what it considers to be a 'significant' risk'' (*Benzene*, 448 U.S. at 655), and it did not ''express any opinion on the . . . difficult question of what factual determinations would warrant a conclusion that significant risks are present which make promulgation of a new standard reasonably necessary or appropriate'' (*Benzene*, 448 U.S. at 659). The Court stated, however, that the section 6(f) (29 U.S.C. 655(b)(f)) substantial evidence standard applicable to OSHA's significant risk determination does not require the Agency ''to support its finding that a significant risk exists with anything approaching scientific certainty'' (*Benzene*, 448 U.S. at 656). Rather, OSHA may rely on ''a body of reputable scientific thought'' to which ''conservative assumptions in interpreting the data . . . '' may be applied, ''risking error on the side of overprotection'' (*Benzene*, 448 U.S. at 656; *see also United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall*, 647 F.2d 1189, 1248 (D.C. Cir. 1980) (''*Lead I*'') (noting the *Benzene* Court's application of this principle to carcinogens and applying it to the lead standard, which was not based on carcinogenic effects)). OSHA may thus act with a ''pronounced bias towards worker safety'' in making its risk determinations (*Bldg & Constr. Trades Dep't* v. *Brock*, 838 F.2d 1258, 1266 (D.C. Cir. 1988) (''*Asbestos II*'').

The Supreme Court further recognized that what constitutes ''significant risk'' is ''not a mathematical straitjacket'' (*Benzene*, 448 U.S. at 655) and will be ''based largely on policy considerations'' (*Benzene*, 448 U.S. at 655 n.62). The Court gave the following example:

> If . . . the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant . . . (*Benzene*, 448 U.S. at 655).

Following *Benzene*, OSHA has, in many of its health standards, considered the one-in-a-thousand metric when determining whether a significant risk exists. Moreover, as ''a prerequisite to more stringent regulation'' in all subsequent health standards, OSHA has, consistent with the *Benzene* plurality decision, based each standard on a finding of significant risk at the ''then prevailing standard'' of exposure to the relevant hazardous substance (*Asbestos II*, 838 F.2d at 1263). Once a significant risk of material impairment of health is demonstrated, it is of no import that the incidence of the illness may be declining (*see Nat'l Min. Assoc.* v. *Sec'y, U.S. Dep't of Labor*, Nos. 14–11942, 14–12163, slip op. at 80 (11th Cir. Jan. 25, 2016) (interpreting the Mine Act, 30 U.S.C. 811(a)(6)(A), which contains the same language as section 6(b)(5) of the OSH Act requiring the Secretary to set standards that assure no employee will suffer material impairment of health)).

The Agency's final risk assessment is derived from existing scientific and enforcement data and its final conclusions are made only after considering all evidence in the rulemaking record. Courts reviewing the validity of these standards have uniformly held the Secretary to the significant risk standard first articulated by the *Benzene* plurality and have generally upheld the Secretary's significant risk determinations as supported by substantial evidence and ''a reasoned explanation for his policy

assumptions and conclusions'' (*Asbestos II*, 838 F.2d at 1266).

Once OSHA makes its significant risk finding, the ''more stringent regulation'' (*Asbestos II*, 838 F.2d at 1263) it promulgates must be ''reasonably necessary or appropriate'' to reduce or eliminate that risk, within the meaning of section 3(8) of the Act (29 U.S.C. 652(8)) and *Benzene* (448 U.S. at 642) (*see Asbestos II*, 838 F.2d at 1269). The courts have interpreted section 6(b)(5) of the OSH Act as requiring OSHA to set the standard that eliminates or reduces risk to the lowest feasible level; as discussed below, the limits of technological and economic feasibility usually determine where the new standard is set (*see UAW* v. *Pendergrass*, 878 F.2d 389, 390 (D.C. Cir. 1989)). In choosing among regulatory alternatives, however, ''[t]he determination that [one standard] is appropriate, as opposed to a marginally [more or less protective] standard, is a technical decision entrusted to the expertise of the agency. . . '' (*Nat'l Mining Ass'n* v. *Mine Safety and Health Admin.*, 116 F.3d 520, 528 (D.C. Cir. 1997)) (analyzing a Mine Safety and Health Administration (''MSHA'') standard under the *Benzene* significant risk standard). In making its choice, OSHA may incorporate a margin of safety even if it theoretically regulates below the lower limit of significant risk (*Nat'l Mining Ass'n*, 116 F.3d at 528 (citing *American Petroleum Inst.* v. *Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1982))).

Working Life Assumption

The OSH Act requires OSHA to set the standard that most adequately protects employees against harmful workplace exposures for the period of their ''working life'' (29 U.S.C. 655(b)(5)). OSHA's longstanding policy is to define ''working life'' as constituting 45 years; thus, it assumes 45 years of exposure when evaluating the risk of material impairment to health caused by a toxic or hazardous substance. This policy is not based on empirical data that most employees are exposed to a particular hazard for 45 years. Instead, OSHA has adopted the practice to be consistent with the statutory directive that ''no employee'' suffer material impairment of health ''even if'' such employee is exposed to the hazard for the period of his or her working life (*see* 74 FR 44796 (8/31/09)). OSHA's policy was given judicial approval in a challenge to an OSHA standard that lowered the permissible exposure limit (PEL) for asbestos (*Asbestos II,* 838 F.2d at 1264–1265). In that case, the petitioners claimed that the median duration of employment in the affected industry sectors was only five years. Therefore, according to petitioners, OSHA erred in assuming a 45-year working life in calculating the risk of health effects caused by asbestos exposure. The D.C. Circuit disagreed, stating,

> Even if it is only the rare worker who stays with asbestos-related tasks for 45 years, that worker would face a 64/1000 excess risk of contracting cancer; Congress clearly authorized OSHA to protect such a worker (Asbestos II, 838 F.2d at 1264–1265).

OSHA might calculate the health risks of exposure, and the related benefits of lowering the exposure limit, based on an assumption of a shorter working life, such as 25 years, but such estimates are for informational purposes only.

Best Available Evidence

Section 6(b)(5) of the Act requires OSHA to set standards ''on the basis of the best available evidence'' and to consider the ''latest available scientific data in the field'' (29 U.S.C. 655(b)(5)). As noted above, the Supreme Court, in its Benzene decision, explained that OSHA must look to ''a body of reputable scientific thought'' in making its material harm and significant risk determinations, while noting that a reviewing court must ''give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge'' (*Benzene,* 448 U.S. at 656). The courts of appeals have afforded OSHA similar latitude to issue health standards in the face of scientific uncertainty. The Second Circuit, in upholding the vinyl chloride standard, stated:

> . . . the ultimate facts here in dispute are 'on the frontiers of scientific knowledge', and, though the factual finger points, it does not conclude. Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient (*Society of the Plastics Industry, Inc.* v. *OSHA,* 509 F.2d 1301, 1308 (2d Cir. 1975) (quoting *Indus. Union Dep't, AFL–CIO* v. *Hodgson,* 499 F.2d 467, 474 (D.C. Cir. 1974) (''*Asbestos I*'')).

The D.C. Circuit, in upholding the cotton dust standard, stated: ''OSHA's mandate necessarily requires it to act even if information is incomplete when the best available evidence indicates a serious threat to the health of workers'' (*Am. Fed'n of Labor & Cong. of Indus. Orgs.* v. *Marshall,* 617 F.2d 636, 651 (D.C. Cir. 1979), *aff'd in part and vacated in part on other grounds, American Textile Mfrs. Inst., Inc.* v. *Donovan,* 452 U.S. 490 (1981)).

When there is disputed scientific evidence, OSHA must review the evidence on both sides and ''reasonably resolve'' the dispute (*Pub. Citizen Health Research Grp.* v. *Tyson,* 796 F.2d 1479, 1500 (D.C. Cir. 1986)). In *Public Citizen,* there was disputed scientific evidence regarding whether there was a threshold exposure level for the health effects of ethylene oxide. The Court noted that, where ''OSHA has the expertise we lack and it has exercised that expertise by carefully reviewing the scientific data,'' a dispute within the scientific community is not occasion for it to take sides about which view is correct (*Pub. Citizen Health Research Grp.,* 796 F.2d at 1500). ''Indeed, Congress did 'not [intend] that the Secretary be paralyzed by debate surrounding diverse medical opinions' '' (*Pub. Citizen Health Research Grp.,* 796 F.2d at 1497 (quoting H.R.Rep. No. 91–1291, 91st Cong., 2d Sess. 18 (1970), reprinted in Legislative History of the Occupational Safety and Health Act of 1970 at 848 (1971))).

A recent decision by the Eleventh Circuit Court of Appeals upholding a coal dust standard promulgated by MSHA emphasized that courts should give ''an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise'' (*Nat'l Min. Assoc.* v. *Sec'y, U.S. Dep't of Labor,* Nos. 14–11942, 14–12163, slip op. at 43 (11th Cir. Jan. 25, 2016) (quoting *Kennecott Greens Creek Min.* Co. v. *MSHA,* 476 F.3d 946, 954–955 (D.C. Cir. 2007) (internal quotation marks omitted)). The Court emphasized that because the Mine Act, like the OSH Act, ''evinces a clear bias in favor of [ ] health and safety,'' the agency's responsibility to use the best evidence and consider feasibility should not be used as a counterweight to the agency's duty to protect the lives and health of workers (*Nat'l Min. Assoc.,* Nos. 14–11942, 14–12163, slip op. at 43 (11th Cir. Jan. 25, 2016)).

Feasibility

The OSH Act requires that, in setting a standard, OSHA must eliminate the risk of material health impairment ''to the extent feasible'' (29 U.S.C. 655(b)(5)). The statutory mandate to consider the feasibility of the standard encompasses both technological and economic feasibility; these analyses have been done primarily on an industry-by-industry basis (*Lead I,* 647 F.2d at 1264, 1301) in general industry. The Agency has also used application groups, defined by common tasks, as the structure for its feasibility analyses in construction (*Pub. Citizen Health Research Grp.* v. *OSHA,* 557 F.3d 165, 177–179 (3d Cir. 2009) (''*Chromium (VI)*''). The Supreme Court has broadly defined feasible as ''capable of being

done'' (*Cotton Dust,* 452 U.S. at 509–510).

Although OSHA must set the most protective PEL that the Agency finds to be technologically and economically feasible, it retains discretion to set a uniform PEL even when the evidence demonstrates that certain industries or operations could reasonably be expected to meet a lower PEL. OSHA health standards generally set a single PEL for all affected employers; OSHA exercised this discretion most recently in its final rule on occupational exposure to chromium (VI) (71 FR 10100, 10337–10338 (2/28/2006); *see also* 62 FR 1494, 1575 (1/10/97) (methylene chloride)). In its decision upholding the chromium (VI) standard, including the uniform PEL, the Court of Appeals for the Third Circuit addressed this issue as one of deference, stating ''OSHA's decision to select a uniform exposure limit is a legislative policy decision that we will uphold as long as it was reasonably drawn from the record'' (*Chromium (VI),* 557 F.3d at 183 (3d Cir. 2009)); *see also Am. Iron & Steel Inst.* v. *OSHA,* 577 F.2d 825, 833 (3d Cir. 1978)). OSHA's reasons for choosing one chromium (VI) PEL, rather than imposing different PELs on different application groups or industries, included: Multiple PELs would create enforcement and compliance problems because many workplaces, and even workers, were affected by multiple categories of chromium (VI) exposure; discerning individual PELs for different groups of establishments would impose a huge evidentiary burden on the Agency and unnecessarily delay implementation of the standard; and a uniform PEL would, by eliminating confusion and simplifying compliance, enhance worker protection (*Chromium (VI),* 557 F.3d at 173, 183–184). The Court held that OSHA's rationale for choosing a uniform PEL, despite evidence that some application groups or industries could meet a lower PEL, was reasonably drawn from the record and that the Agency's decision was within its discretion and supported by past practice (*Chromium (VI),* 557 F.3d at 183–184).

Technological Feasibility

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed (*Lead I,* 647 F.2d at 1272; *Amer. Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991) (''*Lead II*'')). While the test for technological feasibility is normally articulated in terms of the ability of employers to decrease exposures to the PEL, provisions such as exposure measurement requirements must also be technologically feasible (*Forging Indus. Ass'n* v. *Sec'y of Labor,* 773 F.2d 1436, 1453 (4th Cir. 1985)).

OSHA's standards may be ''technology forcing,'' *i.e.,* where the Agency gives an industry a reasonable amount of time to develop new technologies, OSHA is not bound by the ''technological status quo'' (*Lead I,* 647 F.2d at 1264); *see also Kennecott Greens Creek Min. Co.* v. *MSHA,* 476 F.3d 946, 957 (D.C. Cir. 2007) (MSHA standards, like OSHA standards, may be technology-forcing); *Nat'l Petrochemical & Refiners Ass'n* v. *EPA,* 287 F.3d 1130, 1136 (D.C. Cir. 2002) (agency is ''not obliged to provide detailed solutions to every engineering problem,'' but only to ''identify the major steps for improvement and give plausible reasons for its belief that the industry will be able to solve those problems in the time remaining.'').

In its *Lead* decisions, the D.C. Circuit described OSHA's obligation to demonstrate the technological feasibility of reducing occupational exposure to a hazardous substance.

> [W]ithin the limits of the best available evidence . . . OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations . . . The effect of such proof is to establish a presumption that industry can meet the PEL without relying on respirators . . . Insufficient proof of technological feasibility for a few isolated operations within an industry, or even OSHA's concession that respirators will be necessary in a few such operations, will not undermine this general presumption in favor of feasibility. Rather, in such operations firms will remain responsible for installing engineering and work practice controls to the extent feasible, and for using them to reduce . . . exposure as far as these controls can do so (*Lead I,* 647 F.2d at 1272).

Additionally, the D.C. Circuit explained that ''[f]easibility of compliance turns on whether exposure levels at or below [the PEL] can be met in most operations most of the time . . .'' (*Lead II,* 939 F.2d at 990).

Courts have given OSHA significant deference in reviewing its technological feasibility findings.

> So long as we require OSHA to show that any required means of compliance, even if it carries no guarantee of meeting the PEL, will substantially lower . . . exposure, we can uphold OSHA's determination that every firm must exploit all possible means to meet the standard (*Lead I,* 647 F.2d at 1273).

Even in the face of significant uncertainty about technological feasibility in a given industry, OSHA has been granted broad discretion in making its findings (*Lead I,* 647 F.2d at 1285).

> OSHA cannot let workers suffer while it awaits . . . scientific certainty. It can and must make reasonable [technological feasibility] predictions on the basis of 'credible sources of information,' whether data from existing plants or expert testimony (*Lead I,* 647 F.2d at 1266 (quoting *Am. Fed'n of Labor & Cong. of Indus. Orgs.,* 617 F.2d at 658)).

For example, in *Lead I,* the D.C. Circuit allowed OSHA to use, as best available evidence, information about new and expensive industrial smelting processes that had not yet been adopted in the U.S. and would require the rebuilding of plants (*Lead I,* 647 F.2d at 1283–1284). Even under circumstances where OSHA's feasibility findings were less certain and the Agency was relying on its ''legitimate policy of technology forcing,'' the D.C. Circuit approved of OSHA's feasibility findings when the Agency granted lengthy phase-in periods to allow particular industries time to comply (*Lead I,* 647 F.2d at 1279–1281, 1285).

OSHA is permitted to adopt a standard that some employers will not be able to meet some of the time, with employers limited to challenging feasibility at the enforcement stage (*Lead I,* 647 F.2d at 1273 & n. 125; *Asbestos II,* 838 F.2d at 1268). Even when the Agency recognized that it might have to balance its general feasibility findings with flexible enforcement of the standard in individual cases, the courts of appeals have generally upheld OSHA's technological feasibility findings (*Lead II,* 939 F.2d at 980; *see Lead I,* 647 F.2d at 1266–1273; *Asbestos II,* 838 F.2d at 1268). Flexible enforcement policies have been approved where there is variability in measurement of the regulated hazardous substance or where exposures can fluctuate uncontrollably (*Asbestos II,* 838 F.2d at 1267–1268; *Lead II,* 939 F.2d at 991). A common means of dealing with the measurement variability inherent in sampling and analysis is for the Agency to add the standard sampling error to its exposure measurements before determining whether to issue a citation (*e.g.,* 51 FR 22612, 22654 (06/20/86) (Preamble to the Asbestos Standard)).

Economic Feasibility

In addition to technological feasibility, OSHA is required to demonstrate that its standards are economically feasible. A reviewing court will examine the cost of compliance with an OSHA standard ''in relation to the financial health and

profitability of the industry and the likely effect of such costs on unit consumer prices . . .'' (*Lead I,* 647 F.2d at 1265 (omitting citation)). As articulated by the D.C. Circuit in *Lead I,*

> OSHA must construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms (*Lead I,* 647 F.2d at 1272).

A reasonable estimate entails assessing ''the likely range of costs and the likely effects of those costs on the industry'' (*Lead I,* 647 F.2d at 1266). As with OSHA's consideration of scientific data and control technology, however, the estimates need not be precise (*Cotton Dust,* 452 U.S. at 528–29 & n.54) as long as they are adequately explained. Thus, as the D.C. Circuit further explained:

> Standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely. Nor does the concept of economic feasibility necessarily guarantee the continued existence of individual employers. It would appear to be consistent with the purposes of the Act to envisage the economic demise of an employer who has lagged behind the rest of the industry in protecting the health and safety of employees and is consequently financially unable to comply with new standards as quickly as other employers. As the effect becomes more widespread within an industry, the problem of economic feasibility becomes more pressing (*Asbestos I,* 499 F.2d. at 478).

OSHA standards therefore satisfy the economic feasibility criterion even if they impose significant costs on regulated industries so long as they do not cause massive economic dislocations within a particular industry or imperil the very existence of the industry (*Lead II,* 939 F.2d at 980; *Lead I,* 647 F.2d at 1272; *Asbestos I,* 499 F.2d. at 478). As with its other legal findings, OSHA ''is not required to prove economic feasibility with certainty, but is required to use the best available evidence and to support its conclusions with substantial evidence'' (*Lead II,* 939 F.2d at 980–981) (citing *Lead I,* 647 F.2d at 1267)). Granting industries additional time to comply with new PELs may enhance the economic, as well as technological, feasibility of a standard (*Lead I,* 647 F.2d at 1265).

Because section 6(b)(5) of the Act explicitly imposes the ''to the extent feasible'' limitation on the setting of health standards, OSHA is not permitted to use cost-benefit analysis to make its standards-setting decisions (29 U.S.C. 655(b)(5)).

> Congress itself defined the basic relationship between costs and benefits, by placing the ''benefit'' of worker health above all other considerations save those making attainment of this ''benefit'' unachievable. Any standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in § 6(b)(5) (*Cotton Dust,* 452 U.S. at 509).

Thus, while OSHA estimates the costs and benefits of its proposed and final rules, these calculations do not form the basis for the Agency's regulatory decisions; rather, they are performed in acknowledgement of requirements such as those in Executive Orders 12866 and 13563.

Structure of OSHA Health Standards

OSHA's health standards traditionally incorporate a comprehensive approach to reducing occupational disease. OSHA substance-specific health standards generally include the ''hierarchy of controls,'' which, as a matter of OSHA's preferred policy, mandates that employers install and implement all feasible engineering and work practice controls before respirators may be used. The Agency's adherence to the hierarchy of controls has been upheld by the courts (*ASARCO, Inc.* v. *OSHA,* 746 F.2d 483, 496–498 (9th Cir. 1984); *Am. Iron & Steel Inst.* v. *OSHA,* 182 F.3d 1261, 1271 (11th Cir. 1999)). In fact, courts view the legal standard for proving technological feasibility as incorporating the hierarchy:

> OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations. . . . The effect of such proof is to establish a presumption that industry can meet the PEL without relying on respirators (*Lead I,* 647 F.2d at 1272).

The hierarchy of controls focuses on removing harmful materials at their source. OSHA allows employers to rely on respiratory protection to protect their employees only when engineering and work practice controls are insufficient or infeasible. In fact, in the control of ''those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors,'' the employers' primary objective ''shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section'' (29 CFR 1910.134).

The reasons supporting OSHA's continued reliance on the hierarchy of controls, as well as its reasons for limiting the use of respirators, are numerous and grounded in good industrial hygiene principles (see Section XV, Summary and Explanation of the Standards, Methods of Compliance). Courts have upheld OSHA's emphasis on engineering and work practice controls over personal protective equipment in challenges to previous health standards, such as chromium (VI): ''Nothing in . . . any case reviewing an airborne toxin standard, can be read to support a technological feasibility rule that would effectively encourage the routine and widespread use of respirators to comply with a PEL'' (*Chromium (VI),* 557 F.3d at 179; *see Am. Fed'n of Labor & Cong. of Indus. Orgs.* v. *Marshall,* 617 F.2d 636, 653 (D.C. Cir. 1979) *cert. granted, judgment vacated sub nom. Cotton Warehouse Ass'n* v. *Marshall,* 449 U.S. 809 (1980) and aff'd in part, vacated in part sub nom. *Am. Textile Mfrs. Inst., Inc.* v. *Donovan,* 452 U.S. 490 (1981) (finding ''uncontradicted testimony in the record that respirators can cause severe physical discomfort and create safety problems of their own'')).

In health standards such as this one, the hierarchy of controls is augmented by ancillary provisions. These provisions work with the hierarchy of controls and personal protective equipment requirements to provide comprehensive protection to employees in affected workplaces. Such provisions typically include exposure assessment, medical surveillance, hazard communication, and recordkeeping. This approach is recognized as effective in dealing with air contaminants such as respirable crystalline silica; for example, the industry standards for respirable crystalline silica, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, take a similar comprehensive approach (Document ID 1466; 1504).

The OSH Act compels OSHA to require all feasible measures for reducing significant health risks (29 U.S.C. 655(b)(5); *Pub. Citizen Health Research Grp.,* 796 F.2d at 1505 (''if in fact a STEL [short-term exposure limit] would further reduce a significant

health risk and is feasible to implement, then the OSH Act compels the agency to adopt it (barring alternative avenues to the same result)''). When there is significant risk below the PEL, as is the case with respirable crystalline silica, the DC Circuit indicated that OSHA should use its regulatory authority to impose additional requirements on employers when those requirements will result in a greater than de minimis incremental benefit to workers' health (*Asbestos II,* 838 F.2d at 1274). The Supreme Court alluded to a similar issue in *Benzene,* pointing out that ''in setting a permissible exposure level in reliance on less-than-perfect methods, OSHA would have the benefit of a backstop in the form of monitoring and medical testing'' (*Benzene,* 448 U.S. at 657). OSHA believes that the ancillary provisions in this final standard provide significant benefits to worker health by providing additional layers and types of protection to employees exposed to respirable crystalline silica.

Finally, while OSHA is bound by evidence in the rulemaking record, and generally looks to its prior standards for guidance on how to structure and specify requirements in a new standard, it is not limited to past approaches to regulation. In promulgating health standards, ''[w]henever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired'' (29 U.S.C. 655(b)(5)). In cases of industries or tasks presenting unique challenges in terms of assessing and controlling exposures, it may be more practicable and provide greater certainty to require specific controls with a demonstrated track record of efficacy in reducing exposures and, therefore, risk (especially when supplemented by appropriate respirator usage). Such an approach could more effectively protect workers than the traditional exposure assessment-and-control approach when exposures may vary because of factors such as changing environmental conditions or materials, and an assessment may not reflect typical exposures associated with a task or operation. As discussed at length in Section XV, Summary and Explanation of the Standards, the specified exposure control measures option in the construction standard (*i.e.,* Table 1, in paragraph (c)(1)) for respirable crystalline silica represents the type of innovative, objective approach available to the Secretary when fashioning a rule under these circumstances.

III. Events Leading to the Final Standards

The Occupational Safety and Health Administration's (OSHA's) previous standards for workplace exposure to respirable crystalline silica were adopted in 1971, pursuant to section 6(a) of the Occupational Safety and Health Act (29 U.S.C. 651 et seq.) (''the Act'' or ''the OSH Act'') (36 FR 10466 (5/29/71)). Section 6(a) (29 U.S.C. 655(a)) authorized OSHA, in the first two years after the effective date of the Act, to promulgate ''start-up'' standards, on an expedited basis and without public hearing or comment, based on national consensus or established Federal standards that improved employee safety or health. Pursuant to that authority, OSHA in 1971 promulgated approximately 425 permissible exposure limits (PELs) for air contaminants, including crystalline silica, which were derived principally from Federal standards applicable to government contractors under the Walsh-Healey Public Contracts Act, 41 U.S.C. 35, and the Contract Work Hours and Safety Standards Act (commonly known as the Construction Safety Act), 40 U.S.C. 333. The Walsh-Healey Act and Construction Safety Act standards had been adopted primarily from recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH).

For general industry (*see* 29 CFR 1910.1000, Table Z–3), the PEL for crystalline silica in the form of respirable quartz was based on two alternative formulas: (1) A particle-count formula, $PEL_{mppcf}=250/(\%\ quartz + 5)$ as respirable dust; and (2) a mass formula proposed by ACGIH in 1968, $PEL=(10\ mg/m^3)/(\%\ quartz + 2)$ as respirable dust. The general industry PELs for crystalline silica in the form of cristobalite and tridymite were one-half of the value calculated from either of the above two formulas for quartz. For construction (*see* 29 CFR 1926.55, Appendix A) and shipyards (see 29 CFR 1915.1000, Table Z), the formula for the PEL for crystalline silica in the form of quartz ($PEL_{mppcf}=250/(\%\ quartz + 5)$ as respirable dust), which requires particle counting, was derived from the 1970 ACGIH threshold limit value (TLV).[1] Based on the formulas, the PELs for quartz, expressed as time-weighted averages (TWAs), were approximately equivalent to 100 $\mu g/m^3$ for general industry and 250 $\mu g/m^3$ for construction and shipyards. The PELs were not supplemented by additional protective provisions—such as medical surveillance requirements—as are included in other OSHA standards. OSHA believes that the formula based on particle-counting technology used in the general industry, construction, and shipyard PELs has been rendered obsolete by respirable mass (gravimetric) sampling.

In 1974, the National Institute for Occupational Safety and Health (NIOSH), an agency within the Department of Health and Human Services created by the OSH Act and designed to carry out research and recommend standards for occupational safety and health hazards, evaluated crystalline silica as a workplace hazard and issued criteria for a recommended standard (29 U.S.C. 669, 671; Document ID 0388). NIOSH recommended that occupational exposure to crystalline silica be controlled so that no worker is exposed to a TWA of free (respirable crystalline) silica greater than 50 $\mu g/m^3$ as determined by a full-shift sample for up to a 10-hour workday over a 40-hour workweek. The document also recommended a number of ancillary provisions for a standard, such as exposure monitoring and medical surveillance.

In December 1974, OSHA published an Advance Notice of Proposed Rulemaking (ANPRM) based on the recommendations in the NIOSH criteria document (39 FR 44771 (12/27/74)). In the ANPRM, OSHA solicited ''public participation on the issues of whether a new standard for crystalline silica should be issued on the basis of the [NIOSH] criteria or any other information, and, if so, what should be the contents of a proposed standard for crystalline silica'' (39 FR at 44771). OSHA also set forth the particular issues of concern on which comments were requested. The Agency did not issue a proposed rule or pursue a final rule for crystalline silica at that time.

As information on the health effects of silica exposure developed during the 1980s and 1990s, national and international classification organizations came to recognize crystalline silica as a human carcinogen. In June 1986, the International Agency for Research on Cancer (IARC), which is the specialized cancer agency within the World Health Organization, evaluated the available evidence regarding crystalline silica carcinogenicity and concluded, in 1987, that crystalline silica is probably carcinogenic to

[1] The Mineral Dusts tables that contain the silica PELs for construction and shipyards do not clearly express PELs for cristobalite and tridymite. 29 CFR 1926.55; 29 CFR 1915.1000. This lack of textual clarity likely results from a transcription error in the Code of Federal Regulations. OSHA's final rule provides the same PEL for quartz, cristobalite, and tridymite in general industry, maritime, and construction.

humans (*http://monographs.iarc.fr/ENG/Monographs/suppl7/Suppl7.pdf*). An IARC working group met again in October 1996 to evaluate the complete body of research, including research that had been conducted since the initial 1986 evaluation. IARC concluded, more decisively this time, that ''crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans'' (Document ID 2258, Attachment 8, p. 211). In 2012, IARC reaffirmed that ''Crystalline silica in the form of quartz or cristobalite dust is carcinogenic to humans'' (Document ID 1473, p. 396).

In 1991, in the Sixth Annual Report on Carcinogens, the U.S. National Toxicology Program (NTP), within the U.S. Department of Health and Human Services, concluded that respirable crystalline silica was ''reasonably anticipated to be a human carcinogen'' (as referenced in Document ID 1417, p. 1). NTP reevaluated the available evidence and concluded, in the Ninth Report on Carcinogens, that ''respirable crystalline silica (RCS), primarily quartz dust occurring in industrial and occupational settings, is known to be a human carcinogen, based on sufficient evidence of carcinogenicity from studies in humans indicating a causal relationship between exposure to RCS and increased lung cancer rates in workers exposed to crystalline silica dust'' (Document ID 1417, p. 1). ACGIH listed respirable crystalline silica (in the form of quartz) as a suspected human carcinogen in 2000, while lowering the TLV to 0.05 mg/m_3 (50 $\mu g/m_3$) (Document ID 1503, p. 15). ACGIH subsequently lowered the TLV for crystalline silica to 0.025 mg/m_3 (25 $\mu g/m_3$) in 2006, which is ACGIH's current recommended exposure limit (Document ID 1503, pp. 1, 15).

In 1989, OSHA established 8-hour TWA PELs of 0.1 mg/m_3 (100 $\mu g/m_3$) for quartz and 0.05 mg/m_3 (50 $\mu g/m_3$) for cristobalite and tridymite, as part of the Air Contaminants final rule for general industry (54 FR 2332 (1/19/89)). OSHA stated that these limits presented no substantial change from the Agency's former formula limits, but would simplify sampling procedures. In providing comments on the proposed rule, NIOSH recommended that crystalline silica be considered a potential carcinogen.

In 1992, OSHA, as part of the Air Contaminants proposed rule for maritime, construction, and agriculture, proposed the same PELs as for general industry, to make the PELs consistent across all the OSHA-regulated sectors (57 FR 26002 (6/12/92)). However, the U.S. Court of Appeals for the Eleventh Circuit vacated the 1989 Air Contaminants final rule for general industry (*Am. Fed'n of Labor and Cong. of Indus. Orgs.* v. *OSHA,* 965 F.2d 962 (1992)), and also mooted the proposed rule for maritime, construction, and agriculture. The Court's decision to vacate the rule forced the Agency to return to the original 1971 PELs for all compounds, including silica, adopted as section 6(a) standards.

In 1994, OSHA initiated a process to determine which safety and health hazards in the U.S. needed the most attention. A priority planning committee included safety and health experts from OSHA, NIOSH, and the Mine Safety and Health Administration (MSHA). The committee reviewed available information on occupational deaths, injuries, and illnesses and communicated extensively with representatives of labor, industry, professional and academic organizations, the States, voluntary standards organizations, and the public. The OSHA National Advisory Committee on Occupational Safety and Health and the Advisory Committee on Construction Safety and Health (ACCSH) also made recommendations. Rulemaking for crystalline silica exposure was one of the priorities designated by this process. OSHA indicated that crystalline silica would be added to the Agency's regulatory agenda as other standards were completed and resources became available.

In 1996, OSHA instituted a Special Emphasis Program (SEP) to step up enforcement of the crystalline silica standards. The SEP was intended to reduce worker silica dust exposures that can cause silicosis and lung cancer. It included extensive outreach designed to educate and train employers and employees about the hazards of silica and how to control them, as well as inspections to enforce the standards. Among the outreach materials available were slides presenting information on hazard recognition and crystalline silica control technology, a video on crystalline silica and silicosis, and informational cards for workers explaining crystalline silica, health effects related to exposure, and methods of control. The SEP provided guidance for targeting inspections of worksites that had employees at risk of developing silicosis. The inspections resulted in the collection of exposure data from the various worksites visited by OSHA's compliance officers.

As a follow-up to the SEP, OSHA undertook numerous non-regulatory actions to address silica exposures. For example, in October of 1996, OSHA launched a joint silicosis prevention effort with MSHA, NIOSH, and the American Lung Association (*see https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=14110*). This public education campaign involved distribution of materials on how to prevent silicosis, including a guide for working safely with silica and stickers for hard hats to remind workers of crystalline silica hazards. Spanish language versions of these materials were also made available. OSHA and MSHA inspectors distributed materials at mines, construction sites, and other affected workplaces. The joint silicosis prevention effort included a National Conference to Eliminate Silicosis in Washington, DC, in March of 1997, which brought together approximately 650 participants from labor, business, government, and the health and safety professions to exchange ideas and share solutions regarding the goal of eliminating silicosis (*see https://industrydocuments.library.ucsf.edu/documentstore/s/h/d/p//shdp0052/shdp0052.pdf*).

In 1997, OSHA announced in its Unified Agenda under Long-Term Actions that it planned to publish a proposed rule on crystalline silica

> . . . because the agency has concluded that there will be no significant progress in the prevention of silica-related diseases without the adoption of a full and comprehensive silica standard, including provisions for product substitution, engineering controls, training and education, respiratory protection and medical screening and surveillance. A full standard will improve worker protection, ensure adequate prevention programs, and further reduce silica-related diseases (62 FR 57755, 57758 (10/29/97)).

In November 1998, OSHA moved ''Occupational Exposure to Crystalline Silica'' to the pre-rule stage in the Regulatory Plan (63 FR 61284, 61303–61304 (11/9/98)). OSHA held a series of stakeholder meetings in 1999 and 2000 to get input on the rulemaking. Stakeholder meetings for all industry sectors were held in Washington, Chicago, and San Francisco. A separate stakeholder meeting for the construction sector was held in Atlanta.

OSHA initiated Small Business Regulatory Enforcement Fairness Act (SBREFA) proceedings in 2003, seeking the advice of small business representatives on the proposed rule (68 FR 30583, 30584 (5/27/03)). The SBREFA panel, including representatives from OSHA, the Small Business Administration's Office of Advocacy, and the Office of Management and Budget (OMB), was

convened on October 20, 2003. The panel conferred with small entity representatives (SERs) from general industry, maritime, and construction on November 10 and 12, 2003, and delivered its final report, which included comments from the SERs and recommendations to OSHA for the proposed rule, to OSHA's Assistant Secretary on December 19, 2003 (Document ID 0937).

In 2003, OSHA examined enforcement data for the years 1997 to 2002 and identified high rates of noncompliance with the OSHA respirable crystalline silica PELs, particularly in construction. This period covers the first five years of the SEP. These enforcement data, presented in Table III–1, indicate that 24 percent of silica samples from the construction industry and 13 percent from general industry were at least three times the then-existing OSHA PELs. The data indicate that 66 percent of the silica samples obtained during inspections in general industry were in compliance with the PEL, while only 58 percent of the samples collected in construction were in compliance.

Table III-1 Time-Weighted Average (TWA) Exposures to Respirable Crystalline Silica Samples for Construction and General Industry (January 1, 1997 –December 31, 2002)

Exposure (severity relative to the PEL)	Construction		Other than construction	
	No. of samples	Percent	No. of samples	Percent
<1 PEL	424	58%	2226	66%
1 x PEL to < 2 x PEL	86	12%	469	14%
2 x PEL to < 3 x PEL	48	6%	215	6%
≥ 3 x PEL and higher(3+)	180	24%	453	13%
Total # of samples	738		3363	

Source: OSHA Integrated Management Information System.

In an effort to expand the 1996 SEP, on January 24, 2008, OSHA implemented a National Emphasis Program (NEP) to identify and reduce or eliminate the health hazards associated with occupational exposure to crystalline silica (CPL–03–007 (1/24/08)). The NEP targeted worksites with elevated exposures to crystalline silica and included new program evaluation procedures designed to ensure that the goals of the NEP were measured as accurately as possible, detailed procedures for conducting inspections, updated information for selecting sites for inspection, development of outreach programs by each Regional and Area Office emphasizing the formation of voluntary partnerships to share information, and guidance on calculating PELs in construction and shipyards. In each OSHA Region, at least two percent of inspections every year are silica-related inspections. Additionally, the silica-related inspections are conducted at a range of facilities reasonably representing the distribution of general industry and construction work sites in that region.

A more recent analysis of OSHA enforcement data from January 2003 to December 2009 (covering the period of continued implementation of the SEP and the first two years of the NEP) shows that considerable noncompliance with the then-existing PELs continued to occur. These enforcement data, presented in Table III–2, indicate that 14 percent of silica samples from the construction industry and 19 percent for general industry were at least three times the OSHA PEL during this period. The data indicate that 70 percent of the silica samples obtained during inspections in general industry were in compliance with the PEL, and 75 percent of the samples collected in construction were in compliance.

Table III-2 Time-Weighted Average (TWA) Exposures to Respirable Crystalline Silica Samples for Construction and General Industry (January 1, 2003 –December 31, 2009)

Exposure (severity relative to the PEL)	Construction		Other than construction	
	No. of samples	Percent	No. of samples	Percent
<1 PEL	548	75%	948	70%
1 x PEL to < 2 x PEL	49	7%	107	8%
2 x PEL to < 3 x PEL	32	4%	46	3%
≥ 3 x PEL and higher(3+)	103	14%	254	19%
Total # of samples	732		1355	

Source: OSHA Integrated Management Information System

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, ASTM International (originally known as the American Society for Testing and Materials) has published voluntary consensus standards for addressing the hazards of crystalline silica, and the Building and Construction Trades Department, AFL–CIO also has recommended a comprehensive program standard. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance. The National Industrial Sand Association has also developed an occupational exposure program for crystalline silica that addresses exposure assessment and medical surveillance.

Throughout the crystalline silica rulemaking process, OSHA has presented information to, and consulted with, ACCSH and the Maritime Advisory Committee on Occupational Safety and Health. In December of 2009, OSHA representatives met with ACCSH to discuss the rulemaking and receive their comments and recommendations. On December 11, 2009, ACCSH passed motions supporting the concept of Table 1 in the draft proposed construction rule, recognizing that the controls listed in Table 1 are effective. As discussed with regard to paragraph (f) of the proposed standard for construction (paragraph (c) of the final standard for construction), Table 1 presents specified control measures for selected construction tasks. ACCSH also recommended that OSHA maintain the protective clothing provision found in the SBREFA panel draft regulatory text and restore the ''competent person'' requirement and responsibilities to the proposed rule. Additionally, the group recommended that OSHA move forward expeditiously with the rulemaking process.

In January 2010, OSHA completed a peer review of the draft Health Effects Analysis and Preliminary Quantitative Risk Assessment following procedures set forth by OMB in the Final Information Quality Bulletin for Peer Review, published on the OMB Web site on December 16, 2004 (*see* 70 FR 2664 (1/14/05)). Each peer reviewer submitted a written report to OSHA. The Agency revised its draft documents as appropriate and made the revised documents available to the public as part of its Notice of Proposed Rulemaking (NPRM). OSHA also made the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' reports, and the Agency's response to the peer reviewers' reports publicly available with publication of the proposed rule (Document ID 1711; 1716). Five of the seven original peer reviewers submitted post-hearing reports, commenting on OSHA's disposition of their original peer review comments in the proposed rule, as well as commenting on written and oral testimony presented at the silica hearing (Document ID 3574).

On August 23, 2013, OSHA posted its NPRM for respirable crystalline silica on its Web site and requested comments on the proposed rule. On September 12, 2013, OSHA published the NPRM in the **Federal Register** (78 FR 56273 (9/12/13)). In the NPRM, the Agency made a preliminary determination that employees exposed to respirable crystalline silica at the current PELs face a significant risk to their health and that promulgating the proposed standards would substantially reduce that risk. The NPRM required commenters to submit their comments by December 11, 2013. In response to stakeholder requests, OSHA extended the comment period until January 27, 2014 (78 FR 65242 (10/31/13)). On January 14, 2014, OSHA held a web chat to provide small businesses and other stakeholders an additional opportunity to obtain information from the Agency about the proposed rule. Subsequently, OSHA further extended the comment period to February 11, 2014 (79 FR 4641 (1/29/14)).

As part of the instructions for submitting comments, OSHA requested (but did not require) that parties submitting technical or scientific studies or research results and those submitting comments or testimony on the Agency's analyses disclose the nature of financial relationships with (*e.g.,* consulting agreement), and extent of review by, parties interested in or

affected by the rulemaking (78 FR 56274). Parties submitting studies or research results were also asked to disclose sources of funding and sponsorship for their research. OSHA intended for the disclosure of such information to promote the transparency and scientific integrity of evidence submitted to the record and stated that the request was consistent with Executive Order 13563.

The Agency received several comments related to this request. For example, an industrial hygiene engineer supported the disclosure of potential conflict of interest information (Document ID 2278, p. 5). Other commenters, such as congressional representatives and industry associations, opposed the request, asserting that it could lead to prejudgment or questioning of integrity, in addition to dissuading participation in the rulemaking; some also questioned the legality of such a request or OSHA's interpretation of Executive Order 13563 (*e.g.,* Document ID 1811, p. 2; 2101, pp. 2–3). A number of stakeholders from academia and industry submitted information related to the request for funding, sponsorships, and review by interested parties (*e.g.,* Document ID 1766, p. 1; 2004, p. 2; 2211, p. 2; 2195, p. 17). OSHA emphasizes that it reviewed and considered all evidence submitted to the record.

An informal public hearing on the proposed standards was held in Washington, DC from March 18 through April 4, 2014. Administrative Law Judges Daniel F. Solomon and Stephen L. Purcell presided over the hearing. The Agency heard testimony from over 200 stakeholders representing more than 70 organizations, such as public health groups, trade associations, and labor unions. Chief Administrative Law Judge Stephen L. Purcell closed the public hearing on April 4, 2014, allowing 45 days—until May 19, 2014—for participants who filed a notice of intention to appear at the hearings to submit additional evidence and data, and an additional 45 days—until July 3, 2014—to submit final briefs, arguments, and summations (Document ID 3589, Tr. 4415–4416). After the hearing concluded, OSHA extended the deadline to give those participants who filed a notice of intention to appear at the hearings until June 3, 2014 to submit additional information and data to the record, and until July 18, 2014 to submit final briefs and arguments (Document ID 3569). Based upon requests from stakeholders, the second deadline was extended, and parties who filed a notice of intention to appear at the hearing were given until August 18, 2014, to submit their final briefs and arguments (Document ID 4192).

OSHA provided the public with multiple opportunities to participate in the rulemaking process, including stakeholder meetings, the SBREFA panel, two comment periods (pre- and post-hearing), and a 14-day public hearing. Commenters were provided more than five months to comment on the rule before the hearing, and nearly as long to submit additional information, final briefs, and arguments after the hearing. OSHA received more than 2,000 comments on the silica NPRM during the entire pre-and post-hearing public participation period. In OSHA's view, therefore, the public was given sufficient opportunities and ample time to fully participate in this rulemaking.

The final rule on occupational exposure to respirable crystalline silica is based on consideration of the entire record of this rulemaking proceeding, including materials discussed or relied upon in the proposal, the record of the hearing, and all written comments and exhibits timely received. Thus, in promulgating this final rule, OSHA considered all comments in the record, including those that suggested that OSHA withdraw its proposal and merely enforce the existing silica standards, as well as those that argued the proposed rule was not protective enough. Based on this comprehensive record, OSHA concludes that employees exposed to respirable crystalline silica are at significant risk of developing silicosis and other non-malignant respiratory disease, lung cancer, kidney effects, and immune system effects. The Agency concludes that the PEL of 50 $\mu g/m^3$ reduces the significant risks of material impairments of health posed to workers by occupational exposure to respirable crystalline silica to the maximum extent that is technologically and economically feasible. OSHA's substantive determinations with regard to the comments, testimony, and other information in the record, the legal standards governing the decision-making process, and the Agency's analysis of the data resulting in its assessments of risks, benefits, technological and economic feasibility, and compliance costs are discussed elsewhere in this preamble.

IV. Chemical Properties and Industrial Uses

Silica is a compound composed of the elements silicon and oxygen (chemical formula SiO_2). Silica has a molecular weight of 60.08, and exists in crystalline and amorphous states, both in the natural environment and as produced during manufacturing or other processes. These substances are odorless solids, have no vapor pressure, and create non-explosive dusts when particles are suspended in air (Document ID 3637, pp. 1–3).

Silica is classified as part of the ''silicate'' class of minerals, which includes compounds that are composed of silicon and oxygen and which may also be bonded to metal ions or their oxides. The basic structural units of silicates are silicon tetrahedrons (SiO_4), pyramidal structures with four triangular sides where a silicon atom is located in the center of the structure and an oxygen atom is located at each of the four corners. When silica tetrahedrons bond exclusively with other silica tetrahedrons, each oxygen atom is bonded to the silicon atom of its original ion, as well as to the silicon atom from another silica ion. This results in a ratio of one atom of silicon to two atoms of oxygen, expressed as SiO_2. The silicon-oxygen bonds within the tetrahedrons use only one-half of each oxygen's total bonding energy. This leaves negatively charged oxygen ions available to bond with available positively charged ions. When they bond with metal and metal oxides, commonly of iron, magnesium, aluminum, sodium, potassium, and calcium, they form the silicate minerals commonly found in nature (Document ID 1334, p. 7).

In crystalline silica, the silicon and oxygen atoms are arranged in a three-dimensional repeating pattern. Silica is said to be polymorphic, as different forms are created when the silica tetrahedrons combine in different crystalline structures. The primary forms of crystalline silica are quartz, cristobalite, and tridymite. In an amorphous state, silicon and oxygen atoms are present in the same proportions but are not organized in a repeating pattern. Amorphous silica includes natural and manufactured glasses (vitreous and fused silica, quartz glass), biogenic silica, and opals, which are amorphous silica hydrates (Document ID 2258, Attachment 8, pp. 45–50).

Quartz is the most common form of crystalline silica and accounts for almost 12% by volume of the earth's crust. Alpha quartz, the quartz form that is stable below 573 °C, is the most prevalent form of crystalline silica found in the workplace. It accounts for the overwhelming majority of naturally found silica and is present in varying amounts in almost every type of mineral. Alpha quartz is found in igneous, sedimentary, and metamorphic rock, and all soils contain at least a trace amount of quartz (Document ID 1334, p.

9). Alpha quartz is used in many products throughout various industries and is a common component of building materials (Document ID 1334, pp. 11–15). Common trade names for commercially available quartz include: CSQZ, DQ 12, Min-U-Sil, Sil-Co-Sil, Snowit, Sykron F300, and Sykron F600 (Document ID 2258, Attachment 8, p. 43).

Cristobalite is a form of crystalline silica that is formed at high temperatures (≤1470 °C). Although naturally occurring cristobalite is relatively rare, volcanic eruptions, such as Mount St. Helens, can release cristobalite dust into the air. Cristobalite can also be created during some processes conducted in the workplace. For example, flux-calcined diatomaceous earth is a material used as a filtering aid and as a filler in other products (Document ID 2258, Attachment 8, p. 44). It is produced when diatomaceous earth (diatomite), a geological product of decayed unicellular organisms called diatoms, is heated with flux. The finished product can contain between 40 and 60 percent cristobalite. Also, high temperature furnaces are often lined with bricks that contain quartz. When subjected to prolonged high temperatures, this quartz can convert to cristobalite.

Tridymite is another material formed at high temperatures (≤870 °C) that is associated with volcanic activity. The creation of tridymite requires the presence of a flux such as sodium oxide. Tridymite is rarely found in nature and rarely reported in the workplace (Document ID 1424 pp. 5, 14).

When heated or cooled sufficiently, crystalline silica can transition between the polymorphic forms, with specific transitions occurring at different temperatures. At higher temperatures the linkages between the silica tetrahedrons break and reform, resulting in new crystalline structures. Quartz converts to cristobalite at 1470 °C, and at 1723 °C cristobalite loses its crystalline structure and becomes amorphous fused silica. These high temperature transitions reverse themselves at extremely slow rates, with different forms co-existing for a long time after the crystal cools (Document ID 2258, Attachment 8, p. 47).

Other types of transitions occur at lower temperatures when the silica-oxygen bonds in the silica tetrahedron rotate or stretch, resulting in a new crystalline structure. These low-temperature, or alpha to beta, transitions are readily and rapidly reversed as the crystal cools. At temperatures encountered by workers, only the alpha form of crystalline silica exists (Document ID 2258, Attachment 8, pp. 46–48).

Crystalline silica minerals produce distinct X-ray diffraction patterns, specific to their crystalline structure. The patterns can be used to distinguish the crystalline polymorphs from each other and from amorphous silica (Document ID 2258, Attachment 8, p. 45).

The specific gravity and melting point of silica vary between polymorphs. Silica is insoluble in water at 20 °C and in most acids, but its solubility increases with higher temperatures and pH, and it dissolves readily in hydrofluoric acid. Solubility is also affected by the presence of trace metals and by particle size. Under humid conditions water vapor in the air reacts with the surface of silica particles to form an external layer of silinols (SiOH). When these silinols are present the crystalline silica becomes more hydrophilic. Heating or acid washing reduces the amount of silinols on the surface area of crystalline silica particles. There is an external amorphous layer found in aged quartz, called the Beilby layer, which is not found on freshly cut quartz. This amorphous layer is more water soluble than the underlying crystalline core. Etching with hydrofluoric acid removes the Beilby layer as well as the principal metal impurities on quartz (Document ID 2258, Attachment 8, pp. 44–49).

Crystalline silica has limited chemical reactivity. It reacts with alkaline aqueous solutions, but does not readily react with most acids, with the exception of hydrofluoric acid. In contrast, amorphous silica and most silicates react with most mineral acids and alkaline solutions. Analytical chemists relied on this difference in acid reactivity to develop the silica point count analytical method that was widely used prior to the current X-ray diffraction and infrared methods (Document ID 2258, Attachment 8, pp. 48–51; 1355, p. 994).

Crystalline silica is used in industry in a wide variety of applications. Sand and gravel are used in road building and concrete construction. Sand with greater than 98% silica is used in the manufacture of glass and ceramics. Silica sand is used to form molds for metal castings in foundries, and in abrasive blasting operations. Silica is also used as a filler in plastics, rubber, and paint, and as an abrasive in soaps and scouring cleansers. Silica sand is used to filter impurities from municipal water and sewage treatment plants, and in hydraulic fracturing for oil and gas recovery (Document ID 1334, p. 11). Silica is also used to manufacture artificial stone products used as bathroom and kitchen countertops, and the silica content in those products can exceed 85 percent (Document ID 1477, pp. 3 and 11; 2178, Attachment 5, p. 420).

There are over 30 major industries and operations where exposures to crystalline silica can occur. They include such diverse workplaces as foundries, dental laboratories, concrete products and paint and coating manufacture, as well as construction activities including masonry cutting, drilling, grinding and tuckpointing, and use of heavy equipment during demolition activities involving silica-containing materials. A more detailed discussion of the industries affected by the proposed standard is presented in Section VII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis. Crystalline silica exposures can also occur in mining (which is under the jurisdiction of the Mine Safety and Health Administration), and in agriculture during plowing and harvesting.

V. Health Effects

A. Introduction

As discussed more thoroughly in Section II of this preamble, Pertinent Legal Authority, section 6(b)(5) of the Occupational Safety and Health Act (OSH Act or Act) requires the Secretary of Labor, in promulgating standards dealing with toxic materials or harmful physical agents, to ''set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life'' (29 U.S.C. 655). Thus, in order to set a new health standard, the Secretary must determine that there is a significant risk of material impairment of health at the existing PEL and that issuance of a new standard will significantly reduce or eliminate that risk.

The Secretary's significant risk and material impairment determinations must be made ''on the basis of the best available evidence'' (29 U.S.C. 655(b)(5)). Although the Supreme Court, in its decision on OSHA's Benzene standard, explained that OSHA must look to ''a body of reputable scientific thought'' in making its material harm and significant risk determinations, the Court added that a reviewing court must ''give OSHA some leeway where its findings must be made on the frontiers

of scientific knowledge'' (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607, 656 (1980) (plurality opinion) (''*Benzene*'')). Thus, while OSHA's significant risk determination must be supported by substantial evidence, the Agency ''is not required to support the finding that a significant risk exists with anything approaching scientific certainty'' (*Benzene*, 448 U.S. at 656).

This section provides an overview of OSHA's material harm and significant risk determinations: (1) Summarizing OSHA's preliminary methods and findings from the proposal; (2) addressing public comments dealing with OSHA's evaluation of the scientific literature and methods used to estimate quantitative risk; and (3) presenting OSHA's final conclusions, with consideration of the rulemaking record, on the health effects and quantitative risk estimates associated with worker exposure to respirable crystalline silica. The quantitative risk estimates and significance of those risks are then discussed in detail in Section VI, Final Quantitative Risk Assessment and Significance of Risk.

B. Summary of Health and Risk Findings

As discussed in detail throughout this section and in Section VI, Final Quantitative Risk Assessment and Significance of Risk, OSHA finds, based upon the best available evidence in the published, peer-reviewed scientific literature, that exposure to respirable crystalline silica increases the risk of silicosis, lung cancer, other non-malignant respiratory disease (NMRD), and renal and autoimmune effects. In its Preliminary Quantitative Risk Assessment (QRA), OSHA used the best available exposure-response data from epidemiological studies to estimate quantitative risks. After carefully reviewing stakeholder comments on the Preliminary QRA and new information provided to the rulemaking record, OSHA finds there to be a clearly significant risk at the previous PELs for respirable crystalline silica (equivalent to approximately 100 μg/m^3 for general industry and between 250 and 500 μg/m^3 for construction/shipyards), with excess lifetime risk estimates for lung cancer mortality, silicosis mortality, and NMRD mortality each being much greater than 1 death per 1,000 workers exposed for a working life of 45 years. Cumulative risk estimates for silicosis morbidity are also well above 1 case per 1,000 workers exposed at the previous PELs. At the revised PEL of 50 μg/m^3 respirable crystalline silica, these estimated risks are substantially reduced. Thus, OSHA concludes that the new PEL of 50 μg/m^3 provides a large reduction in the lifetime and cumulative risk posed to workers exposed to respirable crystalline silica.

These findings and conclusions are consistent with those of the World Health Organization's International Agency for Research on Cancer (IARC), the U.S. Department of Health and Human Services' (HHS) National Toxicology Program (NTP), the National Institute for Occupational Safety and Health (NIOSH), and many other organizations and individuals, as evidenced in the rulemaking record and further discussed below. Many other scientific organizations and governments have recognized the strong body of scientific evidence pointing to the health risks of respirable crystalline silica and have deemed it necessary to take action to reduce those risks. As far back as 1974, NIOSH recommended that the exposure limit for crystalline silica be reduced to 50 μg/m^3 (Document ID 2177b, p. 2). In 2000, the American Conference of Governmental Industrial Hygienists (ACGIH), a professional society that has recommended workplace exposure limits for six decades, revised their Threshold Limit Value (TLV) for respirable crystalline silica to 50 μg/m^3 and has since further lowered its TLV for respirable crystalline silica to 25 μg/m^3. OSHA is setting its revised PEL at 50 μg/m^3 based on consideration of the body of evidence describing the health risks of crystalline silica as well as on technological feasibility considerations, as discussed in Section VII of this preamble and Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA).

To reach these conclusions, OSHA performed an extensive search and review of the peer-reviewed scientific literature on the health effects of inhalation exposure to crystalline silica, particularly silicosis, lung cancer, other NMRD, and renal and autoimmune effects (Document ID 1711, pp. 7–265). Based upon this review, OSHA preliminarily determined that there was substantial evidence that exposure to respirable crystalline silica increases the risk of silicosis, lung cancer, NMRD, and renal and autoimmune effects (Document ID 1711, pp. 164, 181–208, 229). OSHA also found there to be suitable exposure-response data from many well-conducted epidemiological studies that permitted the Agency to estimate quantitative risks for lung cancer mortality, silicosis and NMRD mortality, renal disease mortality, and silicosis morbidity (Document ID 1711, p. 266).

As part of the preliminary quantitative risk assessment, OSHA calculated estimates of the risk of silica-related diseases assuming exposure over a working life (45 years) to 25, 50, 100, 250, and 500 μg/m^3 respirable crystalline silica (corresponding to cumulative exposures over 45 years to 1.125, 2.25, 4.5, 11.25, and 22.5 mg/m^3-yrs) (*see Bldg & Constr. Trades Dep't* v. *Brock*, 838 F.2d 1258, 1264–65 (D.C. Cir. 1988) approving OSHA's policy of using 45 years for the working life of an employee in setting a toxic substance standard). To estimate lifetime excess mortality risks at these exposure levels, OSHA used, for each key study, the exposure-response risk model(s) and regression coefficient from the model(s) in a life table analysis that accounted for competing causes of death due to background causes and cumulated risk through age 85 (Document ID 1711, pp. 360–378). For these analyses, OSHA used lung cancer, NMRD, or renal disease mortality and all-cause mortality rates to account for background risks and competing risks (U.S. 2006 data for lung cancer and NMRD mortality in all males, 1998 data for renal disease mortality, obtained from cause-specific death rate tables published by the National Center for Health Statistics (2009, Document ID 1104)). The mortality risk estimates were presented in terms of lifetime excess risk per 1,000 workers for exposure over an 8-hour working day, 250 days per year, and a 45-year working lifetime. For silicosis morbidity, OSHA based its risk estimates on the cumulative risk model(s) used in each study to develop quantitative exposure-response relationships. These models characterized the risk of developing silicosis, as detected by chest radiography, up to the time that cohort members, including both active and retired workers, were last examined (78 FR 56273, 56312 (9/12/13)).

OSHA then combined its review of the health effects literature and preliminary quantitative risk assessment into a draft document, entitled ''Occupational Exposure to Respirable Crystalline Silica—Review of Health Effects Literature and Preliminary Quantitative Risk Assessment,'' and submitted it to a panel of scientific experts [2] for independent peer review,

[2] OSHA's contractor, Eastern Research Group, Inc. (ERG), conducted a search for nationally recognized experts in occupational epidemiology, biostatistics and risk assessment, animal and cellular toxicology, and occupational medicine who had no actual or apparent conflict of interest. ERG chose seven of the applicants to be peer reviewers based on their qualifications and the necessity of ensuring a broad and diverse panel in terms of scientific and

in accordance with the Office of Management and Budget's (OMB) ''Final Information Quality Bulletin for Peer Review'' (Document ID 1336). The peer reviewers reviewed OSHA's draft Review of Health Effects Literature and Preliminary QRA. The peer-review panel responded to nearly 20 charge questions from OSHA and commented on various aspects of OSHA's analysis (Document ID 1716).

Overall, the peer reviewers found that OSHA was very thorough in its review of the literature and was reasonable in its interpretation of the studies with regards to the various endpoints examined, such that the Agency's conclusions on health effects were generally well founded (Document ID 1711, p. 381). The reviewers had various comments on OSHA's draft Preliminary QRA (Document ID 1716, pp. 107–218). OSHA provided a response to each comment in the Review of Health Effects Literature and Preliminary QRA and, where appropriate, made revisions (Document ID 1711, pp. 381–399). The Agency then placed the Review of Health Effects Literature and Preliminary QRA into the rulemaking docket as a background document (Document ID 1711). With the publication of the Notice of Proposed Rulemaking (78 FR 56723 on 9/12/13), all aspects of the Review of Health Effects Literature and Preliminary QRA were open for public comment.

Following the publication of the proposed rule (78 FR 56273 (9/12/13)) and accompanying revised Review of Health Effects Literature and Preliminary QRA (Document ID 1711), the peer reviewers were invited to review the revised analysis, examine the written comments in the docket, and attend the public hearing to listen to oral testimony as it applied to the health effects and quantitative risk assessment. Five peer reviewers were available and attended. In their final comments, provided to OSHA following the hearings, all five peer reviewers indicated that OSHA had adequately addressed their original comments (Document ID 3574). The peer reviewers also offered additional comments on concerns raised during the hearing. Many of the reviewers commented on the difficulty of evaluating exposure-response thresholds, and responded to public comments regarding causation and other specific issues (Document ID 3574). OSHA has incorporated many of the peer reviewers' additional comments into its risk assessment discussion in the preamble. Thus, OSHA believes that the external, independent peer-review process supports and lends legitimacy to its risk assessment methods and findings.

OSHA also received substantial public comment and testimony from a wide variety of stakeholders supporting its Review of Health Effects Literature and Preliminary QRA. In general, supportive comments and testimony were received from NIOSH (Document ID 2177; 3998; 4233), the public health and medical community, labor unions, affected workers, private citizens, and others.

Regarding health effects, NIOSH commented that the adverse health effects of exposure to respirable crystalline silica are ''well-known, long lasting, and preventable'' (Document ID 2177b, p. 2). Darius Sivin, Ph.D., of the UAW, commented, ''[o]ccupational exposure to silica has been recognized for centuries as a serious workplace hazard'' (Document ID 2282, Attachment 3, p. 4). Similarly, David Goldsmith, Ph.D., testified:

> There have been literally thousands of research studies on exposure to crystalline silica in the past 30 years. Almost every study tells the occupational research community that workers need better protection to prevent severe chronic respiratory diseases, including lung cancer and other diseases in the future. What OSHA is proposing to do in revising the workplace standard for silica seems to be a rational response to the accumulation of published evidence (Document ID 3577, Tr. 865–866).

Franklin Mirer, Ph.D., CIH, Professor of Environmental and Occupational Health at CUNY School of Public Health, on behalf of the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), reiterated that silica ''is a clear and present danger to workers health at exposure levels prevailing now in a large number of industries. Workers are at significant risk for mortality and illnesses including lung cancer and non-malignant respiratory disease including COPD, and silicosis'' (Document ID 2256, Attachment 3, p. 3). The AFL–CIO also noted that there is ''overwhelming evidence in the record that exposure to respirable crystalline silica poses a significant health risk to workers'' (Document ID 4204, p. 11). The Building and Construction Trades Department, AFL–CIO, further commented that the rulemaking record ''clearly supports OSHA's risk determination'' (Document ID 4223, p. 2). Likewise, the Sorptive Minerals Institute, a national trade association, commented, ''It is beyond dispute that OSHA has correctly determined that industrial exposure to certain types of silica can cause extremely serious, sometimes even fatal disease. In the massive rulemaking docket being compiled by the Agency, credible claims to the contrary are sparse to non-existent'' (Document ID 4230, p. 8). OSHA also received numerous comments supportive of the revised standard from affected workers and citizens (*e.g.,* Document ID 1724, 1726, 1731, 1752, 1756, 1759, 1762, 1764, 1787, 1798, 1800, 1802).

Regarding OSHA's literature review for its quantitative risk assessment, the American Public Health Association (APHA) and the National Consumers League (NCL) commented, ''OSHA has thoroughly reviewed and evaluated the peer-reviewed literature on the health effects associated with exposure to respirable crystalline silica. OSHA's quantitative risk assessment is sound. The agency has relied on the best available evidence and acted appropriately in giving greater weight to those studies with the most robust designs and statistical analyses'' (Document ID 2178, Attachment 1, p. 1; 2373, p. 1).

Dr. Mirer, who has served on several National Academy of Sciences committees setting risk assessment guidelines, further commented that OSHA's risk analysis is ''scientifically correct, and consistent with the latest thinking on risk assessment,'' (Document ID 2256, Attachment 3, p. 3), citing the National Academies' National Research Council's *Science and Decisions: Advancing Risk Assessment* (Document ID 4052), which makes technical recommendations on risk assessment and risk-based decision making (Document ID 3578, Tr. 935–936). In post-hearing comments expanding on this testimony, the AFL–CIO also noted that OSHA's risk assessment methodologies are transparent and consistent with practices recommended by the National Research Council in its publication, *Risk Assessment in the Federal Government: Managing the Process,* and with the Environmental Protection Agency's *Guidelines for Carcinogenic Risk Assessment* (Document ID 4204, p. 20). Similarly, Kyle Steenland, Ph.D., Professor in the Department of Environmental Health at Rollins School of Public Health, Emory University, one of the researchers on whose studies OSHA relied, testified that ''OSHA has

technical expertise (*see* Document ID 1711, pp. 379–381). The seven peer reviewers were: Bruce Allen, Bruce Allen Consulting; Kenneth Crump, Ph.D., Louisiana Tech University Foundation; Murray Finkelstein, MD, Ph.D., McMaster University, Ontario; Gary Ginsberg, Ph.D., Connecticut Department of Public Health; Brian Miller, Ph.D., Institute of Occupational Medicine (IOM) Consulting Ltd., Scotland; Andrew Salmon, Ph.D., private consultant; and Noah Seixas, Ph.D., University of Washington, Seattle (Document ID 1711, p. 380).

done a very capable job in conducting the summary of the literature and doing its own risk assessment'' (Document ID 3580, Tr. 1235). Collectively, these comments and testimony support OSHA's use of the best available evidence and methods to estimate quantitative risks of lung cancer mortality, silicosis and NMRD mortality, renal disease mortality, and silicosis morbidity from exposure to respirable crystalline silica.

Based on OSHA's Preliminary QRA, many commenters recognized that reducing the permissible exposure limit is necessary to reduce significant risks presented by exposure to respirable crystalline silica (Document ID 4204, pp. 11–12; 2080, p. 1; 2339, p. 2). For example, the AFL–CIO stated that ''OSHA based its proposal on more than adequate evidence, but more recent publications have described further the risk posed by silica exposure, and further justify the need for new silica standards'' (Document ID 4204, pp. 11–12). Similarly, the American Society of Safety Engineers (ASSE) remarked that ''[w]hile some may debate the science underlying the findings set forth in the proposed rule, overexposure to crystalline silica has been linked to occupational illness since the time of the ancient Greeks, and reduction of the current permissible exposure limit (PEL) to that recommended for years by the National Institute for Occupational Safety and Health (NIOSH) is long overdue'' (Document ID 2339, p. 2).

Not every commenter agreed, however, as OSHA also received critical comments and testimony from various employers and their representatives, as well as some organizations representing affected industries. In general, these comments were critical of the underlying studies on which OSHA relied for its quantitative risk assessment, or with the methods used by OSHA to estimate quantitative risks. Some commenters also presented additional studies for OSHA to consider. OSHA thoroughly reviewed these and did not find them adequate to alter OSHA's overall conclusions of health risk, as discussed in great detail in the sections that follow.

After considering the evidence and testimony in the record, as discussed below, OSHA affirms its approach to quantify health risks related to exposure to respirable crystalline silica and the Agency's preliminary conclusions. In the final risk assessment that is now presented as part of this final rule in Section VI, Final Quantitative Risk Assessment and Significance of Risk, OSHA concludes that there is a clearly significant risk at the previous PELs for respirable crystalline silica, with excess lifetime risk estimates for lung cancer mortality, silicosis mortality, and NMRD mortality each being much greater than 1 death per 1,000 workers as a result of exposure for 45 working years (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk). At the revised PEL of 50 $\mu g/m^3$ respirable crystalline silica, OSHA finds the estimated risks to be substantially reduced. Cumulative risk estimates for silicosis morbidity are also well above 1 case per 1,000 workers at the previous PELs, with a substantial reduction at the revised PEL (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1).

The health effects associated with silica exposure are well-established and supported by the record. Based on the record evidence, OSHA concludes that exposure to respirable crystalline silica causes silicosis and is the only known cause of silicosis. This causal relationship has long been accepted in the scientific and medical communities. In fact, the Department of Labor produced a video in 1938 featuring then Secretary of Labor Frances Perkins discussing the occurrence of silicosis among workers exposed to silica (*see https://www.osha.gov/silica/index.html*). Silicosis is a progressive disease induced by the inflammatory effects of respirable crystalline silica in the lung, which leads to lung damage and scarring and, in some cases, progresses to complications resulting in disability and death (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk). OSHA used a weight-of-evidence approach to evaluate the scientific studies in the literature to determine their overall quality and whether there is substantial evidence that exposure to respirable crystalline silica increases the risk of a particular health effect.

For lung cancer, OSHA reviewed the published, peer-reviewed scientific literature, including 60 epidemiological studies covering more than 30 occupational groups in over a dozen industrial sectors (*see* Document ID 1711, pp. 77–170). Based on this comprehensive review, and after considering the rulemaking record as a whole, OSHA concludes that the data provide ample evidence that exposure to respirable crystalline silica increases the risk of lung cancer among workers (*see* Document ID 1711, p. 164). OSHA's conclusion is consistent with that of IARC, which is the specialized cancer agency that is part of the World Health Organization and utilizes interdisciplinary (*e.g.,* biostatistics, epidemiology, and laboratory sciences) experts to comprehensively identify the causes of cancer. In 1997, IARC classified respirable crystalline silica dust, in the form of quartz or cristobalite, as Group 1, *i.e.,* ''carcinogenic to humans,'' following a thorough expert committee review of the peer-reviewed scientific literature (Document ID 2258, Attachment 8, p. 211). OSHA notes that IARC classifications and accompanying monographs are well recognized in the scientific community, having been described as ''the most comprehensive and respected collection of systematically evaluated agents in the field of cancer epidemiology'' (Demetriou *et al.,* 2012, Document ID 4131, p. 1273). For silica, IARC's overall finding was based on studies of nine occupational cohorts that it considered to be the least influenced by confounding factors (*see* Document ID 1711, p. 76). OSHA included these studies in its review, in addition to several other studies (Document ID 1711, pp. 77–170).

Since IARC's 1997 determination that respirable crystalline silica is a Group 1 carcinogen, the scientific community has reaffirmed the soundness of this finding. In March of 2009, 27 scientists from eight countries participated in an additional IARC review of the scientific literature and reaffirmed that respirable crystalline silica dust is a Group 1 human carcinogen (Document ID 1473, p. 396). Additionally, in 2000, the NTP, which is a widely-respected interagency program under HHS that evaluates chemicals for possible toxic effects on public health, also concluded that respirable crystalline silica is a known human carcinogen (Document ID 1164, p. 1).

For NMRD other than silicosis, based on its review of several studies and all subsequent record evidence, OSHA concludes that exposure to respirable crystalline silica increases the risk of emphysema, chronic bronchitis, and pulmonary function impairment (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, pp. 181–208). For renal disease, OSHA reviewed the epidemiological literature and finds that a number of epidemiological studies reported statistically significant associations between occupational exposure to silica dust and chronic renal disease, subclinical renal changes, end-stage renal disease morbidity, chronic renal disease mortality, and granulomatosis with polyangitis (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 228). For autoimmune effects, OSHA reviewed

epidemiological information in the record suggesting an association between respirable crystalline silica exposure and increased risk of systemic autoimmune diseases, including scleroderma, rheumatoid arthritis, and systemic lupus erythematosus (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 229). Therefore, OSHA concludes that there is substantial evidence that silica exposure increases the risks of renal and of autoimmune disease (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 229).

OSHA also finds there to be suitable exposure-response data from many well-conducted studies that permit the Agency to estimate quantitative risks for lung cancer mortality, silicosis and NMRD mortality, renal disease mortality, and silicosis morbidity (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 266). OSHA believes the exposure-response data in these studies collectively represent the best available evidence for use in estimating the quantitative risks related to silica exposure. For lung cancer mortality, OSHA relies upon a number of published studies that analyzed exposure-response relationships between respirable crystalline silica and lung cancer. These included studies of cohorts from several industry sectors: Diatomaceous earth workers (Rice *et al.,* 2001, Document ID 1118), Vermont granite workers (Attfield and Costello, 2004, Document ID 0285), North American industrial sand workers (Hughes *et al.,* 2001, Document ID 1060), and British coal miners (Miller and MacCalman, 2009, Document ID 1306). These studies are scientifically sound due to their sufficient size and adequate years of follow-up, sufficient quantitative exposure data, lack of serious confounding by exposure to other occupational carcinogens, consideration (for the most part) of potential confounding by smoking, and absence of any apparent selection bias (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 165). They all demonstrated positive, statistically significant exposure-response relationships between exposure to crystalline silica and lung cancer mortality. Also compelling was a pooled analysis (Steenland *et al.,* 2001a, Document ID 0452) of 10 occupational cohorts (with a total of 65,980 workers and 1,072 lung cancer deaths), which was also used as a basis for IARC's 2009 reaffirmation of respirable crystalline silica as a human carcinogen. This analysis by Steenland *et al.* found an overall positive exposure-response relationship between cumulative exposure to crystalline silica and lung cancer mortality (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, pp. 269–292). Based on these studies, OSHA estimates that the lifetime lung cancer mortality excess risk associated with 45 years of exposure to respirable crystalline silica ranges from 11 to 54 deaths per 1,000 workers at the previous general industry PEL of 100 μg/m^3 respirable crystalline silica, and 5 to 23 deaths per 1,000 workers at the revised PEL of 50 μg/m^3 respirable crystalline silica (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1). These estimates exceed by a substantial margin the one in a thousand benchmark that OSHA has generally applied to its health standards following the Supreme Court's *Benzene* decision (448 U.S. 607, 655 (1980)).

For silicosis and NMRD mortality, OSHA relies upon two published, peer-reviewed studies: A pooled analysis of silicosis mortality data from six epidemiological studies (Mannetje *et al.,* 2002b, Document ID 1089), and an exposure-response analysis of NMRD mortality among diatomaceous earth workers (Park *et al,* 2002, Document ID 0405) (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 292). The pooled analysis had a total of 18,634 subjects, 150 silicosis deaths, and 20 deaths from unspecified pneumoconiosis, and demonstrated an increasing mortality rate with silica exposure (Mannetje *et al.,* 2002b, Document ID 1089; *see also* 1711, pp. 292–295). To estimate the risks of silicosis mortality, OSHA used the model described by Mannetje *et al.* but used rate ratios that were estimated from a sensitivity analysis conducted by ToxaChemica, Inc. that was expected to better control for age and exposure measurement uncertainty (2004, Document ID 0469; 1711, p. 295). OSHA's estimate of lifetime silicosis mortality risk is 11 deaths per 1,000 workers at the previous general industry PEL, and 7 deaths per 1,000 workers at the revised PEL (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1).

The NMRD analysis by Park *et al.* (2002, Document 0405) included pneumoconiosis (including silicosis), chronic bronchitis, and emphysema, since silicosis is a cause of death that is often misclassified as emphysema or chronic bronchitis (*see* Document ID 1711, p. 295). Positive exposure-response relationships were found between exposure to crystalline silica and excess risk for NMRD mortality (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, pp. 204–206, 295–297). OSHA's estimate of excess lifetime NMRD mortality risk, calculated using the results from Park *et al.,* is 85 deaths per 1,000 workers at the previous general industry PEL of 100 μg/m^3 respirable crystalline silica, and 44 deaths per 1,000 workers at the revised PEL (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1).[3]

For renal disease mortality, Steenland *et al.* (2002a, Document ID 0448) conducted a pooled analysis of three cohorts (with a total of 13,382 workers) that found a positive exposure-response relationship for both multiple-cause mortality (*i.e.,* any mention of renal disease on the death certificate) and underlying cause mortality. OSHA used the Steenland *et al.* (2002a, Document ID 0448) pooled analysis to estimate risks, given its large number of workers from cohorts with sufficient exposure data (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, pp. 314–315). OSHA's analysis for renal disease mortality shows estimated lifetime excess risk of 39 deaths per 1,000 workers at the previous general industry PEL of 100 μg/m^3 respirable crystalline silica, and 32 deaths per 1,000 workers exposed at the revised PEL of 50 μg/m^3 (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1). OSHA acknowledges, however, that there are considerably less data for renal disease mortality, and thus the findings based on them are less robust than those for silicosis, lung cancer, and NMRD mortality (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 229). For autoimmune disease, there were no quantitative exposure-response data available for a quantitative risk assessment (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 229).

[3] The risk estimates for silicosis and NMRD are not directly comparable, as the endpoint for the NMRD analysis (Park *et al.,* 2002, Document ID 0405) was death from all non-cancer lung diseases, including silicosis, pneumoconiosis, emphysema, and chronic bronchitis, whereas the endpoint for the silicosis analysis (Mannetje *et al.,* 2002b, Document ID 1089) was deaths coded as silicosis or other pneumoconiosis only (Document ID 1711, pp. 297–298).

For silicosis morbidity, OSHA reviewed the principal studies available in the scientific literature that have characterized the risk to exposed workers of acquiring silicosis, as detected by the appearance of opacities on chest radiographs (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, p. 357). The most reliable estimates of silicosis morbidity came from five studies that evaluated radiographs over time, including after workers left employment: The U.S. gold miner cohort studied by Steenland and Brown (1995b, Document ID 0451); the Scottish coal miner cohort studied by Buchanan *et al.* (2003, Document ID 0306); the Chinese tin mining cohort studied by Chen *et al.* (2001, Document ID 0332); the Chinese tin, tungsten, and pottery worker cohorts studied by Chen *et al.* (2005, Document ID 0985); and the South African gold miner cohort studied by Hnizdo and Sluis-Cremer (1993, Document ID 1052) (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk; Document ID 1711, pp. 316–343). These studies demonstrated positive exposure-response relationships between exposure to crystalline silica and silicosis risk. Based on the results of these studies, OSHA estimates a cumulative risk for silicosis morbidity of between 60 and 773 cases per 1,000 workers for a 45-year exposure to the previous general industry PEL of 100 μg/m^3 respirable crystalline silica depending upon the study used, and between 20 and 170 cases per 1,000 workers exposed at the new PEL of 50 μg/m^3 depending upon the study used (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1). Thus, like OSHA's risk estimates for other health endpoints, the risk is substantially lower, though still significant, at the revised PEL.

In conclusion, OSHA finds, based on the best available evidence and methods to estimate quantitative risks of disease resulting from exposure to respirable crystalline silica, that there are significant risks of material health impairment at the former PELs for respirable crystalline silica, which would be substantially reduced (but not entirely eliminated) at the new PEL of 50 μg/m^3. In meeting its legal burden to estimate the health risks posed by respirable crystalline silica, OSHA has used the best available evidence and methods to estimate quantitative risks of disease resulting from exposure to respirable crystalline silica. As a result, the Agency finds that the lifetime excess mortality risks (for lung cancer, NMRD and silicosis, and renal disease) and cumulative risk (silicosis morbidity) posed to workers exposed to respirable crystalline silica over a working life represent significant risks that warrant mitigation, and that these risks will be substantially reduced at the revised PEL of 50 μg/m^3 respirable crystalline silica.

C. Summary of the Review of Health Effects Literature and Preliminary QRA

As noted above, a wide variety of stakeholders offered comments and testimony in this rulemaking on issues related to health and risk. Many of these comments were submitted in response to OSHA's preliminary risk and material impairment determinations, which were presented in two background documents, entitled ''Occupational Exposure to Respirable Crystalline Silica—Review of Health Effects Literature and Preliminary Quantitative Risk Assessment'' (Document ID 1711) and ''Supplemental Literature Review of Epidemiological Studies on Lung Cancer Associated with Exposure to Respirable Crystalline Silica'' (Document ID 1711, Attachment 1), and summarized in the proposal in Section V, Health Effects Summary, and Section VI, Summary of OSHA's Preliminary Quantitative Risk Assessment.

In this subsection, OSHA summarizes the major findings of the two background documents. The Agency intends for this subsection to provide the detailed background necessary to fully understand stakeholders' comments and OSHA's responses.

1. Background

As noted above, OSHA's Review and Supplemental Review of Health Effects Literature and Preliminary Quantitative Risk Assessment (Document ID 1711; 1711, Attachment 1) were the result of the Agency's extensive search and review of the peer-reviewed scientific literature on the health effects of inhalation exposure to crystalline silica, particularly silicosis, lung cancer and cancer at other sites, non-malignant respiratory diseases (NMRD) other than silicosis, and renal and autoimmune effects. The purposes of this detailed search and scientific review were to determine the nature of the hazards presented by exposure to respirable crystalline silica, and to evaluate whether there was an adequate basis, with suitable data availability, for quantitative risk assessment.

Much of the scientific evidence that describes the health effects and risks associated with exposure to crystalline silica consisted of epidemiological studies of worker populations; OSHA also reviewed animal and in vitro studies. OSHA used a weight-of-evidence approach in evaluating this evidence. Under this approach, OSHA evaluated the relevant studies to determine their overall quality. Factors considered in assessing the quality of studies included: (1) The size of the cohort studied and the power of the study to detect a sufficiently low level of disease risk; (2) the duration of follow-up of the study population; (3) the potential for study bias (*e.g.,* selection bias in case-control studies or survivor effects in cross-sectional studies); and (4) the adequacy of underlying exposure information for examining exposure-response relationships. Studies were deemed suitable for inclusion in OSHA's Preliminary Quantitative Risk Assessment (QRA) where there was adequate quantitative information on exposure and disease risks and the study was judged to be sufficiently high quality according to these criteria.

Based upon this weight-of-evidence approach, OSHA preliminarily determined that there is substantial evidence in the peer-reviewed scientific literature that exposure to respirable crystalline silica increases the risk of silicosis, lung cancer, other NMRD, and renal and autoimmune effects. The Preliminary QRA indicated that, for silicosis and NMRD mortality, lung cancer mortality, and renal disease mortality, there is a significant risk at the previous PELs for respirable crystalline silica, with excess lifetime risk estimates substantially greater than 1 death per 1,000 workers as a result of exposure over a working life (45 years, from age 20 to age 65). At the revised PEL of 50 μg/m^3 respirable crystalline silica, OSHA estimated that these risks would be substantially reduced. Cumulative risk estimates for silicosis morbidity were also well above 1 case per 1,000 workers at the previous PELs, with a substantial reduction at the revised PEL.

2. Summary of the Review of Health Effects Literature

In its Review of Health Effects Literature, OSHA identified the adverse health effects associated with the inhalation of respirable crystalline silica (Document ID 1711). OSHA covered the following topics: Silicosis (including relevant data from U.S. disease surveillance efforts), lung cancer and cancer at other sites, non-malignant respiratory diseases (NMRD) other than silicosis, renal and autoimmune effects, and physical factors affecting the toxicity of crystalline silica. Most of the evidence that described the health risks associated with exposure to silica

consisted of epidemiological studies of worker populations; animal and in vitro studies on mode of action and molecular toxicology were also described. OSHA focused solely on those studies associated with airborne exposure to respirable crystalline silica due to the lack of evidence of health hazards from dermal or oral exposure. The review was further confined to issues related to the inhalation of respirable dust, which is generally defined as particles that are capable of reaching the pulmonary region of the lung (*i.e.,* particles less than 10 microns (μm) in aerodynamic diameter), in the form of either quartz or cristobalite, the two forms of crystalline silica most often encountered in the workplace.

a. Silicosis

i. Types

Silicosis is an irreversible, progressive disease induced by the inflammatory effects of respirable crystalline silica in the lung, leading to lung damage and scarring and, in some cases, progressing to complications resulting in disability and death. Exposure to respirable crystalline silica is the only known cause of silicosis. Three types of silicosis have been described: An acute form following intense exposure to respirable dust of high crystalline silica content for a relatively short period (*i.e.,* a few months or years); an accelerated form, resulting from about 5 to 15 years of heavy exposure to respirable dusts of high crystalline silica content; and, most commonly, a chronic form that typically follows less intense exposure of more than 20 years (Becklake, 1994, Document ID 0294; Balaan and Banks, 1992, 0289). In both the accelerated and chronic forms of the disease, lung inflammation leads to the formation of excess connective tissue, or fibrosis, in the lung. The hallmark of the chronic form of silicosis is the silicotic islet or nodule, one of the few agent-specific lesions in pathology (Balaan and Banks, 1992, Document ID 0289). As the disease progresses, these nodules, or fibrotic lesions, increase in density and can develop into large fibrotic masses, resulting in progressive massive fibrosis (PMF). Once established, the fibrotic process of chronic silicosis is thought to be irreversible (Becklake, 1994, Document ID 0294). There is no specific treatment for silicosis (Davis, 1996, Document ID 0998; Banks, 2005, 0291).

Chronic silicosis is the most frequently observed type of silicosis in the U.S. today. Affected workers may have a dry chronic cough, sputum production, shortness of breath, and reduced pulmonary function. These symptoms result from airway restriction and/or obstruction caused by the development of fibrotic scarring in the alveolar sacs and lower region of the lung. Prospective studies that follow the exposed cohort over a long period of time with periodic examinations can provide the best information on factors affecting the development and progression of silicosis, which has a latency period (the interval between beginning of exposure to silica and the onset of disease) from 10 to 30 years after first exposure (Weissman and Wagner, 2005; Document ID 0481).

ii. Diagnosis

The scarring caused by silicosis can be detected by chest x-ray or computerized tomography (CT) when the lesions become large enough to appear as visible opacities. The clinical diagnosis of silicosis has three requirements: Recognition by the physician that exposure to crystalline silica has occurred; the presence of chest radiographic abnormalities consistent with silicosis; the absence of other illnesses that could resemble silicosis on a chest radiograph (*e.g.,* pulmonary fungal infection or tuberculosis) (Balaan and Banks, 1992, Document ID 0289; Banks, 2005, 0291). A standardized system to classify opacities seen in chest radiographs was developed by the International Labour Organization (ILO) to describe the presence and severity of silicosis on the basis of size, shape, and density of opacities, which together indicate the severity and extent of lung involvement (ILO, 1980, Document ID 1063; ILO, 2002, 1064; ILO, 2011, 1475; Merchant and Schwartz, 1998, 1096; NIOSH, 2011, 1513). The density of opacities seen on chest radiographs is classified on a 4-point category scale (0, 1, 2, or 3), with each category divided into three, giving a 12-subcategory scale between 0/0 and 3/+. For each subcategory, the top number indicates the major category that the profusion most closely resembles, and the bottom number indicates the major category that was given secondary consideration. Category 0 indicates the absence of visible opacities and categories 1 to 3 reflect increasing profusion of opacities and a concomitant increase in severity of disease. The bottom number can deviate from the top number by 1. At the extremes of the scale, a designation of 0/− or 3/+ may be used. Subcategory 0/− represents a radiograph that is obviously absent of small opacities. Subcategory 3/+ represents a radiograph that shows much greater profusion than depicted on a standard 3/3 radiograph.

To address the low sensitivity of chest x-rays for detecting silicosis, Hnizdo *et al.* (1993, Document ID 1050) recommended that radiographs consistent with an ILO category of 0/1 or greater be considered indicative of silicosis among workers exposed to a high concentration of silica-containing dust. In like manner, to maintain high specificity, chest x-rays classified as category 1/0 or 1/1 should be considered as a positive diagnosis of silicosis. A biopsy is not necessary to make a diagnosis and a diagnosis does not require that chest x-ray films or digital radiographic images be rated using the ILO system (NIOSH, 2002, Document ID 1110).

iii. Review of Occupation-Based Epidemiological Studies

The causal relationship between exposure to crystalline silica and silicosis has long been accepted in the scientific and medical communities. OSHA reviewed a large number of cross-sectional and retrospective studies conducted to estimate the quantitative relationship between exposure to crystalline silica and the development of silicosis (*e.g.,* Kreiss and Zhen, 1996, Document ID 1080; Love *et al.,* 1999, 0369; Ng and Chan, 1994, 0382; Rosenman *et al.,* 1996, 0423; Churchyard *et al.,* 2003, 1295; Churchyard *et al.,* 2004, 0986; Hughes *et al.,* 1998, 1059; Muir *et al.,* 1989a, 1102; Muir *et al.,* 1989b, 1101; Park *et al.,* 2002, 0405; Chen *et al.,* 2001, 0332; Chen *et al.,* 2005, 0985; Hnizdo and Sluis-Cremer, 1993, 1052; Miller *et al.,* 1998, 0374; Buchanan *et al.,* 2003, 0306; Steenland and Brown, 1995b, 0451). In general, these studies, particularly those that included retirees, found a risk of radiological silicosis (usually defined as x-ray films classified as ILO major category 1 or greater) among workers exposed near the range of cumulative exposures permitted by current exposure limits. The studies' methods and findings are presented in detail in the Preliminary QRA (Document ID 1711, pp. 316–340); those studies on which OSHA relied for its risk estimates are also discussed in the Summary of the Preliminary QRA, below.

OSHA's review of the silicosis literature also focused on specific issues associated with the factors that affect the progression of the disease and the relationship between the appearance of radiological abnormalities indicative of silicosis and pulmonary function decline. From its review of the health literature, OSHA made a number of preliminary findings. First, the size of opacities apparent on initial x-ray films is a determinant of future disease

progression, with subjects exhibiting large opacities more likely to experience progression than those having smaller opacities (Hughes *et al.,* 1982, Document ID 0362; Lee *et al.,* 2001, 1086; Ogawa *et al.,* 2003, 0398). Second, continued exposure to respirable crystalline silica following diagnosis of radiological silicosis increases the probability of disease progression compared to those who are not further exposed (Hessel *et al.,* 1988, Document ID 1042), although there remains a likelihood of progression even absent continued exposure (Hessel *et al.,* 1988, Document ID 1042; Miller *et al.,* 1998, 0374; Ogawa *et al.,* 2003, 0398; Yang *et al.,* 2006, 1134).

With respect to the relationship between radiological silicosis and pulmonary function declines, literature findings are mixed. A number of studies have reported pulmonary function declines among workers exhibiting a degree of small-opacity profusion consistent with ILO categories 2 and 3 (*e.g.,* Ng and Chan, 1992, Document ID 1107). However, although some studies have not found pulmonary function declines associated with silicosis scored as ILO category 1, a number of other studies have documented declines in pulmonary function in persons exposed to silica and whose radiograph readings are in the major ILO category 1 (*i.e.,* 1/0, 1/1, 1/2), or even before changes were seen on chest x-ray (Cowie, 1998, 0993; Cowie and Mabena, 1991, 0342; Ng *et al.,* 1987(a), 1108; Wang *et al.,* 1997, 0478). Thus, OSHA preliminarily concluded that at least some individuals will develop pulmonary function declines absent radiological changes indicative of silicosis. The Agency posited that this may reflect the relatively poor sensitivity of x-ray films in detecting silicosis or may be due to pulmonary function declines related to silica-induced chronic obstructive pulmonary disease (see Document ID 1711, pp. 49–75).

iv. Surveillance

Unlike most occupational diseases, surveillance statistics are available on silicosis mortality and morbidity in the U.S. The most comprehensive and current source of surveillance data in the U.S. related to occupational lung diseases, including silicosis, is the National Institute for Occupational Safety and Health (NIOSH) Work-Related Lung Disease (WoRLD) Surveillance System (NIOSH, 2008c, Document ID 1308). Other sources are detailed in the Review of Health Effects Literature (Document ID 1711). Mortality data are compiled from death certificates reported to state vital statistics offices, which are collected by the National Center for Health Statistics (NCHS), an agency within the Centers for Disease Control and Prevention (*e.g.,* CDC, 2005, Document ID 0319).

Silicosis-related mortality has declined in the U.S. over the time period for which these data have been collected. From 1968 to 2005, the annual number of silicosis deaths decreased from 1,157 to 161 (NIOSH, 2008c, Document ID 1308; *http://wwwn.cdc.gov/eworld*). The CDC cited two main factors that were likely responsible for the declining trend in silicosis mortality since 1968 (CDC, 2005, Document ID 0319). First, many deaths during the early part of the study period were among workers whose main exposure to respirable crystalline silica probably occurred before introduction of national silica standards established by OSHA and the Mine Safety and Health Administration (MSHA) (*i.e.,* permissible exposure limits (PELs)); these standards likely led to reduced silica dust exposure beginning in the 1970s. Second, employment has declined in heavy industries (*e.g.,* foundries) where silica exposure was prevalent (CDC, 2005, Document ID 0319).

Despite this decline, silicosis deaths among workers of all ages result in significant premature mortality; between 1996 and 2005, a total of 1,746 deaths resulted in a total of 20,234 years of life lost from life expectancy, with an average of 11.6 years of life lost. For the same period, among 307 decedents who died before age 65 (the end of a working life), there were 3,045 years of life lost up to age 65, with an average of 9.9 years of life lost from a working life (NIOSH, 2008c, Document ID 1308).

Surveillance data on silicosis morbidity, primarily from hospital discharge records, are available only from the few states that have administered disease surveillance programs for silicosis. For the reporting period 1993–2002, these states recorded 879 cases of silicosis (NIOSH 2008c, Document ID 1308). Nationwide hospital discharge data compiled by NIOSH (2008c, Document ID 1308) and the Council of State and Territorial Epidemiologists (CSTE, 2005, Document ID 0996) indicate that, for the years 1970 to 2004, there were at least 1,000 hospitalizations that were coded for silicosis each year, except one.

Relying exclusively on such passive case-based disease surveillance systems that depend on the health care community to generate records is likely to understate the prevalence of diseases associated with respirable crystalline silica (Froines *et al.,* 1989, Document ID 0385). In order to diagnose occupational diseases, health care professionals must have information about occupational histories and must be able to recognize occupational diseases (Goldman and Peters, 1981, Document ID 1027; Rutstein *et al.,* 1983, 0425). The first criterion to be met in diagnosing silicosis is knowing a patient's history of exposure to crystalline silica. In addition to the lack of information about exposure histories, difficulty in recognizing occupational illnesses like silicosis, that manifest themselves long after initial exposure, contributes to under-recognition and underreporting by health care providers. Based on an analysis of data from Michigan's silicosis surveillance activities, Rosenman *et al.* (2003, Document ID 0420) estimated that silicosis mortality and morbidity were understated by a factor of between 2.5 and 5, and estimated that between 3,600 and 7,300 new cases of silicosis likely occurred in the U.S. annually between 1987 and 1996.

b. Lung Cancer

i. International Agency for Research on Cancer (IARC) Classification

In 1997, the IARC determined that there was sufficient evidence to regard crystalline silica as a human carcinogen (IARC, 1997, Document ID 1062). This finding was based largely on nine studies of cohorts in four industry sectors that IARC considered to be the least influenced by confounding factors (sectors included quarries and granite works, gold mining, ceramic/pottery/refractory brick industries, and the diatomaceous earth industry). NIOSH also determined that crystalline silica is a human carcinogen after evaluating updated literature (2002, Document ID 1110).

ii. Review of Occupation-Based Epidemiological Studies

OSHA conducted an independent review of the epidemiological literature on exposure to respirable crystalline silica and lung cancer, covering more than 30 occupational groups in over a dozen industrial sectors. OSHA's review included approximately 60 primary epidemiological studies. Based on this review, OSHA preliminarily concluded that the human data provides ample evidence that exposure to respirable crystalline silica increases the risk of lung cancer among workers.

The strongest evidence for carcinogenicity came from studies in five industry sectors:

- Diatomaceous Earth Workers (Checkoway *et al.,* 1993, Document ID 0324; Checkoway *et al.,* 1996, 0325; Checkoway *et al.,* 1997, 0326;

Checkoway *et al.,* 1999, 0327; Seixas *et al.,* 1997, 0431);

- British Pottery Workers (Cherry *et al.,* 1998, Document ID 0335; McDonald *et al.,* 1995, 0371);
- Vermont Granite Workers (Attfield and Costello, 2004, Document ID 0285; Graham *et al.,* 2004, 1031; Costello and Graham, 1988, 0991; Davis *et al.,* 1983, 0999);
- North American Industrial Sand Workers (Hughes *et al.,* 2001, Document ID 1060; McDonald *et al.,* 2001, 1091; McDonald *et al.,* 2005, 1092; Rando *et al.,* 2001, 0415; Sanderson *et al.,* 2000, 0429; Steenland and Sanderson, 2001, 0455); and
- British Coal Miners (Miller *et al.,* 2007, Document ID 1305; Miller and MacCalman, 2009, 1306).

OSHA considered these studies as providing the strongest evidence for several reasons. They were all retrospective cohort or case-control studies that demonstrated positive, statistically significant exposure-response relationships between exposure to crystalline silica and lung cancer mortality. Except for the British pottery studies, where exposure-response trends were noted for average exposure only, lung cancer risk was found to be related to cumulative exposure. In general, these studies were of sufficient size and had adequate years of follow up, and had sufficient quantitative exposure data to reliably estimate exposures of cohort members. As part of their analyses, the authors of these studies also found positive exposure-response relationships for silicosis, indicating that underlying estimates of worker exposures were not likely to be substantially misclassified. Furthermore, the authors of these studies addressed potential confounding due to other carcinogenic exposures through study design or data analysis.

In the diatomaceous earth industry, Checkoway *et al.* developed a ''semi-quantitative'' cumulative exposure estimate that demonstrated a statistically significant positive exposure-response trend between duration of employment or cumulative exposure and lung cancer mortality (1993, Document ID 0324). The quartile analysis with a 15-year lag showed an increasing trend in relative risks (RR) of lung cancer mortality, with the highest exposure quartile having a RR of 2.74 for lung cancer mortality. Checkoway *et al.* conducted a re-analysis to address criticisms of potential confounding due to asbestos and again demonstrated a positive exposure-response risk gradient when controlling for asbestos exposure and other variables (1996, Document ID 0325). Rice *et al.* (2001, Document ID 1118) conducted a re-analysis and quantitative risk assessment of the Checkoway *et al.* (1997, Document ID 0326) study, finding that exposure to crystalline silica was a significant predictor of lung cancer mortality. OSHA included this re-analysis in its Preliminary QRA (Document ID 1711).

In the British pottery industry, excess lung cancer risk was found to be associated with crystalline silica exposure among workers in a proportionate mortality ratio (PMR) study [4] (McDonald *et al.,* 1995, Document ID 0371) and in a cohort and nested case-control study [5] (Cherry *et al.,* 1998, Document ID 0335). In the former, elevated PMRs for lung cancer were found after adjusting for potential confounding by asbestos exposure. In the study by Cherry *et al.,* odds ratios for lung cancer mortality were statistically significantly elevated after adjusting for smoking. Odds ratios were related to average, but not cumulative, exposure to crystalline silica.

In the Vermont granite cohort, Costello and Graham (1988, Document ID 0991) and Graham *et al.* (2004, Document ID 1031) in a follow-up study found that workers employed prior to 1930 had an excess risk of lung cancer. Lung cancer mortality among granite workers hired after 1940 (post-implementation of controls), however, was not elevated in the Costello and Graham study and was only somewhat elevated (not statistically significant) in the Graham *et al.* study. Graham *et al.* (2004, Document ID 1031) concluded that their results did not support a causal relationship between granite dust exposure and lung cancer mortality.

Looking at the same population, Attfield and Costello (2004, Document ID 0285) developed a quantitative estimate of cumulative exposure (8 exposure categories) adapted from a job exposure matrix developed by Davis *et al.* (1983, Document ID 0999). They found a statistically significant trend between lung cancer mortality and log-transformed cumulative exposure to crystalline silica. Lung cancer mortality rose reasonably consistently through the first seven increasing exposure groups, but fell in the highest cumulative exposure group. With the highest exposure group omitted, a strong positive dose-response trend was found for both untransformed and log-transformed cumulative exposures. The authors explained that the highest exposure group would have included the most unreliable exposure estimates being reconstructed from exposures 20 years prior to study initiation when exposure estimation was less precise. OSHA expressed its belief that the study by Attfield and Costello (2004, Document ID 0285) was of superior design in that it used quantitative estimates of exposure and evaluated lung cancer mortality rates by exposure group. In contrast, the findings by Graham *et al.* (2004, Document ID 1031) were based on a dichotomous comparison of risk among high- versus low-exposure groups, where date-of-hire before and after implementation of ventilation controls was used as a surrogate for exposure. Consequently, OSHA used the Attfield and Costello study in its Preliminary QRA (Document ID 1711). In its Supplemental Literature Review of Epidemiological Studies on Lung Cancer Associated with Exposure to Respirable Crystalline Silica, OSHA also discussed a more recent study of Vermont granite workers by Vacek *et al.* (2011, Document ID 1486) that did not find an association between silica exposure and lung cancer mortality (Document ID 1711, Attachment 1, pp. 2–5). (OSHA examines this study in great length in Section V.F, Comments and Responses Concerning Lung Cancer Mortality.)

In the North American industrial sand industry, studies of two overlapping cohorts found a statistically significant increased risk of lung cancer mortality with increased cumulative exposure in both categorical and continuous analyses (Hughes *et al.*, 2001, Document ID 1060; McDonald *et al.*, 2001, 1091; McDonald *et al.*, 2005, 1092; Rando *et al.*, 2001, 0415; Sanderson *et al.*, 2000, 0429; Steenland and Sanderson, 2001, 0455). McDonald *et al.* (2001, Document ID 1091) examined a cohort that entered the workforce, on average, a decade earlier than the cohorts that Steenland and Sanderson (2001, Document ID 0455) examined. The McDonald cohort, drawn from eight plants, had more years of exposure in the industry (19 versus 8.8 years). The Steenland and Sanderson (2001, Document ID 0455) cohort worked in 16 plants, 7 of which overlapped with the McDonald, *et al.*

[4] A PMR is the number of deaths within a population due to a specific disease (*e.g.,* lung cancer) divided by the total number of deaths in the population during some time period.

[5] A cohort study is a study in which the occurrence of disease (*e.g.,* lung cancer) is measured in a cohort of workers with potential for a common exposure (*e.g.,* silica). A nested case-control study is a study in which workers with disease are identified in an occupational cohort, and a control group consisting of workers without disease is selected (independently of exposure status) from the same cohort to determine whether there is a difference in exposure between cases and controls. A number of controls are matched to each case to control for potentially confounding factors, such as age, gender, etc.

(2001, Document ID 1091) cohort. McDonald *et al.* (2001, Document ID 1091), Hughes *et al.* (2001, Document ID 1060), and Rando *et al.* (2001, Document ID 0415) had access to smoking histories, plant records, and exposure measurements that allowed for historical reconstruction and the development of a job exposure matrix. The McDonald *et al.* (2005, Document ID 1092) study was a later update, with follow-up through 2000, of both the cohort and nested case-control studies. Steenland and Sanderson (2001, Document ID 0455) had limited access to plant facilities, less detailed historic exposure data, and used MSHA enforcement records for estimates of recent exposure. These studies (Hughes *et al.*, 2001, Document ID 1060; McDonald *et al.*, 2005, 1092; Steenland and Sanderson, 2001, 0455) showed very similar exposure-response patterns of increased lung cancer mortality with increased exposure. OSHA included the quantitative exposure-response analysis from the Hughes *et al.* (2001, Document ID 1060) study in its Preliminary QRA, as it allowed for individual job, exposure, and smoking histories to be taken into account.

OSHA noted that Brown and Rushton (2005a, Document ID 0303; 2005b, 0304) found no association between risk of lung cancer mortality and exposure to respirable crystalline silica among British industrial sand workers. However, a large portion of the cohort had relatively short service times in the industry, with over one-half the cohort deaths and almost three-fourths of the lung cancer mortalities having had less than 10 years of service. Considering the apparent high turnover in this industry and the absence of prior occupational histories, exposures from work experience other than in the industrial sand industry could be a significant confounder (Document ID 1711, p. 131). Additionally, as Steenland noted in a letter review (2005a, Document ID 1313), the cumulative exposures of workers in the Brown and Ruston (2005b, Document ID 0304) study were over 10 times lower than the cumulative exposures experienced by the cohorts in the pooled analysis that Steenland *et al.* (2001a, Document ID 0452) performed. The low exposures experienced by this cohort would have made detecting a positive association with lung cancer mortality even more difficult.

In British coal miners, excess lung cancer mortality was reported in a large cohort study, which examined the mortality experience of 17,800 miners through the end of 2005 (Miller *et al.*, 2007, Document ID 1305; Miller and MacCalman, 2009, 1306). By that time, the cohort had accumulated 516,431 person years of observation (an average of 29 years per miner), with 10,698 deaths from all causes. Overall lung cancer mortality was elevated (SMR = 115.7, 95% C.I. 104.8–127.7), and a positive exposure-response relationship with crystalline silica exposure was determined from Cox regression after adjusting for smoking history. Three of the strengths of this study were the detailed time-exposure measurements of both quartz and total mine dust, detailed individual work histories, and individual smoking histories. For lung cancer, analyses based on Cox regression provided strong evidence that, for these coal miners, although quartz exposures were associated with increased lung cancer risk, simultaneous exposures to coal dust did not cause increased lung cancer risk. Because of these strengths, OSHA included this study in its Preliminary QRA (Document ID 1711).

In addition to the studies in these cohorts, OSHA also reviewed studies of lung cancer mortality in metal ore mining populations. Many of these mining studies, which showed mixed results, were subject to confounding due to exposure to other potential carcinogens such as radon and arsenic. IARC noted that only a few ore mining studies accounted for confounding from other occupational carcinogens and that, when confounding was absent or accounted for, an association between silica exposure and lung cancer was absent (1997, Document ID 1062). Many of the studies conducted since IARC's review, however, more strongly implicate crystalline silica as a human carcinogen (1997, Document ID 1062). Pelucchi *et al.* (2006, Document ID 0408), in a meta-analysis of studies conducted since IARC's (1997, Document ID 1062) review, reported statistically significantly elevated relative risks of lung cancer mortality in underground and surface miners in three cohort and four case-control studies. Cassidy *et al.*, in a pooled case-control analysis, showed a statistically significant increased risk of lung cancer mortality among miners (OR = 1.48), and demonstrated a linear trend of increasing odds ratios with increasing exposures (2007, Document ID 0313).

OSHA also preliminarily determined that the results of the studies conducted in three industry sectors (foundry, silicon carbide, and construction sectors) were confounded by the presence of exposures to other carcinogens. Exposure data from these studies were not sufficient to distinguish between exposure to silica dust and exposure to other occupational carcinogens. IARC previously made a similar determination in reference to the foundry industry. However, with respect to the construction industry, Cassidy *et al.* (2007, Document ID 0313), in a large European community-based case-control study, reported finding a clear linear trend of increasing odds ratios with increasing cumulative exposure to crystalline silica (estimated semi-quantitatively) after adjusting for smoking and exposure to insulation and wood dusts.

In addition, an analysis of 4.8 million death certificates from 27 states within the U.S. for the years 1982 to 1995 showed statistically significant excesses in lung cancer mortality, silicosis mortality, tuberculosis, and NMRD among persons with occupations involving medium and high exposure to respirable crystalline silica (Calvert *et al.*, 2003, Document ID 0309). A national records and death certificate study was also conducted in Finland by Pukkala *et al.*, who found a statistically significant excess of lung cancer incidence among men and women with estimated medium and heavy exposures (2005, Document ID 0412).

One of the more compelling studies OSHA evaluated and used in the Preliminary QRA (Document ID 1711) was Steenland *et al.*'s (2001a, Document ID 0452) pooled analysis of 10 occupational cohorts (5 mines and 5 industrial facilities), which demonstrated an overall positive exposure-response relationship between cumulative exposure to crystalline silica and lung cancer mortality. These 10 cohorts included 65,980 workers and 1,072 lung cancer deaths, and were selected because of the availability of raw data on exposure to crystalline silica and health outcomes. The investigators found lung cancer risk increased with increasing cumulative exposure, log cumulative exposure, and average exposure. Exposure-response trends were similar between mining and non-mining cohorts.

iii. Confounding

Smoking is known to be a major risk factor for lung cancer. However, OSHA maintained in the Preliminary QRA that it is unlikely that smoking explained the observed exposure-response trends in the studies described above (Document ID 1711). Studies by Hnizdo *et al.* (1997, Document ID 1049), McLaughlin *et al.* (1992, Document ID 0372), Hughes *et al.* (2001, Document ID 1060), McDonald *et al.* (2001, Document ID 1091; 2005, 1092), Miller and MacCalman (2009, Document ID 1306), and Cassidy *et al.* (2007, Document ID 0313) had detailed smoking histories with sufficiently large

populations and a sufficient number of years of follow-up time to quantify the interaction between crystalline silica exposure and cigarette smoking. In a cohort of white South African gold miners (Hnizdo and Sluis-Cremer, 1991, Document ID 1051) and in the follow-up nested case-control study (Hnizdo *et al.*, 1997, Document ID 1049), the combined effect of exposure to respirable crystalline silica and smoking was greater than additive, suggesting a multiplicative effect. This effect appeared to be greatest for miners with greater than 35 pack-years of smoking and higher cumulative exposure to silica. In the Chinese nested case-control studies (McLaughlin *et al.*, 1992, Document ID 0372), cigarette smoking was associated with lung cancer, but control for smoking did not influence the association between silica and lung cancer in the mining and pottery cohorts studied. The studies of industrial sand workers (Hughes *et al.*, 2001, Document ID 1060) and British coal workers (Miller and MacCalman, 2009, Document ID 1306) found positive exposure-response trends after adjusting for smoking histories, as did Cassidy *et al.* (2007, Document ID 0313) in their community-based case-control study of exposed European workers.

Given these findings of investigators who have accounted for the impact of smoking, OSHA preliminarily determined that the weight of the evidence reviewed identified respirable crystalline silica as an independent risk factor for lung cancer mortality. OSHA also determined that its finding was further supported by animal studies demonstrating that exposure to silica alone can cause lung cancer (*e.g.,* Muhle *et al.*, 1995, Document ID 0378).

iv. Lung Cancer and Silicosis

Animal and in vitro studies have demonstrated that the early steps in the proposed mechanistic pathways that lead to silicosis and lung cancer seem to share some common features (*see* Document ID 1711, pp. 171–172). This has led some researchers to suggest that silicosis is a prerequisite to lung cancer. Some have suggested that any increased lung cancer risk associated with silica may be a consequence of inflammation (and concomitant oxidative stress) and increased epithelial cell proliferation associated with the development of silicosis. However, other researchers have noted additional genotoxic and non-genotoxic mechanisms that may also be involved in carcinogenesis induced by silica (*see* Section V.H, Mechanisms of Silica-Induced Adverse Health Effects, and Document ID 1711, pp. 230–239). IARC also noted that a direct genotoxic mechanism from silica to induce a carcinogenic effect cannot be ruled out (2012, Document ID 1473). Thus, OSHA preliminarily concluded that available animal and in vitro studies do not support the hypothesis that development of silicosis is necessary for silica exposure to cause lung cancer.

In general, studies of workers with silicosis, as well as meta-analyses that include these studies, have shown that workers with radiologic evidence of silicosis have higher lung cancer risk than those without radiologic abnormalities or mixed cohorts. Three meta-analyses attempted to look at the association of increasing ILO radiographic categories of silicosis with increasing lung cancer mortality. Two of these analyses (Kurihara and Wada, 2004, Document ID 1084; Tsuda *et al.*, 1997, 1127) showed no association with increasing lung cancer mortality, while Lacasse *et al.* (2005, Document ID 0365) demonstrated a positive dose-response for lung cancer with increasing ILO radiographic category. A number of other studies found increased lung cancer risk among exposed workers absent radiological evidence of silicosis (Cassidy *et al.*, 2007, Document ID 0313; Checkoway *et al.*, 1999, 0327; Cherry *et al.*, 1998, 0335; Hnizdo *et al.*, 1997, 1049; McLaughlin *et al.*, 1992, 0372). For example, the diatomaceous earth study by Checkoway *et al.* showed a statistically significant exposure-response relationship for lung cancer among persons without silicosis (1999, Document ID 0327). Checkoway and Franzblau, reviewing the international literature, found that all epidemiological studies conducted to that date were insufficient to conclusively determine the role of silicosis in the etiology of lung cancer (2000, Document ID 0323). OSHA preliminarily concluded that the more recent pooled and meta-analyses do not provide compelling evidence that silicosis is a necessary precursor to lung cancer.

c. Non-Malignant Respiratory Diseases (Other Than Silicosis)

In addition to causing silicosis, exposure to crystalline silica has been associated with increased risks of other non-malignant respiratory diseases (NMRD), primarily chronic obstructive pulmonary disease (COPD), chronic bronchitis, and emphysema. COPD is a disease state characterized by airflow limitation that is usually progressive and not fully reversible. In patients with COPD, either chronic bronchitis or emphysema may be present or both conditions may be present together.

As detailed in the Review of Health Effects Literature, OSHA reviewed several studies of NMRD morbidity and preliminarily concluded that exposure to respirable crystalline silica may increase the risk of emphysema, chronic bronchitis, and pulmonary function impairment, regardless of whether signs of silicosis are present (Document ID 1711). Smokers may be at an increased risk relative to nonsmokers.

OSHA also reviewed studies of NMRD mortality that focused on causes of death other than silicosis. Wyndham *et al.* found a significant excess mortality for chronic respiratory diseases in a cohort of white South African gold miners (1986, Document ID 0490). A case-referent analysis found that, although the major risk factor for chronic respiratory disease was smoking, there was a statistically significant additional effect of cumulative exposure to silica-containing dust. A multiplicative effect of smoking and cumulative dust exposure on mortality from COPD was found in another study of white South African gold miners (Hnizdo, 1990, Document ID 1045). Analysis of various combinations of dust exposure and smoking found a trend in odds ratios that indicated this synergism. There was a statistically significant increasing trend for dust particle-years and for cigarette-years of smoking.

Park *et al.* (2002, Document ID 0405) analyzed the California diatomaceous earth cohort data originally studied by Checkoway *et al.* (1997, Document ID 0326), consisting of 2,570 diatomaceous earth workers employed for 12 months or more from 1942 to 1994, to quantify the relationship between exposure to cristobalite and mortality from chronic lung disease other than cancer (LDOC). Diseases in this category included pneumoconiosis (which included silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. Smoking information was available for about 50 percent of the cohort and for 22 of the 67 LDOC deaths available for analysis, permitting at least partial adjustment for smoking. Using the exposure estimates developed for the cohort by Rice *et al.* (2001, Document ID 1118) in their exposure-response study of lung cancer risks, Park *et al.* (2002, Document 0405) evaluated the quantitative exposure-response relationship for LDOC mortality and found a strong positive relationship with exposure to respirable crystalline silica. OSHA found this study particularly compelling because of the strengths of the study design and availability of smoking history data on part of the cohort, as well as the high-

quality exposure and job history data. The study authors noted:

> Data on smoking, collected since the 1960s in the company's radiographic screening programme, were available for 1171 of the subjects (50%). However, smoking habits were unknown for 45 of the 67 workers that died from LDOC (67%). Our Poisson regression analyses for LDOC, stratified on smoking, have partially rectified the confounding by smoking issue. Furthermore, analyses performed without control for smoking produced slightly smaller and less precise estimates of the effects of silica, suggesting that smoking is a negative confounder. In their analysis of this cohort, Checkoway *et al.* applied the method of Axelson concluding that it was very unlikely that cigarette smoking could account for the association found between mortality from LDOC and cumulative exposure to silica (Document ID 0405, p. 41).

Consequently, OSHA used this study in its Preliminary QRA (Document ID 1711, pp. 295–298).

Based on this evidence, and the other studies discussed in the Review of Health Effects Literature, OSHA preliminarily concluded that respirable crystalline silica increases the risk for mortality from non-malignant respiratory disease (not including silicosis) in an exposure-related manner. The Agency also preliminarily concluded that the risk is strongly influenced by smoking, and opined that the effects of smoking and silica exposure may be synergistic.

d. Renal Disease and Autoimmune Diseases

In its Review of Health Effects Literature, OSHA described the available experimental and epidemiological data evaluating respirable crystalline silica exposure and renal and/or autoimmune effects (Document ID 1711). In addition to a number of case reports, epidemiological studies have found statistically significant associations between occupational exposure to silica dust and chronic renal disease (Calvert *et al.*, 1997, Document ID 0976), subclinical renal changes (Ng *et al.*, 1992c, Document ID 0386), end-stage renal disease morbidity (Steenland *et al.*, 1990, Document ID 1125), chronic renal disease mortality (Steenland *et al.*, 2001b, Document ID 0456; 2002a, 0448), and granulomatosis with polyangitis, a condition that can affect the kidneys (Nuyts *et al.*, 1995, Document ID 0397). In other findings, silica-exposed individuals, both with and without silicosis, had an increased prevalence of abnormal renal function (Hotz *et al.*, 1995, Document ID 0361), and renal effects have been reported to persist after cessation of silica exposure (Ng *et al.*, 1992c, Document ID 0386). Possible mechanisms suggested for silica-induced renal disease include a direct toxic effect on the kidney, deposition of immune complexes (IgA) in the kidney following silica related pulmonary inflammation, and an autoimmune mechanism (Calvert *et al.*, 1997, Document ID 0976; Gregorini *et al.*, 1993, 1032).

In a pooled cohort analysis, Steenland *et al.* (2002a, Document ID 0448) combined the industrial sand cohort from Steenland *et al.* (2001b, Document ID 0456), the gold mining cohort from Steenland and Brown (1995a, Document ID 0450), and the Vermont granite cohort studies by Costello and Graham (1988, Document ID 0991). In all, the combined cohort consisted of 13,382 workers with exposure information available for 12,783. The analysis demonstrated statistically significant exposure-response trends for acute and chronic renal disease mortality with quartiles of cumulative exposure to respirable crystalline silica. In a nested case-control study design, a positive exposure-response relationship was found across the three cohorts for both multiple-cause mortality (*i.e.*, any mention of renal disease on the death certificate) and underlying cause mortality. Renal disease risk was most prevalent among workers with cumulative exposures of 500 $\mu g/m^3$ or more (Steenland *et al.*, 2002a, Document ID 0448).

OSHA noted that other studies failed to find an excess renal disease risk among silica-exposed workers. Davis *et al.* (1983, Document ID 0999) found elevated, but not statistically significant, mortality from diseases of the genitourinary system among Vermont granite shed workers. There was no observed relationship between mortality from this cause and cumulative exposure. A similar finding was reported by Koskela *et al.* (1987, Document ID 0363) among Finnish granite workers, where there were 4 deaths due to urinary tract disease compared to 1.8 expected. Both Carta *et al.* (1994, Document ID 0312) and Cocco *et al.* (1994, Document ID 0988) reported finding no increased mortality from urinary tract disease among workers in an Italian lead mine and zinc mine. However, Cocco *et al.* (1994, Document ID 0988) commented that exposures to respirable crystalline silica were low, averaging 7 and 90 $\mu g/m^3$ in the two mines, respectively, and that their study in particular had low statistical power to detect excess mortality.

OSHA expressed its belief that there is substantial evidence, particularly the 3-cohort pooled analysis conducted by Steenland *et al.* (2002a, Document ID 0448), on which to base a finding that exposure to respirable crystalline silica increases the risk of renal disease mortality and morbidity. The pooled analysis by Steenland *et al.* involved a large number of workers from three cohorts with well-documented, validated job-exposure matrices; it found a positive, monotonic increase in renal disease risk with increasing exposure for both underlying and multiple cause data (2002a, Document ID 0448). However, there are considerably less data available for renal disease than there are for silicosis mortality and lung cancer mortality. The findings based on these data are, therefore, less robust. Nevertheless, OSHA preliminarily concluded that the underlying data are sufficient to provide useful estimates of risk and included the Steenland *et al.* (2002a, Document ID 0448) analysis in its Preliminary QRA.

For autoimmune effects, OSHA reviewed epidemiological information suggesting an association between respirable silica exposure and autoimmune diseases, including scleroderma (Sluis-Cremer *et al.*, 1985, Document ID 0439), rheumatoid arthritis (Klockars et al., 1987, Document ID 1075; Rosenman and Zhu, 1995, 0424), and systemic lupus erythematosus (Brown *et al.*, 1997, Document ID 0974). However, there were no quantitative exposure-response data available on which to base a quantitative risk assessment for autoimmune diseases.

e. Physical Factors Affecting Toxicity of Crystalline Silica

OSHA also examined evidence on the comparative toxicity of the silica polymorphs (quartz, cristobalite, and tridymite). A number of animal studies appear to suggest that cristobalite and tridymite are more toxic to the lung than quartz and more tumorigenic (*e.g.*, King *et al.*, 1953, Document ID 1072; Wagner *et al.*, 1980, 0476). However, in contrast to these findings, several authors have reviewed the studies done in this area and concluded that cristobalite and tridymite are not more toxic than quartz (*e.g.*, Bolsaitis and Wallace, 1996, Document ID 0298; Guthrie and Heaney, 1995, 1035). Furthermore, a difference in toxicity between cristobalite and quartz has not been observed in epidemiological studies (tridymite has not been studied) (NIOSH, 2002, Document ID 1110). In an analysis of exposure-response for lung cancer, Steenland *et al.* found similar exposure-response trends between cristobalite-exposed workers and other cohorts

exposed to quartz (2001a, Document ID 0452).

OSHA also discussed other physical factors that may influence the toxicologic potency of crystalline silica. A number of animal studies compared the toxicity of freshly fractured silica to that of aged silica (Porter *et al.*, 2002, Document ID 1114; Shoemaker *et al.*, 1995, 0437; Vallyathan *et al.*, 1995, 1128). These studies have demonstrated that although freshly fractured silica is more toxic than aged silica, aged silica still retains significant toxicity. There have been no studies comparing workers exposed to freshly fractured silica to those exposed to aged silica. However, similarities between the results of animal and human studies involving freshly fractured silica suggest that the animal studies involving aged silica may also apply to humans. For example, studies of workers exposed to freshly fractured silica have demonstrated that these workers exhibit the same cellular effects as seen in animals exposed to freshly fractured silica (Castranova *et al.*, 1998, Document ID 1294; Goodman *et al.*, 1992, 1029). Animal studies also suggest that pulmonary reactions of rats to short-duration exposure to freshly fractured silica mimic those seen in acute silicosis in humans (Vallyathan *et al.*, 1995, Document ID 1128).

Surface impurities, particularly metals, have been shown to alter silica toxicity. Iron, depending on its state and quantity, has been shown to either increase or decrease toxicity (*see* Document ID 1711, pp. 247–258). Aluminum has been shown to decrease toxicity (Castranova *et al.*, 1997, Document ID 0978; Donaldson and Borm, 1998, 1004; Fubini, 1998, 1016). Silica coated with aluminosilicate clay exhibits lower toxicity, possibly as a result of reduced bioavailability of the silica particle surface (Donaldson and Borm, 1998, Document ID 1004; Fubini, 1998, 1016). Aluminum as well as other metal ions are thought to modify silanol groups on the silica surface, thus decreasing the membranolytic and cytotoxic potency and resulting in enhanced particle clearance from the lung before damage can take place (Fubini, 1998, Document ID 1016). An epidemiological study found that the risk of silicosis was less in pottery workers than in tin and tungsten miners (Chen *et al.*, 2005, Document ID 0985; Harrison *et al.*, 2005, 1036), possibly reflecting that pottery workers were exposed to silica particles having less biologically-available, non-clay-occluded surface area than was the case for miners.

Although it is evident that a number of factors can act to mediate the toxicological potency of crystalline silica, it is not clear how such considerations should be taken into account to evaluate lung cancer and silicosis risks to exposed workers. After evaluating many in vitro studies that investigated the surface characteristics of crystalline silica particles and their influence on fibrogenic activity, NIOSH concluded that further research is needed to associate specific surface characteristics that can affect toxicity with specific occupational exposure situations and consequent health risks to workers (2002, Document ID 1110). Thus, OSHA preliminarily concluded that while there was considerable evidence that several environmental influences can modify surface activity to either enhance or diminish the toxicity of silica, the available information was insufficient to determine in any quantitative way how these influences may affect disease risk to workers in any particular workplace setting.

3. Summary of the Preliminary QRA

OSHA presented in the Preliminary QRA estimates of the risk of silica-related diseases assuming exposure over a working life (45 years, from age 20 to age 65) to the revised 8-hour time-weighted average (TWA) PEL of 50 μg/m^3 respirable crystalline silica, the new action level of 25 μg/m^3, and the previous PELs. OSHA's previous general industry PEL for respirable quartz was expressed both in terms of a particle count formula and a gravimetric concentration formula; the previous construction and shipyard employment PELs for respirable quartz were only expressed in terms of a particle count formula. For general industry, as the quartz content increases, the gravimetric PEL approached a limit of 100 μg/m^3 respirable quartz. For construction and shipyard employment, OSHA's previous PELs used a formula that limits exposure to respirable dust, depending upon the quartz content, expressed as a respirable particle count concentration. There was no single mass concentration equivalent for the construction and shipyard employment PELs; OSHA reviewed several studies that suggest that the previous construction/shipyard PEL likely was between 250 and 500 μg/m^3 respirable quartz. In general industry, for both the gravimetric and particle count PELs, OSHA's previous PELs for cristobalite and tridymite were half the value for quartz. Based upon these previous PELs and the new action level, OSHA presented risk estimates associated with exposure over a working life to 25, 50, 100, 250, and 500 μg/m^3 respirable silica (corresponding to cumulative exposures over 45 years to 1.125, 2.25, 4.5, 11.25, and 22.5 mg/m^3-yrs).

To estimate lifetime excess mortality risks at these exposure levels, OSHA implemented each of the risk models in a life table analysis that accounted for competing causes of death due to background causes and cumulated risk through age 85. For these analyses, OSHA used lung cancer, NMRD, or renal disease mortality and all-cause mortality rates to account for background risks and competing risks (U.S. 2006 data for lung cancer and NMRD mortality in all males, 1998 data for renal disease mortality, obtained from cause-specific death rate tables published by the National Center for Health Statistics (2009, Document ID 1104)). OSHA calculated these risk estimates assuming occupational exposure from age 20 to age 65. The mortality risk estimates were presented in terms of lifetime excess risk per 1,000 workers for exposure over an 8-hour working day, 250 days per year, and a 45-year working life.

For silicosis morbidity, OSHA based its risk estimates on cumulative risk models used by various investigators to develop quantitative exposure-response relationships. These models characterized the risk of developing silicosis (as detected by chest radiography) up to the time that cohort members (including both active and retired workers) were last examined. Thus, risk estimates derived from these studies represented less-than-lifetime risks of developing radiographic silicosis. OSHA did not attempt to estimate lifetime risk (*i.e.,* up to age 85) for silicosis morbidity because the relationships between age, time, and disease onset post-exposure have not been well characterized.

a. Silicosis and NMRD Mortality

i. Exposure-Response Studies

In the Preliminary QRA, OSHA relied upon two published quantitative risk studies of silicosis and NMRD mortality (Document ID 1711). The first, Mannetje *et al.* (2002b, Document ID 1089) conducted a pooled analysis of silicosis mortality in which there were 18,634 subjects, 150 silicosis deaths, and 20 deaths from unspecified pneumoconiosis. Rates for silicosis adjusted for age, calendar time, and study were estimated by Poisson regression and increased nearly monotonically with deciles of cumulative exposure, from a mortality rate of 5/100,000 person-years in the lowest exposure category (0–0.99

mg/m³-yrs) to 299/100,000 person-years in the highest category (>28.10 mg/m³-yrs).

As previously discussed, the second, Park *et al.* (2002, Document ID 0405) analyzed the California diatomaceous earth cohort data from Checkoway *et al.* (1997, Document ID 0326), and examined mortality from chronic lung disease other than cancer (LDOC; also known as non-malignant respiratory disease (NMRD)). Smoking information was available for about 50 percent of the cohort and for 22 of the 67 LDOC deaths available for analysis, permitting Park *et al.* (2002, Document ID 0405) to partially adjust for smoking. Estimates of LDOC mortality risks were derived via Poisson and Cox proportional hazards models; a variety of relative rate model forms were fit to the data, with a linear relative rate model selected for estimating risks.

ii. Risk Estimates

As silicosis is only caused by exposure to respirable crystalline silica (*i.e.,* there is no background rate of silicosis in the unexposed population), absolute risks of silicosis mortality rather than excess risks were calculated for the Mannetje *et al.* pooled analysis (2002b, Document ID 1089). These risk estimates were derived from the rate ratios incorporating simulated measurement error reported by ToxaChemica (Document ID 0469). OSHA's estimate of lifetime risk of silicosis mortality, for 45 years of exposure to the previous general industry PEL, was 11 deaths per 1,000 workers for the pooled analysis (Document ID 1711). At the revised PEL, the risk estimate was 7 deaths per 1,000.

OSHA also calculated preliminary risk estimates for NMRD mortality. These estimates were derived from Park *et al.* (2002, Document ID 0405). For 45 years of exposure to the previous general industry PEL, OSHA preliminarily estimated lifetime excess risk at 83 deaths per 1,000 workers. At the revised PEL, OSHA estimated 43 deaths per 1,000 workers.

OSHA noted that, for exposures up to 250 μg/m³, the mortality risk estimates based on Park *et al.* (2002, Document ID 0405) are about 5 to 11 times as great as those calculated for the pooled analysis of silicosis mortality (Mannetje *et al.,* 2002b, Document ID 1089). These two sets of risk estimates, however, are not directly comparable, as the endpoint for the Park *et al.* (2002, Document ID 0405) analysis was death from all non-cancer lung diseases, including pneumoconiosis, emphysema, and chronic bronchitis, whereas the pooled analysis by Mannetje *et al.* (2002b, Document ID 1089) included only deaths coded as silicosis or other pneumoconiosis. Less than 25 percent of the LDOC deaths in the Park *et al.* analysis were coded as silicosis or other pneumoconiosis (15 of 67), suggesting that silicosis as a cause of death may be misclassified as emphysema or chronic bronchitis. Thus, Mannetje *et al.*'s (2002b, Document ID 1089) selection of deaths may tend to underestimate the true risk of silicosis mortality, and Park *et al.'s* (2002, Document ID 0405) analysis may more completely capture the total respiratory mortality risk from all non-malignant causes.

Since the time of OSHA's analysis, NCHS has released updated all-cause mortality and NMRD mortality background rates from 2011 (*http://wonder.cdc.gov/ucd-icd10.html*); OSHA's final risk estimates for NMRD mortality, which incorporate these updated rates (ICD10 codes J40–J47, chronic lower respiratory diseases; J60–J66, J68, pneumoconiosis and chemical effects), are available in Section VI, Final Quantitative Risk Assessment and Significance of Risk.

b. Lung Cancer Mortality

i. Exposure-Response Studies

In 1997, when IARC determined that there was sufficient evidence to regard crystalline silica as a human carcinogen, it also noted that some epidemiological studies did not demonstrate an excess risk of lung cancer and that exposure-response trends were not always consistent among studies that were able to describe such trends (Document ID 1062). These findings led Steenland et al. (2001a, Document ID 0452) to conduct a comprehensive exposure-response analysis—the IARC multi-center study—of the risk of lung cancer associated with exposure to crystalline silica. This study relied on all available cohort data from previously-published epidemiological studies for which there were adequate quantitative data on worker silica exposures to derive pooled estimates of disease risk. In addition, as discussed previously, OSHA identified four more recent studies suitable for quantitative risk assessment: (1) An exposure-response analysis by Rice *et al.* (2001, Document ID 1118) of a cohort of diatomaceous earth workers primarily exposed to cristobalite; (2) an analysis by Attfield and Costello (2004, Document ID 0285) of U.S. granite workers; (3) an exposure-response analysis by Hughes *et al.* (2001, Document ID 1060) of U.S. industrial sand workers; and (4) a risk analysis by Miller *et al.* (2007, Document ID 1305) and Miller and MacCalman (2009, Document ID 1306) of British coal miners. OSHA thoroughly described each of these studies in its Preliminary QRA (Document ID 1711); a brief summary of the exposure-response models used in each study is provided here.

The Steenland *et al.* pooled exposure-response analysis was based on data obtained from ten cohorts of silica-exposed workers (65,980 workers, 1,072 lung cancer deaths) (2001a, Document ID 0452). The pooled analysis cohorts included U.S. gold miners (Steenland and Brown, 1995a, Document ID 0450), U.S. diatomaceous earth workers (Checkoway *et al.,* 1997, Document ID 0326), Australian gold miners (de Klerk and Musk, 1998, Document ID 0345), Finnish granite workers (Koskela *et al.,* 1994, Document ID 1078), U.S. industrial sand employees (Steenland and Sanderson, 2001, Document ID 0455), Vermont granite workers (Costello and Graham, 1988, Document ID 0991), South African gold miners (Hnizdo and Sluis-Cremer, 1991, Document ID 1051; Hnizdo *et al.,*1997, 1049), and Chinese pottery workers, tin miners, and tungsten miners (Chen *et al.,* 1992, Document ID 0329).

Steenland *et al.* (2001a, Document ID 0452) performed a nested case-control analysis via Cox regression. There were 100 controls chosen for each case randomly from among cohort members who survived past the age at which the case died; controls were matched on age (the time variable in Cox regression), study, race/ethnicity, sex, and date of birth within 5 years. Steenland et al. found that the use of any of the following continuous exposure variables in a log linear relative risk model resulted in positive statistically significant ($p \leq 0.05$) exposure-response coefficients: (1) Cumulative exposure with a 15-year lag; (2) the log of cumulative exposure with a 15-year lag; and (3) average exposure (2001a, Document ID 0452). The models that provided the best fit to the data used cumulative exposure and log-transformed cumulative exposure. Models that used log-transformed cumulative exposure also showed no statistically significant heterogeneity among cohorts ($p = 0.36$), possibly because they are less influenced by very high exposures. At OSHA's request, Steenland (2010, Document ID 1312) also conducted a categorical analysis of the pooled data set and additional analyses using linear relative risk models (with and without the log transformation of cumulative exposure) as well as a two-piece spline model (see Document ID 1711, pp. 276–278).

Rice *et al.* (2001, Document ID 1118) applied a variety of exposure-response models to the California diatomaceous earth cohort data originally studied by Checkoway *et al.* (1993, Document ID 0324; 1996, 0325; 1997, 0326) and included in the Steenland *et al.* (2001a, Document ID 0452) pooled analysis. The cohort consisted of 2,342 white males employed for at least one year between 1942 and 1987 in a California diatomaceous earth mining and processing plant. The cohort was followed until 1994, and included 77 lung cancer deaths. Rice et al. reported that exposure to crystalline silica was a significant predictor of lung cancer mortality for nearly all of the models employed, with the linear relative risk model providing the best fit to the data in the Poisson regression analysis (2001, Document ID 1118).

Attfield and Costello (2004, Document ID 0285) analyzed the U.S. granite cohort originally studied by Costello and Graham (1988, Document ID 0991) and Davis *et al.* (1983, Document ID 0999) and included in the Steenland *et al.* (2001a, Document ID 0452) pooled analysis. The cohort consisted of 5,414 male granite workers who were employed in the Vermont granite industry between 1950 and 1982 and who had received at least one chest x-ray from the surveillance program of the Vermont Department of Industrial Hygiene. The 2004 report by Attfield and Costello extended follow-up from 1982 to 1994, and found 201 deaths (Document ID 0285). Using Poisson regression models, the results of a categorical analysis showed a generally increasing trend of lung cancer rate ratios with increasing cumulative exposure.

As mentioned previously, however, the rate ratio for the highest exposure group in the Attfield and Costello analysis (cumulative exposures of 6.0 mg/m^3-yrs or higher) was substantially lower than that for other exposure groups (2004, Document ID 0285). The authors reported that the best-fitting model had a 15-year lag, untransformed cumulative exposure, and the omission of this highest exposure group. The authors argued that it was appropriate to omit the highest exposure group for several reasons, including that the exposure estimates for the highest exposure group were less reliable, and there was a greater likelihood of cohort selection effects, competing causes of death, and misdiagnosis (Document ID 0285, p. 136).

McDonald *et al.* (2001, Document ID 1091), Hughes *et al.* (2001, Document ID 1060) and McDonald *et al.* (2005, Document ID 1092) followed up on a cohort study of North American industrial sand workers included in the Steenland *et al.* (2001a, Document ID 0452) pooled analysis. The McDonald *et al.* cohort included 2,670 men employed before 1980 for three years or more in one of nine North American (8 U.S. and 1 Canadian) sand-producing plants, including 1 large associated office complex (2001, Document ID 1091). A nested case-control study based on 90 lung cancer deaths (through 1994) from this cohort was conducted by Hughes *et al.* (2001, Document ID 1060). A subsequent update (through 2000, 105 lung cancer deaths) eliminated the Canadian plant, following 2,452 men from the eight U.S. plants (McDonald *et al.,* 2005, Document ID 1092). These nested case-control studies, Hughes *et al.* (2001, Document ID 1060) and McDonald *et al.* (2005, Document ID 1092), allowed for individual job, exposure, and smoking histories to be taken into account in the exposure-response analysis. Hughes *et al.* (2001, Document ID 1060) found statistically significant positive exposure-response trends for lung cancer for both cumulative exposure (lagged 15 years) and average exposure concentration, but not for duration of employment. With exposure lagged 15 years and after adjusting for smoking, increasing quartiles of cumulative silica exposure were also associated with lung cancer mortality (p-value for trend = 0.04). McDonald *et al.* (2005, Document ID 1092) found very similar results, with increasing quartiles of cumulative silica exposure (lagged 15 years) associated with lung cancer mortality (p-value for trend = 0.006). Because McDonald *et al.* (2005, Document ID 1092) did not report the medians of the exposure categories, and given the similar results of both case-control studies, OSHA chose to base its risk estimates on the Hughes *et al.* (2001, Document ID 1060) study.

Miller *et al.* (2007, Document ID 1305) and Miller and MacCalman (2009, Document ID 1306) continued a follow-up mortality study, begun in 1970, of coal miners from 10 British coal mines initially followed through the end of 1992 (Miller *et al.,* 1997, Document ID 1304) and extended it to 2005. In the analysis using internal controls and Cox regression methods, the relative risk of lung cancer mortality, adjusted for concurrent dust exposure and smoking status, at a cumulative quartz exposure (lagged 15 years) equivalent of approximately 55 μg/m^3 for 45 years was 1.14 (95% C.I., 1.04 to 1.25).

ii. Risk Estimates

In the Preliminary QRA, OSHA presented estimates of excess lung cancer mortality risk from occupational exposure to crystalline silica, based on data from the five epidemiology studies discussed above (Document ID 1711). In its preliminary analysis, OSHA used background all-cause mortality and lung cancer mortality rates from 2006, as reported by the National Center for Health Statistics (NCHS) (Document ID 1104). These rates were used in life table analyses to estimate lifetime risks at the exposure levels of interest, ranging from 25 to 500 μg/m^3 respirable crystalline silica.

OSHA's preliminary estimates of lifetime excess lung cancer risk associated with 45 years of exposure to crystalline silica at 100 μg/m^3 (approximately the previous general industry PEL) ranged between 13 and 60 deaths per 1,000 workers, depending upon the study used. For exposure to the revised PEL of 50 μg/m^3, the lifetime risk estimates were in the range of between 6 and 26 deaths per 1,000 workers, depending upon the study used. For a 45 year exposure at the new action level of 25 μg/m^3, OSHA estimated the risk to range between 3 and 23 deaths per 1,000 workers. The Agency found that the results from these preliminary assessments were reasonably consistent despite the use of data from different cohorts and the reliance on different analytical techniques for evaluating dose-response relationships.

OSHA also estimated the lung cancer risk associated with 45 years of exposure to the previous construction/shipyard PEL (in the range of 250 μg/m^3 to 500 μg/m^3) to range between 37 and 653 deaths per 1,000 workers, depending upon the study used. OSHA acknowledges that the 653 deaths is the upper limit for 45 years of exposure to 500 μg/m^3, and recognizes that actual risk, to the extent that workers are exposed for less than 45 years or intermittently, is likely to be lower. In addition, exposure to 250 or 500 μg/m^3 over 45 years represents cumulative exposures of 11.25 and 22.5 mg/m^3-yrs, respectively. This range of cumulative exposure is well above the median cumulative exposure for most of the cohorts used in the preliminary risk assessment. Thus, OSHA explained that estimating lung cancer excess risks over this higher range of cumulative exposures of interest to OSHA required some degree of upward extrapolation of the exposure-response function to model these high exposures, thus adding uncertainty to the estimates.

Since the time of that original analysis, NCHS has released updated all-cause mortality and lung cancer mortality background rates from 2011.

OSHA's final risk estimates, which incorporate these updated rates, are available in this preamble at Section VI, Final Quantitative Risk Assessment and Significance of Risk.

c. Uncertainty Analysis of Pooled Studies of Lung Cancer Mortality and Silicosis Mortality

In the Preliminary QRA, OSHA recognized that risk estimates can be inherently uncertain and can be affected by confounding, selection bias, and measurement error (Document ID 1711). OSHA presented several reasons as to why it does not believe that confounding or selection bias had a substantial impact on the risk estimates for lung cancer or silicosis mortality (Document ID 1711, pp. 299–302). However, because it was more difficult to assess the importance of exposure measurement error, OSHA's contractor, ToxaChemica, Inc., commissioned Drs. Kyle Steenland and Scott Bartell to perform an uncertainty analysis to examine the effect of uncertainty due to measurement error in the pooled studies (Steenland *et al.,* 2001a, Document ID 0452; Mannetje 2002b, 1089) on the lung cancer and silicosis mortality risk estimates (ToxaChemica, Inc., 2004, Document ID 0469).

There are two main sources of error in the silica exposure measurements. The first arises from the assignment of individual workers' exposures based on either exposure measurements for a sample of workers in the same job or estimated exposure levels for specific jobs in the past when no measurements were available, via a job-exposure matrix (JEM) (Mannetje *et al.,* 2002a, Document ID 1090). The second arises from the conversion of historically-available dust measurements, typically particle count concentrations, to gravimetric respirable silica concentrations. ToxaChemica, Inc. conducted an uncertainty analysis using the raw data from the IARC multi-centric study to address these sources of error (2004, Document ID 0469).

i. Lung Cancer Mortality

To examine the effect of error in the assignment of individual exposure values in the cohorts studied by Steenland *et al.* (2001a, Document ID 0452), ToxaChemica, Inc. used a Monte Carlo analysis (a type of simulation analysis that varies the values of an uncertain input to an analysis—in this case, exposure estimates—to explore the effects of different values on the outcome of the analysis) to randomly sample new values for each worker's job-specific exposure levels from a distribution that they believed characterized the variability in exposures of individual workers in each job (see Document ID 1711, pp. 303–305). That is, ToxaChemica created a distribution of values for each member of each cohort where the mean exposure for each member was equal to the original exposure value and the distribution of exposure values was based on a log-normal distribution having a standard deviation that was based on the exposure variation observed in industrial sand plants observed by Steenland and Sanderson (2001, Document ID 0455). From this distribution, new sets of exposure values from each cohort member were randomly drawn for 50 trials. This simulation was designed to test whether sets of exposure values that were plausibly different from the original estimates would lead to substantially different results of the exposure-response analysis. Except for the simulated exposure values and the correction of a few minor errors in the original data sets, the simulation analysis used the same data as the original analyses conducted by Steenland *et al.* (2001a, Document ID 0452).

When an entire set of cumulative exposure values was assembled for all workers based on these randomly sampled values, the set was used in a conditional logistic regression to fit a new exposure-response model. The extent to which altering the exposure values led to changes in the results indicated how sensitive the previously presented risk estimates may have been to error in the exposure estimates. Among the individual cohorts, most of the mean regression coefficients resulting from the simulation analysis were consistent with the coefficients from the exposure-response analyses reported in Steenland *et al.* (2001, Document ID 0455) and ToxaChemica, Inc. (2004, Document ID 0469) (following correction for minor data entry and rounding errors). An exception was the mean of the simulation coefficients based on the South Africa gold cohort (0.26), which was lower than the previously calculated exposure coefficient (0.582). ToxaChemica, Inc. (2004, Document ID 0469) concluded that this error source probably did not appreciably change the estimated exposure-response coefficient for the pooled data set.

To examine the effect of error in estimating gravimetric respirable crystalline silica exposures from historical dust concentration data (*i.e.,* particle count data), ToxaChemica, Inc. (2004, Document ID 0469) used a procedure similar to that used to assess uncertainties in individual exposure value assignments. ToxaChemica, Inc. assumed that, for each job in the dataset, a specific conversion factor existed that related workers' exposures measured as particle concentrations to gravimetric respirable silica exposures, and that this conversion factor came from a normal distribution with a standard deviation $\sigma = \frac{1}{2}$ its mean μ. The use of a normal distribution was a reasonable choice in that it allowed the sampled conversion factors to fall above or below the original values with equal probability, as the authors had no information to suggest that error in either direction was more likely. The normal distribution also assigned higher probability to conversion values closer to the original values. The choice of the normal distribution therefore reflected the study authors' judgment that their original conversion factors were more likely to be approximately correct than not, while allowing for the possibility of significant error in the original values.

A new conversion factor was then sampled for each job from the appropriate distribution, and the complete set of sampled conversion factors was then used to re-run the risk analysis used by Steenland *et al.* (2001a, Document ID 0452). The results were similar to the coefficients originally derived from each cohort; the only coefficient substantially affected by the procedure was that for the South African cohort, with an average value of 0.350 across ten runs compared to the original value of 0.582 (*see* Table II–5, Document ID 1711, p. 307). This suggests that the results of exposure-response analyses conducted using the South African cohort are sensitive to error in exposure estimates; therefore, there is greater uncertainty due to potential exposure estimation error in an exposure-response model based on this cohort than is the case for the other nine cohorts in Steenland *et al*'s analysis.

To explore the potential effects of both kinds of random uncertainty described above, ToxaChemica, Inc. (2004, Document ID 0469) used the distributions representing the error in job-specific exposure assignment and the error in converting exposure metrics to generate 50 new exposure simulations for each cohort. A study-specific coefficient and a pooled coefficient were fit for each new simulation, with the assumption that the two sources of uncertainty were independent. The results indicated that the only cohort for which the mean of the exposure coefficients derived from the 50 simulations differed substantially from the previously calculated exposure

coefficient was the South African gold cohort (simulation mean of 0.181 vs. original coefficient of 0.582). For the pooled analysis, the mean coefficient estimate from the simulations was 0.057, just slightly lower than the previous estimate of 0.060. Based on these results, OSHA concludes that random error in the underlying exposure estimates in the Steenland *et al.* (2001a, Document ID 0452) pooled cohort study of lung cancer is not likely to have substantially influenced the original risk estimates derived from the pooled data set, although the model coefficient for one of the ten cohorts (the South African gold miner cohort) appeared to be sensitive to measurement errors (*see* Table II–5, Document ID 1711, p. 307).

Drs. Steenland and Bartell also examined the effects of systematic bias in conversion factors, considering the possibility that these may have been consistently under-estimated or over-estimated for any given cohort. They addressed possible biases in either direction, conducting simulations where the true silica content was assumed to be either half or double the estimated silica content of measured exposures. For the conditional logistic regression model using log cumulative exposure with a 15-year lag, doubling or halving the exposure for a specific study resulted in virtually no change in the exposure-response coefficient for that study or for the pooled analysis overall. This is due to the use of log-transformed exposure metrics, which ensured that any multiplicative bias in exposure would have virtually no effect on conditional logistic regression coefficients (Document ID 0469, p. 17). That is, for this model, a systematic error in exposure estimation for any study had little effect on the lung cancer response rate for either the specific study or the pooled analysis overall.

ii. Silicosis Mortality

Following the procedures described above for the lung cancer analysis, Toxachemica, Inc. (2004, Document ID 0469) combined both sources of random measurement error in a Monte Carlo analysis of the silicosis mortality data from Mannetje *et al.* (2002b, Document ID 1089). Categorical analyses were performed with a nested case control model, in contrast to the Poisson model used previously by Mannetje *et al.* (2002b, Document ID 1089). The nested case control model was expected to control more effectively for age. This model yielded categorical rate ratio results using the original data (prior to simulation of measurement error) which were approximately 20–25 percent lower than those reported by Mannetje *et al.* (2002b, Document ID 1089). The silicosis mortality dataset thus appeared to be more sensitive to possible error in exposure measurement than the lung cancer dataset, for which the mean of the simulation coefficients was virtually identical to the original. OSHA notes that its risk estimates derived from the pooled analysis (Mannetje *et al.,* 2002b, Document ID 1089), incorporated ToxaChemica, Inc.'s simulated measurement error (2004, Document ID 0469). More information is provided in the Preliminary QRA (Document ID 1711, pp. 310–314).

d. Renal Disease Mortality

i. Exposure-Response Studies

Steenland *et al.* (2002a, Document ID 0448) examined renal disease mortality in a pooled analysis of three cohorts, as discussed previously. These cohorts were chosen because data were available for both underlying cause mortality and multiple cause mortality. The combined cohort for the pooled analysis (Steenland *et al.,* 2002a, Document ID 0448) consisted of 13,382 workers with exposure information available for 12,783 (95 percent). SMRs (compared to the U.S. population) for renal disease (acute and chronic glomerulonephritis, nephrotic syndrome, acute and chronic renal failure, renal sclerosis, and nephritis/nephropathy) were statistically significantly elevated using multiple cause data (SMR 1.29, 95% CI 1.10–1.47, 193 deaths) and underlying cause data (SMR 1.41, 95% CI 1.05–1.85, 51 observed deaths).

ii. Risk Estimates

As detailed in the Preliminary QRA, OSHA estimated that exposure to the previous (100 μg/m^3) and revised (50 μg/m^3) general industry PELs, over a 45-year working life, would result in a lifetime excess renal disease mortality risk of 39 and 32 deaths per 1,000 workers, respectively. For exposure to the previous construction/shipyard PELs, OSHA estimated the lifetime excess risk to range from 52 to 63 deaths per 1,000 workers at exposures of 250 and 500 μg/m^3, respectively. These risks reflect the 1998 background all-cause mortality and renal mortality rates for U.S. males. Background rates were not adjusted for the renal disease risk estimates because the CDC significantly changed the classification of renal diseases after 1998; they are now inconsistent with those used by Steenland *et al.* (2002a, Document ID 0448) to ascertain the cause of death of workers in their study.

e. Silicosis Morbidity

i. Exposure-Response Studies

OSHA summarized, in its Preliminary QRA, the principal cross-sectional and cohort studies that quantitatively characterized relationships between exposure to crystalline silica and the development of radiographic evidence of silicosis (Document ID 1711). Each of these studies relied on estimates of cumulative exposure to evaluate the relationship between exposure and silicosis prevalence. The health endpoint of interest in these studies was the appearance of opacities on chest radiographs indicative of pulmonary fibrosis. Most of the studies reviewed by OSHA considered a finding consistent with an ILO classification of 1/1 to be a positive diagnosis of silicosis, although some also considered an x-ray classification of 1/0 or 0/1 to be positive. OSHA noted its belief, in the Preliminary QRA, that the most reliable estimates of silicosis morbidity, as detected by chest radiographs, come from the studies that evaluated radiographs over time, included radiographic evaluation of workers after they left employment, and derived cumulative or lifetime estimates of silicosis disease risk. OSHA also pointed out that the low sensitivity of chest radiography in detecting silicosis suggests that risk estimates derived from radiographic evidence likely underestimate the true risk.

Hnizdo and Sluis-Cremer (1993, Document ID 1052) described the results of a retrospective cohort study of 2,235 white gold miners in South Africa. A total of 313 miners had developed silicosis (x-ray with ILO 1/1 or greater) and had been exposed for an average of 27 years at the time of diagnosis. The average latency for the cohort was 35 years (range of 18–50 years) from the start of exposure to diagnosis. The average respirable dust exposure for the cohort overall was 290 μg/m^3 (range 110–470), corresponding to an estimated average respirable silica concentration of 90 μg/m^3 (range 33–140). The average cumulative dust exposure for the overall cohort was 6.6 mg/m^3-yrs (range 1.2–18.7). Silicosis risk increased exponentially with cumulative exposure to respirable dust in models using log-logistic regression. Using the exposure-response relationship developed by Hnizdo and Sluis-Cremer (1993, Document ID 1052), and assuming a quartz content of 30 percent in respirable dust, Rice and Stayner (1995, Document ID 0418) estimated the risk of silicosis to be 13 percent for a 45-year exposure to 50 μg/m^3 respirable crystalline silica.

Steenland and Brown (1995b, Document ID 0451) studied 3,330 South Dakota gold miners who had worked at least a year underground between 1940 and 1965. Chest x-rays were obtained in cross-sectional surveys in 1960 and 1976 and used along with death certificates to ascertain cases of silicosis; 128 cases were found via death certificate, 29 were found by x-ray (defined as ILO 1/1 or greater), and 13 were found by both. OSHA notes that the inclusion of death certificate diagnoses complicates interpretation of the risk estimate from this study since, as noted by Finkelstein (2000, Document ID 1015), it is not known how well such diagnoses correlate with ILO radiographic interpretations; as such, the risk estimates derived from this study may not be directly comparable to others that rely exclusively on radiographic findings to evaluate silicosis morbidity risk. The mean exposure concentration was 50 μg/m^3 for the overall cohort, with those hired before 1930 exposed to an average of 150 μg/m^3. The average duration of exposure for workers with silicosis was 20 years (s.d. = 8.7) compared to 8.2 years (s.d. = 7.9) for the rest of the cohort. This study found that cumulative exposure was the best disease predictor, followed by duration of exposure and average exposure. Lifetime risks were estimated from Poisson regression models using standard life table techniques; the results indicated an estimated risk of 47 percent associated with 45 years of exposure to 90 μg/m^3 respirable crystalline silica, which reduced to 35 percent after adjustment for age and calendar time.

OSHA used the same life table approach as described for estimating lung cancer and NMRD mortality risks to estimate lifetime silicosis risk based on the silicosis rates, adjusted for age and calendar time, calculated by Steenland and Brown (1995b, Table 2, Document ID 0451). Silicosis risk was estimated through age 85, assuming exposure from age 20 through 65, and assuming that the silicosis rate remains constant after age 65. All-cause mortality rates to all males for calendar year 2006 were used to account for background competing risk. From this analysis, OSHA estimated the risk from exposure to the previous general industry PEL of 100 μg/m^3 to be 43 percent; this is somewhat higher than estimated by Steenland and Brown (1995b) because of the use by OSHA of more recent mortality data and calculation of risk through age 85 rather than 75. For exposure to the revised PEL of 50 μg/m^3, OSHA estimated the lifetime risk to be 7 percent. Since the time of the original analysis, NCHS has released updated all-cause mortality background rates from 2011; OSHA's final risk estimates, which incorporate these updated rates, are available in Section VI, Final Quantitative Risk Assessment and Significance of Risk.

Miller *et al.* (1995, Document ID 1097; 1998, 0374) and Buchanan *et al.* (2003, Document ID 0306) reported on a follow-up study conducted in 1990 and 1991 of 547 survivors of a 1,416 member cohort of Scottish coal workers from a single mine. These men all worked in the mine during a period between early 1971 and mid-1976, during which they had experienced ''unusually high concentrations of freshly cut quartz in mixed coalmine dust'' (Document ID 0374, p.52). Thus, this cohort allowed for the study of exposure-rate effects on the development of silicosis. The men all had radiographs dating from before, during, or just after this high concentration period, and the 547 participating survivors received follow-up chest x-rays between November 1990 and April 1991.

Buchanan *et al.* (2003, Document ID 0306) presented logistic regression models in stages. In the first stage they compared the effect of pre- vs. post-1964 cumulative quartz exposures on odds ratios; this yielded a statistically significant odds ratio estimate for post-1964 exposures. In the second stage they added total dust levels both pre- and post-1964, age, smoking status, and the number of hours worked pre-1954; only post-1964 cumulative exposures remained significant. Finally, in the third stage, they started with only the statistically significant post-1964 cumulative exposures, and separated these exposures into two quartz bands, one for exposure to concentrations less than 2,000 μg/m^3 respirable quartz and the other for concentrations greater than or equal to 2,000 μg/m^3. Both concentration bands were highly statistically significant in the presence of the other, with the coefficient for exposure concentrations greater than or equal to 2000 μg/m^3 being three times that of the coefficient for concentrations less than 2000 μg/m^3. From this, the authors concluded that their analysis showed that ''the risks of silicosis over a working lifetime can rise dramatically with exposure to such high concentrations over a timescale of merely a few months'' (Buchanan *et al.* 2003, Document ID 0306, p. 163). The authors then used the model to estimate the risk of acquiring a chest x-ray classified as ILO category 2/1+, 15 years after exposure, as a function of both low (<2000 μg/m^3) and high (>2000 μg/m^3) quartz concentrations. OSHA chose to use this model to estimate the risk of radiological silicosis consistent with an ILO category 2/1+ chest x-ray for several exposure scenarios; in each, it assumed 45 years of exposure, 2000 hours/year of exposure, and no exposure above a concentration of 2000 μg/m^3. The results showed that occupational exposures to the revised PEL of 50 μg/m^3 led to an estimated risk of 55 cases per 1,000 workers. Exposure at the previous general industry PEL of 100 μg/m^3 increased the estimate to 301 cases per 1,000 workers. At higher exposure levels the risk estimates rose quickly to near certainty.

Chen *et al.* (2001, Document ID 0332) reported the results of a retrospective study of a Chinese cohort of 3,010 underground miners who had worked in tin mines at least one year between 1960 and 1965. They were followed through 1994, by which time 2,426 (80.6 percent) workers had either retired or died, and only 400 (13.3 percent) remained employed at the mines. Annual radiographs were taken beginning in 1963 and cohort members continued to have chest x-rays taken every 2 or 3 years after leaving work. Silicosis was diagnosed when at least 2 of 3 radiologists classified a radiograph as being a suspected case or at Stage I, II, or III under the 1986 Chinese pneumoconiosis roentgen diagnostic criteria, which the authors reported agreed closely with ILO categories 0/1, Category 1, Category 2, and Category 3, respectively. Silicosis was observed in 33.7 percent of the group; 67.4 percent of the cases developed after exposure ended.

Chen *et al.* (2001, Document ID 0332) found that a Weibull model provided the best fit to relate cumulative silicosis risk to eight categories of cumulative total dust exposure. The risk of silicosis was strongly related to cumulative silica exposure. The investigators predicted a 55-percent risk of silicosis associated with 45 years of exposure to 100 μg/m^3. The paper did not report the risk associated with a 45-year exposure to 50 μg/m^3, but OSHA estimated the risk to be about 17 percent (based on the parameters of the Weibull model).

In a later study, Chen *et al.* (2005, Document ID 0985) investigated silicosis morbidity risks among three cohorts to determine if the risk varied among workers exposed to silica dust having different characteristics. The cohorts consisted of 4,547 pottery workers, 4,028 tin miners, and 14,427 tungsten miners, all employed after January 1, 1950 and selected from a total of 20 workplaces. The approximate

mean cumulative exposures to respirable silica for pottery, tin, and tungsten workers were 6.4 mg/m^3-yrs, 2.4 mg/m^3-yrs, and 3.2 mg/m^3-yrs, respectively. Measurement of particle surface occlusion (presence of a mineral coating that may affect the biological availability of the quartz component) indicated that, on average, 45 percent of the surface area of respirable particles collected from pottery factory samples was occluded, compared to 18 percent of the particle surface area for tin mine samples and 13 percent of particle surface area for tungsten mines. When cumulative silica exposure was adjusted to reflect exposure to surface-active quartz particles (*i.e.,* not occluded), the estimated cumulative risk among pottery workers more closely approximated those of the tin and tungsten miners, suggesting to the authors that alumino silicate occlusion of the crystalline particles in pottery factories at least partially explained the lower risk seen among pottery workers, despite their having been more heavily exposed. Based on Chen *et al.* (2005, Document ID 0985), OSHA estimated the cumulative silicosis risk associated with 45 years of exposure to 100 μg/m^3 respirable crystalline silica to be 6 percent for pottery workers, 12 percent for tungsten miners, and 40 percent for tin miners. For 45 years of exposure to 50 μg/m^3, cumulative silicosis morbidity risks were estimated to be 2 percent for pottery workers, 2 percent for tungsten miners, and 10 percent for tin miners.

ii. Risk Estimates

OSHA's risk estimates for silicosis morbidity ranged between 60 and 773 per 1,000 workers for a 45-year exposure to the previous general industry PEL of 100 μg/m^3, and between 20 and 170 per 1,000 workers for a 45-year exposure to the revised PEL of 50 μg/m^3, depending upon the study used. OSHA recognizes that actual risk, to the extent that workers are exposed for less than 45 years or intermittently, is likely to be lower, but also recognizes that silicosis can progress for years after exposure ends. Also, given the consistent finding of a monotonic exposure-response relationship for silicosis morbidity with cumulative exposure in the studies reviewed, OSHA continues to find that cumulative exposure is a reasonable exposure metric upon which to base risk estimates in the exposure range of interest.

D. Comments and Responses Concerning Silicosis and Non-Malignant Respiratory Disease Mortality and Morbidity

In this section, OSHA focuses on comments pertaining to the literature used by the Agency to assess risk for silicosis and non-malignant respiratory disease (NMRD) mortality and morbidity. As discussed in the Review of Health Effects Literature and Preliminary QRA (Document ID 1711) and in Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA, of this preamble, OSHA used two studies (ToxaChemica, 2004, Document ID 0469; Park *et al.,* 2002, 0405) to determine lifetime risk for silicosis and NMRD mortality and five studies (Buchanan *et al.,* 2003, Document ID 0306; Chen *et al.,* 2001, 0332; Chen *et al.,* 2005, 0985; Hnizdo and Sluis-Cremer, 1993, 1052; and Steenland and Brown, 1995b, 0451) to determine cumulative risk for silicosis morbidity. OSHA discussed the reasons for selecting these scientific studies for quantitative risk assessment in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 340–342). Briefly, OSHA concluded that the aforementioned studies used scientifically accepted techniques to measure silica exposures and health effects in order to determine exposure-response relationships. The Agency believed, and continues to believe, that these studies, as a group, provide the best available evidence of the exposure-response relationships between silica exposure and silicosis morbidity, silicosis mortality, and NMRD mortality and that they constitute a solid and reliable foundation for OSHA's final risk assessment.

OSHA received both supportive and critical comments and testimony regarding these studies. Comments largely focused on how the authors of these studies analyzed their data, and concerns expressed by commenters generally focused on exposure levels and measurement, potential biases, confounding, statistical significance of study results, and model forms. This section does not include extensive discussion on exposure measurement error, potential biases, thresholds, confounding factors, and the use of the cumulative exposure metric, which are discussed in depth in other sections of this preamble, including V.J Comments and Responses Concerning Biases in Key Studies and V.K Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis. OSHA addresses comments on general model form and various other issues here and concludes that these comments do not meaningfully affect OSHA's reliance on the studies discussed herein or the results of the Agency's final risk assessment.

1. Silicosis and NMRD Mortality

There are two published studies that report quantitative risk assessments of silicosis and NMRD mortality (*see* Document ID 1711, pp. 292–298). The first is an exposure-response analysis of diatomaceous earth (DE) workers (Park *et al.,* 2002, Document ID 0405). Park *et al.* quantified the relationship between cristobalite exposure and mortality caused by NMRD, which includes silicosis, pneumoconiosis, emphysema, and chronic bronchitis (Park *et al.* refers to these conditions as ''lung disease other than cancer (LDOC),'' while OSHA uses the term ''NMRD''). Because NMRD captures much of the silicosis misclassification that results in underestimation of the disease and includes risks from other lung diseases associated with crystalline silica exposures, OSHA believes the risk estimates derived from the Park *et al.* study reasonably reflect the risk of death from silica-related respiratory diseases, including silicosis (Document ID 1711, pp. 297–298). The second study (Mannetje *et al.* 2002b, Document ID 1089) is a pooled analysis of six epidemiological studies that were part of an IARC effort. OSHA's contractor ToxaChemica later conducted a reanalysis and uncertainty analysis using these data (ToxaChemica, 2004, Document ID 0469). OSHA believes that the estimates from the pooled study represent credible estimates of mortality risk from silicosis across a range of industrial workplaces, but are likely to understate the actual risk because silicosis is under-reported as a cause of death.

a. Park *et al.* (2002)

The American Chemistry Council (ACC) submitted several comments pertaining to the Park *et al.* (2002, Document ID 0405) study, including comments on the cohort's exposure concentrations. In its post-hearing brief, the ACC noted that the mean crystalline silica exposure in Park's DE cohort was estimated to be more than three times the former general industry PEL of 100 μg/m^3 and the mean estimated exposure of the workers with silicosis could have been close to 10 times that level. According to the ACC, extrapolating risks from the high exposure levels in this cohort to the much lower levels relevant to OSHA's risk assessment (the previous general industry PEL of 100

μg/m³ and the revised PEL of 50 μg/m³) is ''fraught with uncertainty'' (Document ID 4209, pp. 84–85).

OSHA acknowledges that there is some uncertainty in using models heavily influenced by exposures above the previous PEL due to potential deviance at areas of the relationship with fewer data points. However, OSHA believes that the ACC's characterization of exposures in the Park *et al.* (2002) study as vastly higher than the final and former PELs is incorrect. The ACC focused on mean exposure concentrations, reported by Park *et al.* as 290 μg/m³, to make this argument (Document ID 0405, p. 37). However, in the Park *et al.* study, the mean cumulative exposure of the cohort was 2.16 mg/m³-yrs, lower than what the final rule would permit over 45 years of exposure (2.25 mg/m³-yrs) (Document ID 0405, p. 37). Thus, whereas some participants in the Park *et al.* study had higher average-8-hour exposures than were typical under the previous PEL, they were quite comparable to the exposures workers might accumulate over their working lives under the final PEL of 50 μg/m³. In addition, as discussed in Section V.M, Comments and Responses Concerning Working Life, Life Tables, and Dose Metric, OSHA believes that the evidence in the rulemaking record, including comments and testimony from NIOSH (Document ID 3579, Tr. 127), Kyle Steenland, Ph.D. (Document ID 3580, Tr. 1227), and OSHA peer reviewer Kenneth Crump, Ph.D. (Document ID 1716, p. 166), points to cumulative exposure as a reasonable and appropriate dose metric for deriving exposure-response relationships. In sum, OSHA does not agree that the Park study should be discounted based on the ACC's concerns about the estimated exposure concentrations in the diatomaceous earth cohort.

The ACC also criticized the Park study for its treatment of possible confounding by smoking and exposure to asbestos. The ACC commented in its pre-hearing brief that data on smoking was available for only half of the cohort (Document ID 2307, Attachment A, p. 108). The Panel also wrote that, ''while Park *et al.* dismissed asbestos as a potential confounder and omitted asbestos exposure in their final models, the situation is not as clear-cut as they would have one believe'' (Document ID 2307, Attachment A, p. 109). The Panel highlighted that Checkoway *et al.* (1997), the study upon which Park relied to dismiss asbestos as a potential confounder, noted that ''misclassification of asbestos exposure may have hindered our ability to control for asbestos as a potential confounder'' (Document ID 0326, p. 685; 2307, Attachment A, p. 109).

OSHA has reviewed the ACC's concerns, and maintains that Park *et al.* adequately addressed the issues of possible confounding by smoking and exposure to asbestos in this data set. Smoking habits of a third of the individuals who died from NMRD were known in the Park *et al.* (2002) study. Based on that partial knowledge of smoking habits, Park *et al.* presented analyses indicating that confounding by smoking was unlikely to significantly impact the observed relationship between cumulative exposure to crystalline silica and NMRD mortality (Document ID 0405, p. 41). Specifically, Park *et al.* (2002) performed internally standardized analyses, which tend to be less susceptible to confounding by smoking since they compare the mortality experience of groups of workers within the cohort rather than comparing the mortality experience of the cohort with an external population (such as by using national mortality rates); the authors found that the internally standardized models yielded only slightly lower exposure-response coefficients than externally adjusted models (Document ID 0405; 1711, p. 302). These results suggested that estimates of NMRD mortality risks based on this cohort are not likely to be exaggerated due to cohort members' smoking habits. Park *et al.* also stated that the authors' findings regarding possible confounding by smoking were consistent with those of Checkoway *et al.*, who also concluded there it was ''very unlikely'' that smoking could explain the association between mortality from NMRD and silica exposure in this cohort (Document ID 0405, p. 41; 0326, p. 687). NIOSH noted that ''[r]esidual confounding from poorly characterized smoking could have an effect,'' but that effect could be either positive or negative (Document ID 4233, pp. 32–33). While OSHA agrees that comprehensive smoking data would be ideal, the Agency believes that the approach taken by Park *et al.* to address this issue was reasonable.

Asbestos exposure was estimated for all workers in Park *et al.*, which enabled the researchers to directly test confounding. They ''found no confounding by asbestos'' and, accordingly, omitted asbestos exposure in their final modeling (Document ID 0405, p. 41). As discussed in the Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 301–302), exposure to asbestos was particularly prevalent among workers employed prior to 1930; after 1930, asbestos was presumably no longer used in the process (Gibbs, 1998, Document ID 1024, p. 307; Checkoway *et al.*, 1998, 0984, p. 309). Checkoway *et al.* (1998), who evaluated the issue of asbestos confounding for the same cohort used by Park *et al.*, found that the risk ratio for the highest silica exposure group after excluding the workers employed before 1930 from the cohort (Relative Risk (RR) = 1.73) was almost identical to the risk ratio of the high-exposure group before excluding those same workers (RR = 1.74) (Document ID 0984, p. 309). In addition, Checkoway's reanalysis of the original cohort study (Checkoway *et al.*, 1993) examined those members of the cohort for whom there was quantitative information on asbestos exposure, based on a mixture of historical exposure monitoring data, production records, and recorded quantities of asbestos included in mixed products of the plant (Checkoway *et al.*, 1996, Document ID 0325). The authors found an increasing trend in lung cancer mortality with exposure to crystalline silica after controlling for asbestos exposure and found only minor changes in relative risk estimates after adjusting for asbestos exposure (1996, Document ID 0325). Finally, Checkoway *et al.* (1998) reported that the prevalence of pleural abnormalities (indicators of asbestos exposure) among workers hired before 1930 (4.2 percent) was similar to that of workers hired after 1930 who presumably had no asbestos exposure (4.9 percent), suggesting that asbestos exposure was not a confounder for lung abnormalities in this group of workers (Document ID 0984, p. 309). Therefore, Checkoway *et al.* (1998) concluded that asbestos was not likely to significantly confound the exposure-response relationship observed between lung cancer mortality and exposure to crystalline silica in diatomaceous earth workers.

Rice *et al.* also utilized Checkoway's (1997, Document ID 0326) data to test for confounding by asbestos in their Poisson and Cox proportional hazards models. Finding no evidence of confounding, Rice *et al.* did not include asbestos exposure as a variable in the final models presented in their 2001 paper (Document ID 1118, p. 41). Based on these numerous assessments of the effects of exposure to asbestos in the diatomaceous earth workers cohort used by Park *et al.* (2002), OSHA concludes that concerns about asbestos confounding in this cohort have been adequately addressed and that the additional analyses performed by Park *et al.* on this issue confirmed the findings of prior researchers that

confounding by asbestos exposure was not likely to have a large effect on exposure-response relationships.

The ACC also expressed concern about model selection. Louis Anthony Cox, Jr., Ph.D., of Cox Associates, on behalf of the ACC, was concerned that the linear relative rate model was not appropriate because it is not designed to test for exposure-response thresholds and, similarly, the ACC has argued that threshold models are appropriate for crystalline silica-related diseases (Document ID 2307, Attachment 4, pp. 91). The ACC claimed that the Park *et al.* (2002) study is ''fully consistent'' with a threshold above the 100 μg/m^3 concentration for NMRD, including silicosis, mortality (Document ID 2307, Attachment A, p. 107).

In its post-hearing comments, NIOSH explained that categorical analysis for NMRD indicated no threshold existed with cumulative exposure corresponding to 25 μg/m^3 over 40 years of exposure, which is below the cumulative exposure equivalent to the new PEL over 45 years (Document ID 4233, p. 27). Park *et al.* did not estimate a threshold below that level because the data lacked the power needed to discern a threshold (Document ID 4233, p. 27). OSHA agrees with NIOSH's assessment. In addition, as discussed extensively in Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases, OSHA has carefully reviewed the issue of thresholds and has concluded, based on the best available evidence, that workers with cumulative and average exposure levels permitted under the previous PEL of 100 μg/m^3 are at risk of silica-related disease (that is, there is unlikely to be an exposure-response threshold at or near 100 μg/m^3). For these reasons, OSHA disagrees with Dr. Cox's criticism of Park *et al.*'s reliance on the linear relative rate model.

The ACC then questioned the use of unlagged cumulative exposures as the metric in Park et al. (2002). Dr. Cox noted that ''[u]nlagged models are not very biologically plausible for dust-related NMRD deaths (if any) caused by exposure concentrations in the range of interest. Unresolved chronic inflammation and degradation of lung defenses takes years to decades to manifest'' (Document ID 2307, Attachment 4, p. 92). OSHA considers this criticism overstated. Park *et al.* considered a range of lag periods, from two years to 15. They found that ''[u]nlagged models seemed to provide the best fit to the data in Poisson analyses although lagged models performed almost as well'' (Document ID 0405, p. 37). Based on those findings, as well as acknowledgments that NMRD effects other than silicosis (*e.g.*, chronic bronchitis) may be observable without a relatively long lag time (unlike cancer) and that the majority of deaths observed in the cohort were indeed NMRD other than silicosis, the researchers decided to use an unlagged model. Because Park found the differences between the lagged and unlagged models for this cohort and the NMRD endpoint to be insignificant, OSHA finds that Park's final choice to use an unlagged model does not detract from OSHA's decision to utilize lagged models in its risk assessment.

The ACC was also concerned about the truncation of cumulative exposures in the Park *et al.* (2002) paper. Peter Morfeld, Dr. rer. medic, stated that Park *et al.*:

> suffers from a methodological drawback. . . . The authors truncated the cumulative RCS dust exposures before doing the final analyses based on their observation of where the cases were found. The maximum in the study was 62.5 mg/m^3-years but exposures were only used up to 32 mg/m^3-years because no LDOC deaths occurred at exposures higher than that level. Such a selection distorts the estimated exposure-response relationship because it is based on the outcome of the study and on the exposure variable. Because high exposures with no effects were deliberately ignored, the exposure-response effect estimates are biased upward (Document ID 2307, Attachment 2, p. 27).

OSHA acknowledges this concern about the truncation of data in the study, and asked Mr. Park about it at the public hearing. Mr. Park testified that there were good reasons to truncate the part of the exposed workforce at the high end of cumulative exposure. He noted several plausible reasons for the drop-off in the number of cases at high exposures (attenuation), including random variance in susceptibility to disease among different people and the healthy worker survivor effect [6] (Document ID 3579, Tr. 242–243). He also stated that this attenuation is a common occurrence in studies of workers (Document ID 3579, Tr. 242). Mr. Park then emphasized that how one describes the higher end of the exposure-response relationship is inconsequential for the risk assessment process because the relationship at the lower end of the spectrum, where the PEL was determined, is more important for rulemaking (Document ID 3579, Tr. 242–243). He also stated, in a post-hearing comment, that ''[f]or the purpose of low exposure extrapolation, adding a quadratic term [to better describe the entirety of the exposure-response relationship] would result in loss of precision with no advantage [gained] over truncation of high cumulative exposure observation time'' (Document ID 4233, p. 26). To summarize, Mr. Park stated that there are good scientific reasons to expect attenuation of exposure-response at the high end of the cumulative exposure range and that use of higher-exposure data affected by healthy worker survivor effect or other issues could reduce precision of the exposure-response model at the lower exposures that are more relevant to the final silica standard. OSHA finds that Mr. Park's approach in his study, along with his explanations in the rulemaking record, are reasonable and that he has fully responded to the concerns of the ACC.

Dr. Morfeld also noted that alternative techniques that do not require truncation are available to account for a healthy worker survivor effect (Document ID 2307, Attachment 2, pp. 27–28). OSHA believes such techniques, such as g-estimation, to be relatively new or not yet in standard use in occupational epidemiology. As discussed above, OSHA finds Mr. Park's approach in his study to be reasonable.

Finally, Dr. Cox stated in his comments that:

> key studies relied on by OSHA, such as Park *et al.* (2002), do not correct for biases in reported ER [exposure-response] relations due to residual confounding by age (within age categories), *i.e.*, the fact that older workers may tend to have both higher lung cancer risks and higher values of occupational exposure metrics, even if one does not cause the other. This can induce a non-causal association between the occupational exposure metrics and the risk of cancer (Document ID 2307, Attachment 4, p. 29).

Confounding occurs in an epidemiological study when the contribution of a causal factor cannot be separated from the effect of another variable (*e.g.*, age) not accounted for in the analysis. Residual confounding occurs when attempts to control for confounding are not precise enough (*e.g.*, controlling for age by using groups with age spans that are too wide), or subjects are misclassified with respect to confounders (Document ID 3607, p. 1). However, the Park *et al.* (2002) study of non-malignant respiratory disease mortality, which Dr. Cox cited as not

[6] Briefly, if individuals cease working due to illness, then those individuals will not be represented in cohort subgroups having the highest cumulative exposures. That exclusion may enable individuals with greater physiological resilience to silica exposures to be overrepresented in cohorts exposed to greater amounts of silica. Further discussion on the healthy worker survivor effect can be found in Section V.F, Comments and Responses on Lung Cancer Mortality.

considering residual confounding by age, actually addressed this issue by using 13 five-year age groups (<25, 25–29, 30–34, etc.) in the models (Document ID 0405, p. 37). Further discussion on residual confounding bias is found in Section V.J, Comments and Responses Concerning Biases in Key Studies.

The inclusion of Park *et al.* (2002) (Document ID 0405) in OSHA's risk assessment has additional support in the record. OSHA's expert peer-review panel supported including the Park *et al.* study in the risk assessment, with Gary Ginsberg, Ph.D., stating that it ''represents a reasonable estimate of silica-induced total respiratory mortality'' (Document ID 3574, p. 29). In addition, as OSHA noted in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 355–356), the Park *et al.* study is complemented by the Mannetje *et al.* multi-cohort silicosis mortality pooled study, which included several cohorts that had exposure concentrations in the range of interest for this rulemaking and also showed clear evidence of significant risk of silicosis and other NMRD at the previous general industry and construction PELs (2002b, Document ID 1089).

b. Mannetje *et al.* (2002b) and ToxaChemica (2004)

The ACC also submitted several comments on the Mannetje *et al.* (2002b) study of silicosis mortality; the data from Mannetje *et al.* were used in the ToxaChemica (2004) re-analysis. As noted above, the Mannetje *et al.* (2002b) study was a pooled analysis of silicosis mortality data from six epidemiological cohorts. This study showed a statistically significant association between silicosis mortality and workers' cumulative exposure, as well as with average exposure and exposure duration. The ACC's pre-hearing brief stated that the study ''provided no justification for the relative rate model forms [Mannetje *et al.*] used to evaluate exposure-response'' (Document ID 2307, Attachment A, p. 113). The concern expressed was that the study may not have considered all potential exposure-response relationships and was unable to discern differences between monotonic and non-monotonic characteristics (Document ID 2307, Attachment A, p. 113–114).

Mannetje *et al.* (2002b, Document ID 1089) did not discuss whether models other than relative rate models were tested. However, Mannetje's data was reexamined by ToxaChemica, Inc. on request from OSHA and the reexamined data was used by OSHA to help estimate lifetime risk for silicosis mortality (2004, Document ID 0469; 1711, pp. 310–314). The ToxaChemica reanalysis of the data included a categorical analysis and a five-knot restricted spline analysis, in addition to a logistic model, using the log of cumulative exposure (Document ID 0469, p. 50). ToxaChemica also corrected some errors found in the original data set and used a nested case-control approach, which they stated would control more precisely for age than the Poisson regression approach used by Mannetje *et al.* (Document ID 0469, p. 18). As shown in Figure 5 of ToxaChemica's report, the restricted spline model (which has considerable flexibility to represent non-monotonic features of exposure-response data) appeared to be monotonic, while the categorical analysis appeared largely monotonic but for one exposure group (Document ID 0469, p. 40, 50). When not adjusted for measurement error, the second highest exposure group deviated from the monotonic relationship existing between the other groups. However, the deviation was resolved when two sources of measurement error were accounted for (Document ID 0469, p. 40). The categorical analysis, restricted spline model, and logistic model yielded roughly similar exposure-response curves (Document ID 0469, p. 50). OSHA concludes that the ToxaChemica reanalysis addresses the concerns raised by the ACC by finding similar exposure-response relationships regardless of the model as well as providing greater validation of a monotonic curve.

The ACC next questioned the odds ratios generated in the Mannetje *et al.* (2002b) study (Document ID 2307, p. 114; 4209, p. 88). The Panel noted that ''the exposure-response relationship is not even fully monotonic'' and that the silica odds ratios in the pooled analysis have overlapping confidence intervals, suggesting no statistically significant difference (Document ID 2307, p. 114). The Panel concluded that ''the data indicate that there is no clear effect of exposure on odds ratios over the entire range considered by the authors; hence, the study provides no basis for concluding that reducing exposures will reduce the odds ratio for silicosis mortality'' (Document ID 4209, p. 88). Essentially, the ACC argued that the data do not appear to fit a monotonic relationship and that the confidence intervals for each exposure level overlap too much to discern any differences in risk ratios between those exposures.

OSHA believes that the ACC overstated its contention about confidence interval overlap between groups in the Mannetje *et al.* (2002b) paper. Although the original data set reported in the study lacks a monotonic relationship on the upper end of the exposure spectrum (>9.58 mg/m^3-yrs) (possibly due to a healthy worker survivor effect, as explained above), OSHA notes that the 95 percent confidence intervals reported do not contradict the presence of a monotonic relationship (Document ID 1089). First, the confidence intervals of the lower exposed groups did not overlap with those of the higher exposed groups in that study (Document ID 1089). Second, even if they did, overlap in confidence intervals does not mean that there is not a significant difference between those groups. While it is true that, if 95 percent confidence intervals do not overlap, the represented populations are statistically significantly different, the converse—that, if confidence intervals do overlap, there is no statistically significant difference—is not always true (Nathaniel Schenker and Jane F. Gentleman. ''On Judging the Significance of Differences by Examining the Overlap Between Confidence Intervals.'' The American Statistician. 55(3): 2001. 182–186. (*http://www.tandfonline.com/doi/abs/10.1198/000313001317097960*).

Finally, as discussed above and in detail in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis, the ToxaChemica *et al.* (2004) re-analysis of the corrected Mannetje *et al.* (2002b) data adjusting for two sources of measurement error resulted in a monotonic relationship for the risk ratios (Document ID 0469).

2. Silicosis Morbidity

OSHA relied on five studies for determining risk for silicosis morbidity: Buchanan *et al.*, 2003 (Document ID 0306), Chen *et al.*, 2001 (Document ID 0332), Chen *et al.*, 2005 (Document ID 0985), Hnizdo and Sluis-Cremer, 1993 (Document ID 1052), and Steenland and Brown, 1995b (Document ID 0451). OSHA finds that the most reliable estimates of silicosis morbidity, as detected by chest radiographs, come from these five studies because they evaluated radiographs over time, included post-employment radiographic evaluations, and derived cumulative or lifetime estimates of silicosis disease risk. OSHA received several comments about these studies.

a. Buchanan *et al.* (2003)

Buchanan *et al.* (2003) reported on a cohort of Scottish coal workers (Document ID 0306). The authors found a statistically significant relationship

between silicosis and cumulative exposure acquired after 1964 (Document ID 0306). They also found that the risks of silicosis over a working lifetime can rise dramatically with exposure to high concentrations over a timescale of merely a few months (Document ID 0306). In the Preliminary QRA, OSHA considered this study to be of the highest overall quality of the studies relied upon to assess silicosis morbidity risks, in large measure because the underlying exposure data was based on modern exposure measurement methods and avoided the need to estimate historical exposures. The risk estimates derived from this study were lower than those derived from any of the other studies criticized by the ACC. One reason for this is because Buchanan *et al.* only included cases with chest x-ray findings having an ILO score of 2/1 or higher, whereas the other studies included cases with less damage, having a lower degree of perfusion on x-ray (ILO 1/0 or 1/1) (Document ID 0306). Thus, OSHA considered the risk estimates derived from the Buchanan *et al.* study to be more likely to understate risks.

Dr. Cox commented that age needed to be included for modeling in Dr. Miller's 1998 paper, the data from which were used in the Buchanan *et al.* (2003) paper (Document ID 2307, Attachment 4, p. 97). However, the Miller *et al.* (1998) study explicitly states that age was one of several variables that were tried in the model but did not improve the model's fit, as was time spent working in the poorly characterized conditions before 1954 (Document ID 0374, p. 57). OSHA concludes that the original paper did assess these variables and how they related to the exposure-response relationship. Buchanan *et al.* (2003) also noted their own finding that differences in age and exposure both failed to improve fit, in agreement with Miller *et al.*'s conclusion (Document ID 0306, p. 161). OSHA therefore finds no credible reason that age should have been included as a variable in Miller *et al.* (1998).

Dr. Cox also questioned the modeling methods in the Buchanan paper, which presented logistic regression in progressive stages to search for significance (Document ID 2307, Attachment 4, pp. 97–98; 0306, pp. 161–163). Dr. Cox claimed that this is an example of uncorrected multiple testing bias where the post hoc selection of data, variables, and models can make independent variables appear to be statistically significant in the prediction model. He suggested that corrections for bias are needed to determine if the reported significance is causal or statistical (Document ID 2307, Attachment 4, pp. 97–98). OSHA peer reviewer Brian Miller, Ph.D., stated that Dr. Cox's claim that the model was affected by multiple testing bias is unfounded (Document ID 3574, pp. 31–32). He noted that the model was based on a detailed knowledge of the history of exposures at that colliery, and represented the researchers' attempt to build ''a reality-driven and 'best-fitting' model,'' (Document ID 3574, p. 31, quoting 2307, Attachment 4, p. 4). Furthermore, none of OSHA's peer reviewers raised any concerns about the approach taken by Buchanan *et al.* to develop their exposure-response model and none suggested that corrections needed to be made for multiple testing bias; all of them supported the study's inclusion in OSHA's risk assessment (Document ID 3574). Finally, the cumulative risk for silicosis morbidity derived from this study is similar to values from other papers reported in the QRA (*see* OSHA's Final Quantitative Risk Assessment in Section VI). Therefore, for the reasons discussed above, OSHA is not convinced by Dr. Cox's arguments and finds no credible reason to remove Buchanan *et al.* (2003) from consideration.

b. Chen *et al.* (2001, 2005), Steenland and Brown (1995), and Hnizdo and Sluis-Cremer (1993)

The ACC also commented on several other studies used by OSHA to estimate silicosis morbidity risks; these were the studies by Chen *et al.* (2001, Document ID 0332; 2005, 0985), Steenland and Brown (1995b, Document ID 0451), and Hnizdo and Sluis-Cremer (1993, Document ID 1052). The ACC's comments focus on uncertainties in estimating the historical exposures of cohort members (Document ID 2307, Attachment A, pp. 117–122, 124–130, 132–136). Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis, discusses the record in detail with respect to the general issue of uncertainties in estimating historical exposures to respirable crystalline silica in epidemiological studies. The issues specific to the studies relied upon by OSHA in its risk estimates for silicosis morbidity will be discussed below.

In the Chen *et al.* studies, which focused on mining (*i.e.*, tin, tungsten) and pottery cohorts, high volume area samplers collected dust and the respirable crystalline silica concentration was determined from those samples (2001, Document ID 0332; 2005, 0985). However, according to the ACC, the rest of the collected dust was not assessed for chemicals that potentially could also cause radiographic opacities (Document ID 2307, Attachment A, pp. 132–135). Neither study expressed reason to be concerned about the non-silica portion of the dust samples. OSHA recognizes that uncertainty about potential unknown exposures exists in retrospective studies, which describes most epidemiological research. However, OSHA emphasizes that the risk values derived from the Chen *et al.* studies do not differ remarkably from other silicosis morbidity studies used in the risk assessment (Document ID 0306, 1052, 0451). Therefore, OSHA concludes that it is unlikely that an unknown compound significantly impacted the exposure-response relationships reported in both Chen studies.

The study on gold miners (Steenland and Brown, 1995b, Document ID 0451), which found that cumulative exposure was the best disease predictor, followed by duration of exposure and average exposure, was also criticized by the ACC, which alleged that the exposure assessment suffered from ''enormous uncertainty'' (Document ID 2307, Attachment A, pp. 146–147). The ACC noted that exposure measurements were not available for the years prior to 1937 or after 1975 and that this limitation of the exposure information may have resulted in an underestimation of exposures (Document ID 2307, Attachment A, pp. 124–126). OSHA agrees that these are potential sources of uncertainty in the exposure estimates, but recognizes exposure uncertainty to be a common occurrence in occupational epidemiology studies. OSHA believes that the authors used the best measurement data available to them in their study.

The ACC also took issue with Steenland and Brown's conversion factor for converting particle count to respirable silica mass (10 mppcf = 100 $\mu g/m^3$), which was somewhat higher than that used in the Vermont granite worker studies (10 mppcf = 75 $\mu g/m^3$) (Document ID 2307, Attachment A, p. 126). OSHA notes that the study's reasoning for adopting that specific particle count conversion factor was to address the higher percentage of silica found in the gold mine samples applicable to their cohort in comparison to the Vermont granite study (Document ID 0451, p. 1373). OSHA finds this decision, which was based on the specific known exposure conditions of this cohort, to be reasonable.

With respect to the Hnizdo and Sluis-Cremer (1993, Document ID 1052)

study, which found that silicosis risk increased exponentially with cumulative exposure to respirable dust (Document ID 1052, p. 447), the ACC questioned three assumptions the study made about exposures. First, exposures were assumed to be static from the 1930s to the 1960s, based on measurements from the late 1950s to mid-1960s, an assumption that, according to the ACC, might underestimate exposure for workers employed before the late 1950s (Document ID 2307, Attachment A, pp. 117–119). Second, although respirable dust, by definition, includes particles up to 10 μm, the study only considered particles sized between 0.5 and 5 μm in diameter (Document ID 1052, p. 449). The ACC contends this exclusion may have resulted in underestimated exposure and overestimated risk (Document ID 2307, Attachment A, p. 119). OSHA agrees that uncertainty in exposure estimates is an important issue in the silica risk assessment, and generally discusses the issue of exposure measurement uncertainty in depth in a quantitative uncertainty analysis described in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis. As discussed there, after accounting for the likely effects of exposure measurement uncertainty in the risk assessment, OSHA affirms the conclusion of the risk assessment that there is significant risk of silicosis to workers exposed at the previous PELs.

Thirdly, the ACC challenged the authors' estimate of the quartz content of the dust as 30 percent when it should have been 54 percent (Document ID 1052, p. 450; 2307, Attachment A, p. 120). According to the ACC, the 30 percent estimate was based on an incorrect assumption that the samples had been acid-washed (resulting in a reduction in silica content) before the quartz content was measured (Document ID 2307, Attachment A, pp. 120–122). This assumption would greatly underestimate the exposures of the cohort and the exposures needed to cause adverse effects, thus overestimating actual risk (Document ID 2307, Attachment A, pp. 121–122). The ACC recommended that the quartz content in the Hnizdo and Sluis-Cremer study be increased from 30 to 54 percent, based on the Gibbs and Du Toit study (2002, Document ID 1025, p. 602).

OSHA considered this issue in the Preliminary QRA (Document ID 1711, p. 332). OSHA noted that the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment reviewed the source data for Hnizdo and Sluis-Cremer, located in the Page-Shipp and Harris (1972, Document ID 0583) study, and compared them to the quartz exposures calculated by Hnizdo and Sluis-Cremer (OEHHA, 2005, Document ID 1322, p. 29). OEHHA concluded after analyzing the data that the samples likely were not acid-washed and that the Hnizdo and Sluis-Cremer paper erred in describing that aspect of the samples. Additionally, OEHHA reported data that suggests that the 30 percent quartz concentration may actually overestimate the exposure. It noted that recent investigations found the quartz content of respirable dust in South African gold mines to be less than 30 percent (Document ID 1322). In summary, OSHA concludes that no meaningful evidence was submitted to the rulemaking record that changes OSHA's original decision to include the Hnizdo and Sluis-Cremer study in its risk assessment.

Despite the uncertainties inherent in estimating the exposures of occupational cohorts in silicosis morbidity studies, the resulting estimates of risk for the previous general industry PEL of 100 $\mu g/m^3$ are in reasonable agreement and indicate that lifetime risks of silicosis morbidity at this level, and, by extension, risks at the higher previous PELs for maritime and construction (*see* section VI, Final Quantitative Risk Assessment and Significance of Risk) are in the range of hundreds of cases per 1,000 workers. Even in the unlikely event that exposure estimates underlying all of these studies were systematically understated by several fold, the magnitude of resulting risks would likely still be such that OSHA would determine them to be significant.

3. Conclusion

After carefully considering all of the comments on the studies relied on by OSHA to estimate silicosis and NMRD mortality and silicosis morbidity risks, OSHA concludes that the scientific evidence used in its quantitative risk assessment substantially supports the Agency's finding of significant risk for silicosis and non-malignant respiratory disease. In its risk estimates in the Preliminary QRA, OSHA acknowledged the uncertainties raised by the ACC and other commenters, but the Agency nevertheless concluded that the assessment was sufficient for evaluating the significance of the risk. After evaluating the evidence in the record on this topic, OSHA continues to conclude that its risk assessment (*see* Final Quantitative Risk Assessment in Section VI.C of this preamble) provides a reasonable and well-supported estimate of the risk faced by workers who are exposed to respirable crystalline silica.

E. Comments and Responses Concerning Surveillance Data on Silicosis Morbidity and Mortality

As discussed above in this preamble, OSHA has relied on epidemiological studies to assess the risk of silicosis, a debilitating and potentially fatal occupationally-related lung disease caused by exposure to respirable crystalline silica. In the proposed rule (78 FR 56273, 56298; also Document ID 1711, pp. 31–49), OSHA also discussed data from silicosis surveillance programs that provide some information about the number of silicosis-associated deaths or the extent of silicosis morbidity in the U.S. (78 FR at 56298). However, as OSHA explained, the surveillance data are not sufficient for estimating the risks of health effects associated with exposure to silica, nor are they sufficient for estimating the benefits of any potential regulatory action. This is because silicosis-related surveillance data are only available from a few states and do not provide exposure data that can be matched to surveillance data. Consequently, there is no way of knowing how much silica a person was exposed to before developing fatal silicosis (78 FR at 56298).

In addition, the available data likely understate the resulting death and disease rates in U.S. workers exposed to crystalline silica (78 FR 56298). This understatement is due in large part to: (1) The passive nature of these surveillance systems, which rely on healthcare providers' awareness of a reporting requirement and submission of the appropriate information on standardized forms to health departments; (2) the long latency period of silicosis; (3) incomplete occupational exposure histories, and (4) other factors that result in a lack of recognition of silicosis by healthcare providers, including the low sensitivity, or ability of chest x-rays to identify cases of silicosis (78 FR 56298). Specific to death certificate data, information on usual industry and occupation are available from only 26 states for the period 1985 to 1999, and those codes are not verifiable (Document ID 1711). Added to these limitations is the ''lagging'' nature of surveillance data; it often takes years for cases to be reported, confirmed, and recorded. Furthermore, in many cases, the available surveillance systems lack information about actual exposures or even information about the usual occupation or industry of the deceased individual, which could provide some information about occupational

exposure (*see* 78 FR at 56298). Therefore, the Agency did not use these surveillance data to estimate the risk of silicosis for the purpose of meeting its legal requirements to prove a significant risk of material impairment of health (*see* 29 U.S.C. 655(b)(5); *Benzene*, 448 U.S. 607, 642 (1980)).

Comments and testimony focusing on the silicosis surveillance data alleged that OSHA should have used the surveillance data in its risk estimates. Stakeholders argued that the declining numbers of reported silicosis deaths prove the lack of necessity for a new silica standard. Commenters also claimed that the surveillance data prove that OSHA overestimated both the risks at the former permissible exposure limits (PELs) and the benefits of the new rule.

After reviewing the rulemaking record, OSHA maintains its view that these silicosis surveillance data, although useful for providing context and an illustration of a significant general trend in the reduction of deaths associated with silicosis over the past 4–5 decades, are not sufficient for estimating the magnitude of the risk or the expected benefits. In the case of silicosis, surveillance data are useful for describing general trends nationally and a few states have the ability to use the data at the local or state level to identify ''sentinel events'' that would justify initiating an inspection of a workplace, for example. The overall data, however, are inadequate and inappropriate for estimating risks or benefits associated with various exposure levels, as is required of OSHA's regulatory process, in part because they significantly understate the extent of silicosis in workers in the United States and because they lack information about exposure levels, exposure sources (*e.g.*, type of job), controls, and health effects that is necessary to examine the effects of lowering the PEL. Thus, for these reasons and the ones discussed below, OSHA has continued to rely on epidemiological data to meet its burden of demonstrating that workers exposed to respirable crystalline silica at the previous PELs face a significant risk of developing silicosis and that risk will be reduced when the new limit is fully implemented. Another related concern identified by stakeholders is the apparent inconsistency between surveillance data and risk and benefits estimates derived from modeling epidemiological data (Document ID 4194, pp. 7–10; 4209, pp. 3–4). However, this difference is not an inconsistency, but the result of comparing two distinctly different items. Surveillance data, primarily death certificate data, are known to be under-reported and lack associated exposure data necessary to model relationships between various exposure levels and observance of health effects. For these reasons, OSHA relied on epidemiologic studies with detailed exposure-response relationships to evaluate the significance of risk at the preceding and new PELs. Thus, the silicosis mortality data derived from death certificates and estimates of silica-related mortality risks derived from well-conducted epidemiologic studies cannot be directly compared in any meaningful way. With respect to silicosis morbidity, OSHA notes that the estimates by Rosenman *et al.* (2003, Document ID 0420) of the number of cases of silicosis estimated to occur in the U.S. (between 2,700 and 5,475 estimated to be in OSHA's jurisdiction (*i.e.*, excluding miners)) each year is in reasonable agreement with the estimates derived from epidemiologic studies, assuming either a 13-year or 45-year working life (*see* Chapter VII, Table VII–2 of the FEA).

1. Surveillance Data on Silicosis Mortality

The principal source of data on annual silicosis mortality in the U.S. is the National Institute for Occupational Safety and Health (NIOSH) Work-Related Lung Disease (WoRLD) Surveillance System (*e.g.*, NIOSH, 2008c, Document ID 1308), which compiles cause-of-death data from death certificates reported to state vital statistics offices and collected by the National Center for Health Statistics (NCHS). Paper copies were published in 2003 and 2008 (Document ID 1307; 1308) and data are updated periodically in the electronic version on the CDC Web site (*http://www.cdc.gov/eworld*). NIOSH also developed and manages the National Occupational Respiratory Mortality System (NORMS), a data-storage and interactive data retrieval system that reflects death certificate data compiled by NCHS (*http://webappa.cdc.gov/ords/norms.html*).

From 1968 to 2002, silicosis was recorded as an underlying or contributing cause of death on 16,305 death certificates; of these, a total of 15,944 (98 percent) deaths occurred in males (CDC, 2005, Document ID 0319). Over time, silicosis-related mortality has declined in the U.S., but has not been eliminated. Based on the death certificate data, the number of recognized and coded deaths for which silicosis was an underlying or contributing cause decreased from 1,157 in 1968 to 161 in 2005, corresponding to an 86-percent decline (Document ID 1711, p. 33; 1308, p. 55) (*http://wwwn.cdc.gov/eworld*). The crude mortality rate, expressed as the number of silicosis deaths per 1,000,000 general population (age 15 and higher) fell from about 8.9 per million to about 0.5 per million over that same time frame, a decline of 94 percent (Document ID 1711, p. 33; 1308, p. 55) (*http://wwwn.cdc.gov/eworld*).

OSHA's Review of Health Effects Literature and Preliminary QRA included death certificate statistics for silicosis up to and including 2005 (Document ID 1711, p. 33). OSHA has since reviewed the more recent NORMS and NCHS data, up to and including 2013, which appear to show a general downward trend in mortality, as presented in Table V–1.

Table V-1. Total Number of Deaths with Silicosis Mentioned on Death Certificate, as an Underlying or Contributing Cause (U.S. residents, age 15 and older, all races, both sexes) 1970-2013.		
Years	Total number of Silicosis Deaths	Percent Change (Reduction)
1970-1974	4,263	
1975-1979	2,711	36%
1980-1984	1,958	28%
1985-1989	1,601	18%
1990-1994	1,389	13%
1995-1999	1,018	27%
2000-2004	809	20%
2005-2009	679	16%
2010-2013†	563	17%
Source: NORMS database (http://webappa.cdc.gov/ords/norms.html). † Represents most recent data available from CDC Wonder database (http://wonder.cdc.gov/mcd-icd10.html). Database accessed July 30, 2015.		

However, more detailed examination of the most recent data collected through NCHS (Table V–2) indicates that the decline in the number of deaths with silicosis as an underlying or contributing cause has leveled off in more recent years, suggesting that the number of silicosis deaths being recorded and captured by death certificates may be stabilizing after 30 or more years of decline.

Table V-2. Deaths Attributed to Silicosis, 2000-2013	
Year	Underlying or Contributing Cause
2000	152
2001	164
2002	148
2003	179
2004	166
2005	161
2006	126
2007	123
2008	148
2009	121
2010	101
2011	89
2012	103
2013*	111*
Source: NORMS database (http://webappa.cdc.gov/ords/norms.html). * http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a7.htm#Tab. Database accessed August 18, 2015.	

Robert Cohen, M.D., representing the American Thoracic Society, noted this apparent plateau effect, testifying that ''[t]he data from the NIOSH work-related lung disease surveillance report and others show a plateau in silicosis

mortality since the 1990s, and we are concerned that that has been the same without any further reduction for more than 20 years. So we think that we still have work to do'' (Document ID 3577, p. 775).

Some commenters raised the question about whether decedents who died more recently were exposed to high levels of silica (pre-1970s) and therefore wouldn't necessarily reflect mortalities relevant to the current OSHA standard (Document ID 4194, p. 9; 4209, pp. 7–8). OSHA has no information on the age of these decedents, or the timing of their exposure to silica. If we assume that workers born in 1940–1950 would have started working around 1960, at the earliest, and into the 1970's, and life expectancy in general of 70 years, or 60–70 years to account for years of life lost due to silicosis, most of these workers' working life would have been spent after the 1971 PEL went into effect. It is likely that some of the more recent decedents were exposed to silica prior to 1971; however, it is less likely that all were exposed prior to 1971. At the end of the day, there is no actual exposure information on these decedents, and this generalization does not account for overexposures, which have persisted over time.

2. Surveillance Data on Silicosis Morbidity

There is no nation-wide system for collecting silicosis morbidity case data. The data available are from three sources: (1) The National Hospital Discharge Survey (Document ID 1711, p. 40–43); (2) the Agency for Healthcare Research and Quality's (AHRQ) Nationwide Inpatient Survey (Document ID 3425, p. 2; *https://www.hcup-us.ahrq.gov/nisoverview.jsp*); and (3) states that administer silicosis and/or pneumoconiosis disease surveillance (*see* Document ID 1711, p. 40–43; *http://www.cdc.gov/niosh/topics/surveillance/ords/StateBasedSurveillance/stateprograms.html*).

Both of the first two sources of data on silicosis morbidity cases are surveys that provide estimates of hospital discharges. The first is the National Hospital Discharge Survey (NHDS), which was conducted annually from 1965–2010. The NHDS was a national probability survey designed to meet the need for information on characteristics of inpatients discharged from non-Federal short-stay hospitals in the United States (*see http://www.cdc.gov/nchs/nhds.htm*). Estimates of silicosis listed as a diagnosis on hospital discharge records are available from the NHDS for the years 1985 to 2010 (*see http://www.cdc.gov/nchs/nhds.htm*). National estimates were rounded to the nearest 1,000, and the NHDS has consistently reported approximately 1,000 discharges/hospitalizations annually since 1980 (*e.g.,* Document ID 1307; 1308). The second survey, the National (Nationwide) Inpatient Sample (NIS), is conducted annually by the AHRQ. Dr. Kenneth Rosenman, Division Chief and Professor of Medicine at Michigan State University and who oversees one of the few occupational disease surveillance systems in the U.S., testified that data from the NIS indicated that the nationwide number of hospitalizations where silicosis was one of the discharge diagnoses has remained constant, with 2,028 hospitalizations reported in 1993 and 2,082 in 2011 (Document ID 3425, p. 2).

Morbidity data are also available from the states that administer silicosis and/or pneumoconiosis disease surveillance. These programs rely primarily on hospital discharge records and also may get some reports of cases from the medical community and workers' compensation programs. Currently, NIOSH funds the State-Based Occupational Safety and Health Surveillance cooperative agreements (Document ID 1711, p. 40–41; *http://www.cdc.gov/niosh/topics/surveillance/ords/StateBasedSurveillance.html*). All states funded under a cooperative agreement conduct population-based surveillance for pneumoconiosis (hospitalizations and mortality), and a few states (currently Michigan and New Jersey) have expanded surveillance specifically for silicosis (Document ID 1711, p. 40–42; *http://www.cdc.gov/niosh/topics/surveillance/ords/StateBasedSurveillance/stateprograms.html*).

State-based hospital discharge data are a useful population-based surveillance data source for quantifying pneumoconiosis (including silicosis), even though only a small number of individuals with pneumoconiosis are hospitalized for that condition (Document ID 0996), and the data refer to hospitalizations with a diagnosis of silicosis, and not specific people. In addition to mortality data, NIOSH has updated its WoRLD Surveillance System with some state-based morbidity case data (*http://wwwn.cdc.gov/eworld/Grouping/Silicosis/94*). State-based surveillance systems can provide more detailed information on a few cases of silicosis.

NIOSH has published aggregated state case data in its WoRLD Reports (Document ID 1308; 1307) for two ten-year periods that overlap, 1989 to 1998 and 1993 to 2002. State morbidity case data are compiled and evaluated by variables such as ascertainment source, primary industry, and occupations. For the time period 1989 to 1998, Michigan reported 589 cases of silicosis, New Jersey 191 cases, and Ohio 400 cases (Document ID 1307, p. 69). In its last published report, for the later and partially overlapping time period 1993 to 2002, Michigan reported 465 cases, New Jersey 135, and Ohio 279 (Document ID 1308, p. 72). Data for the years 2003 to 2011, from the CDC/NIOSH electronic report, eWoRld, show a modest decline in the number of cases of silicosis in these three states; however, decreases are not nearly as substantial as are those seen in the mortality rates (see Table V–3). Annual averages for the two ten-year periods and the nine-year time period were calculated by OSHA solely for the purpose of comparing cases of silicosis reported over time.

Table V-3. Number of cases of silicosis reported to selected state surveillance systems

	1989-1998	Annual average	1993-2002	Annual average	2003-2011	Annual average
Michigan	589	59	465	47	201	22
New Jersey	191	19	135	14	102	11
Ohio	400	40	279	28		

http://wwwn.cdc.gov/eworld/Data/Silicosis_Number_of_cases_by_ascertainment_sourceMichigan_and_New_Jersey_19932011/843.

3. Critical Comments Received on Surveillance Data

Industry representatives, including ACC's Crystalline Silica Panel and Dr. Jonathan Borak, representing the Chamber of Commerce (Chamber), contended that the steep decline seen in the number and rate of silicosis deaths since 1968 proves that OSHA cannot meet its burden of demonstrating that a more protective standard is necessary (*e.g.,* Document ID 4209, p. 10; 2376, p. 8; 4016, p. 9). Similarly, other commenters, such as the American Petroleum Institute, the Independent Petroleum Association of America, the National Mining Association, the American Foundry Society (AFS), the National Utility & Excavating Contractors Association, Acme Brick, the National Ready Mixed Concrete Association, and the Small Business Administration's Office of Advocacy stated that surveillance data demonstrate that the previous OSHA PEL was sufficiently effective in reducing the number of deaths from silicosis (Document ID 3589, Tr. 4041; 4122; 2301, pp. 3, 7–9; 2211, p. 2; 2379, pp. 23–25; 2171, p. 1; 3730, p. 5; 3586, Tr. 3358–3360; 3589, Tr. 4311; 2349, pp. 3–4). Industry commenters also argued that the number of recorded silicosis-related deaths in recent years, as reflected in the surveillance data, is far lower than the number of lives that OSHA projected would be saved by a more stringent rule, indicating that OSHA's risk assessment is flawed (*e.g.,* Document ID 3578, Tr. 1074–1075; 4209, p. 3–4).

The Chamber, along with others, declared that OSHA ignored steep declines in silicosis mortality, which in its view indicates that there is no further need to reduce the PEL (Document ID 4194, pp. 7–8). OSHA has not ignored the fact that the available surveillance data indicate a decline in silicosis mortality. As discussed above and in the proposal, the Agency has acknowledged that the available surveillance data do show a decline in the silicosis mortality since 1968. Furthermore, OSHA has no information on whether underreporting has increased or decreased over time, and does not believe that differing rates of reporting and underreporting of silicosis on death certificates explains the observed decline in silicosis mortality. OSHA believes that the reductions in deaths attributable to silicosis are real, and not a statistical artifact. However, OSHA disagrees with commenters' argument that this trend shows the lack of a need for this new rule. First, as explained above, there is strong evidence that the death certificate data do not capture the entirety of silicosis mortality that actually exists, due to underreporting of silicosis as a cause of death. Second, the stakeholders' argument assumes that mortality will continue to decline, even in the absence of a stronger silica standard, and that OSHA and workers should wait for this decline to hit bottom (*e.g.,* Document ID 4209, p. 7). However, testimony in the record suggests that the decline in the number of deaths has leveled off since 2000, probably because of the deaths of those historically exposed to higher levels of silica occurred before then (*e.g.,* Document ID 3577, p. 775).

Third, the decline in silicosis deaths recorded over the past several decades cannot be solely explained by improved working conditions, but also reflects the decline in employment in industries that historically were associated with high workplace exposures to crystalline silica. One of OSHA's peer reviewers for the Review of Health Effects Literature and Preliminary QRA, Bruce Allen, commented that the observed decline in mortality ''. . . in no way adjusts for the declining employment in jobs with silica exposure,'' making ''its interpretation problematic. To emphasize the contribution of historic declines in exposure as the underlying cause is spurious; no information is given to allow one to account for declining employment'' (Document ID 3574, p. 7). The CDC/NIOSH also identified declining employment in heavy industries where silica exposure was prevalent as a ''major factor'' in the reduction over time in silicosis mortality (Document ID 0319, p. 2). As discussed below, however, some silica-generating operations or industries are new or becoming more prevalent.

In his written testimony, Dr. Rosenman pointed out that there are ''two aspects to the frequency of occurrence of disease (1) . . . the risk of disease based on the level of exposure and (2) the number of individuals at risk'' (Document ID 3425, pp. 3–4). Dr. Rosenman estimated the decline in the number of workers in Michigan foundries (75 percent) and the number of abrasive blasting companies in Michigan (71 percent), and then compared these percentages to the percentage decline in the number of recorded silicosis deaths (80 percent) over a similar time period. The similarities in these values led him to attribute ''almost all'' of the decrease in silicosis deaths to a decrease in the population at risk (Document ID 3425, pp. 3–4).

Finally, OSHA's reliance on epidemiological data for its risk assessment purposes does not suggest that the Agency ignored the available surveillance data. As discussed above, the data are inadequate and inappropriate for estimating risks or benefits associated with various exposure levels, as is required of OSHA's regulatory process. Even in the limited cases where surveillance data are available, OSHA generally relies on epidemiological data, to the extent they include sufficiently detailed information on exposures, exposure sources (*e.g.*, type of job), and health effects, to satisfy its statutory requirement to use the best available evidence to evaluate the significance of risk associated with exposure to hazardous substances.

Some stakeholders provided comments to the rulemaking record consistent with OSHA's assessment. For example, Dr. Borak stated that the surveillance data ''provide little or no basis'' (Document ID 2376, p. 8) for OSHA to evaluate the protectiveness of the previous PELs. Similarly, NIOSH asserted that relying on the surveillance data to show that there is no need for a lower PEL or that there is no significant risk at 100 $\mu g/m^3$ would be ''a misuse of surveillance data'' (Document ID 3579, Tr. 167). NIOSH also added that, because the surveillance data do not include information about exposures, it is not the kind of data that could be used for a quantitative risk assessment. NIOSH concluded that surveillance data are, in fact, ''really not germane to the risk assessment'' (Document ID 3579, Tr. 248). OSHA agrees with both Dr. Borak and NIOSH that the surveillance data cannot and do not inform the Agency on the need for a lower PEL, nor is there a role for surveillance data in making its significant risk findings. Therefore, for its findings of significant risk at the current PEL, the Agency relied on evidence derived from detailed exposure-response relationships from well-conducted epidemiologic studies, and not surveillance data, which have no associated exposure information. In this case, epidemiologic data provided the best available evidence.

In its testimony, the AFL–CIO pointed out that a recent U.S. Government Accountability Office (GAO) report on the Mine Safety and Health Administration's (MSHA) proposed coal dust standard references the National Academy of Sciences (NAS) conclusion that risk assessments based on epidemiological data, not surveillance data, were an appropriate means to assess risk for coal-dust exposures (Document ID 4204, p. 21; 4072, Attachment 48, pp. 7–8). The NAS

emphasized that the surveillance data available to MSHA did not include individual miners' levels of exposure to coal mine dust and, therefore, could not be used for the purpose of estimating disease risk for miners. ''Based on principles of epidemiology and statistical modeling, measures of past exposures to coal mine dust are critical to assessing the relationship between miners' cumulative coal mine dust exposure and their risk of developing [pneumoconiosis]'' (Document ID 4072, Attachment 48, p. 8). The same rationale applies here. Thus, OSHA's decision to rely on epidemiological data is well supported by the record.

Commenters from companies and industry groups also argued that they had no knowledge of workers acquiring silicosis in their companies or industry (*e.g.*, Document ID 2384, p. 2; 2338, p. 3; 2365, p. 2; 2185, p. 3; 2426, p. 1). OSHA received similar comments as part of a letter campaign in which over 100 letters from brick industry representatives claimed there to be little or no silicosis observed in the industry despite historical exposures above the PEL (*e.g.*, Document ID 2009). OSHA considered these comments and believes that many companies, including companies in the brick industry, may not have active medical surveillance programs for silicosis. Silicosis may not develop until after retirement as a result of its long latency period. In addition, silica exposures in some workplaces may be well below the final PEL as a result of the environment in which workers operate, including existing controls. Thus, OSHA believes that it is difficult to draw conclusions about the rate of silicosis morbidity in specific workplaces without having detailed information on medical surveillance, silica exposures, and follow-up. This is why OSHA relies heavily on epidemiological studies with detailed exposure data and extended follow-up, and uses these data to evaluate exposure-response relationships to assess health risks at the preceding and new PELs.

Commenters also argued that, due to the long latency of the disease, silicosis cases diagnosed today are the result of exposures that occurred before the former PELs were adopted, and thus reflect exposures considerably higher than the previous PELs (*e.g.*, Document ID 2376, p. 3; 2307, p. 12; 4194, p. 9; 3582, Tr. 1935). OSHA notes that the evidence shows that the declining trend in silicosis mortality does not provide a complete picture with regard to silicosis trends in the United States. Although many silicosis deaths reported today are likely the result of higher exposures (both magnitude and duration), some of which may have occurred before OSHA adopted the previous PELs, silicosis cases continue to occur today—some in occupations and industries where exposures are new and/or increasing. For example, five states reported cases of silicosis in dental technicians for the years 1994 to 2000 (CDC, MMWR Weekly, 2004, 53(09), pp. 195–197), for the first time. For the patients described in this report, the only identified source of crystalline silica exposure was their work as dental technicians. Exposure to respirable crystalline silica in dental laboratories can occur during procedures that generate airborne dust (*e.g.*, mixing powders, removing castings from molds, grinding and polishing castings and porcelain, and using silica sand for abrasive blasting). In 2015, the CDC reported the first case of silicosis (progressive massive fibrosis) associated with exposure to quartz surfacing materials (countertop fabrication and installation) in the U.S. The patient was exposed to dust for 10 years from working with conglomerate or quartz surfacing materials containing 70%–90% crystalline silica. Cases had previously been reported in Israel, Italy and Spain (MMWR, 2015, 64(05); 129–130). Recently, hazardous silica exposures have been newly documented during hydraulic fracturing of gas and oil wells (Bang *et al.*, MMWR, 2015, 64(05); 117–120).

Dr. Rosenman's testimony provides support for this point. He testified that newer industries with high silica exposures may also be under-recognized because workers in those industries have not yet begun to be diagnosed with silicosis due to the latency period (Document ID 3577, p. 858). Dr. Rosenman submitted to the record a study by Valiante *et al.* (2004, Document ID 3926) that identified newly exposed construction workers in the growing industry of roadway repair, which began using current methods for repair in the 1980s. These methods use quick-setting concrete that generates dust containing silica above the OSHA PEL when workers perform jackhammering, and sawing and milling concrete operations. State surveillance systems identified 576 confirmed silicosis cases in New Jersey, Michigan, and Ohio that were reported to NIOSH for the years 1993 through 1997. Of these, 45 (8 percent) cases were in construction workers, three of which had been engaged in highway repair.

Sample results for this study indicated a significant risk of overexposure to crystalline silica for workers who performed the five highway repair tasks involving concrete. Sample results in excess of the OSHA PEL were found for operating a jackhammer (88 percent of samples), sawing concrete and milling concrete tasks (100 percent of samples); cleaning up concrete tasks (67 percent of samples); and drilling dowels (100 percent of samples). No measured exposures in excess of the PEL were found for milling asphalt and cleaning up asphalt; however, of the eight samples collected for milling asphalt, six (55 percent) results approached the OSHA PEL, and one was at 92 percent of the PEL. No dust-control measures were in place during the sampling of these highway repair operations.

The authors pointed out that surveillance systems such as those implemented by these states are limited in their ability to detect diseases with long latencies in highway repair working populations because of the relatively short period of time that modern repair methods had been in use when the study was conducted. Nevertheless, a few cases were identified, although the authors explain that the work histories of these cases were incomplete, and the authors recommended ongoing research to evaluate the silicosis disease potential among this growing worker population (Document ID 3926, pp. 876–880). In construction, use of equipment such as blades used on handheld saws to dry-cut masonry materials have increased both efficiency and silica exposures for workers over the past few decades (Document ID 4223, p. 11–13). Exposure data collected by OSHA as part of its technological feasibility analysis demonstrates that exposures frequently exceed previous exposure limits for these operations when no dust controls are used (*see* Chapter IV of the FEA). Another operation seeing new and increasing exposures to respirable crystalline silica is hydraulic fracturing in the oil and gas industry (Document ID 3588, p. 3773). Information in the record from medical professionals noted that lung diseases caused by silica exposures are ''not relics of the past,'' and that they continue to see cases of silicosis and other related diseases, even among younger workers who entered the workforce after the former PEL was enacted (*see* Document ID 3577, Tr. 773).

Furthermore, the general declining trend seen in the death certificate data is considerably more modest in silicosis morbidity data. In his written testimony, Dr. Rosenman stated that the nationwide number of hospitalizations where silicosis was one of the discharge diagnoses has remained constant, with 2,028 hospitalizations reported in 1993

and 2,082 in 2011 (Document ID 3425, p. 2). It is the opinion of medical professionals including the American Thoracic Society and the American College of Chest Physicians that these hospitalizations likely represent ''the tip of the iceberg'' (of silicosis cases) since milder cases are not likely to be admitted to the hospital (Document ID 2175, p. 3). Again, this evidence shows that the declining trend observed in silicosis mortality statistics does not provide a complete picture with regard to silicosis trends in the United States. While silicosis mortality has decreased substantially since records were first available in 1968, the number of silicosis related deaths appears to have leveled off (*see* Table V–2; Document ID 3577, Tr. 775). Workers are still dying from silicosis today, and new cases are being identified by surveillance systems, where they exist.

Based on the testimony and evidence described above, OSHA finds that the surveillance data describing trends in silicosis mortality and morbidity provide useful evidence of a continuing problem, but are not suitable for evaluating either the adequacy of the previous PELs or whether a more protective standard is needed. In fact, it would not be possible to derive estimates of risk at various exposure levels from the available surveillance data for silica. OSHA therefore appropriately continues to rely on epidemiological data and its quantitative risk assessment to support the need to reduce the previous PELs in its final rule.

Commenters also argued that OSHA has failed to prove that a new standard is necessary because silica-associated deaths are due to existing exposures in excess of the previous PELs; therefore, the Agency should focus on better enforcing the previous PELs, rather than enacting a new standard (*e.g.*, Document ID 2376, p. 8; 2307, p. 12; 4016, pp. 9–10; 3582, Tr. 1936). OSHA does not find this argument persuasive. First, many of the commenters used OSHA's targeted enforcement data to make this point. These data were obtained during inspections where OSHA suspected that exposures would be above the previous PELs. Consequently, the data by their very nature are skewed in the direction of exceeding the previous PELs, and such enforcement serves a deterrence function, encouraging future compliance with the PEL.

Second, not all commenters agreed that overexposures were ''widespread.'' A few other commenters (*e.g.*, AFS) thought that OSHA substantially overstated the number of workers occupationally exposed above 100 μg/m^3 in its PEA (Document ID 2379, p. 25). However OSHA's risk analyses evaluated various exposure levels in determining risks to workers, and did not rely on surveillance data, which rarely have associated exposure data. Although OSHA relied on exposure data from inspections to assess technological feasibility, it did not rely on inspection data for its risk assessment because these exposure data are not tied to specific health outcomes. Instead, the exposure data used for risk assessment purposes is found in the scientific studies discussed throughout this preamble section.

The surveillance data are also not comparable to OSHA's estimate of deaths avoided by the final rule because, as is broadly acknowledged, silicosis is underreported as a cause of death on death certificates. Thus, the surveillance data capture only a portion of the actual silicosis mortality. This point was raised by several rulemaking participants, including Dr. Rosenman; Dr. James Cone, MD, MPH, Occupational Medicine Physician at the New York City Department of Health, the AFL–CIO; and the American Thoracic Society (ATS) (Document ID 3425, p. 2; 3577, Tr. 855, 867; 4204, p. 17; 2175, p. 3; 3577, Tr. 772).

The rulemaking record includes one study that evaluated underreporting of silicosis mortality. Goodwin *et al.* (2003, Document ID 1030) estimated, through radiological confirmation, the prevalence of unrecognized silicosis in a group of decedents presumed to be occupationally exposed to silica, but whose causes of death were identified as respiratory diseases other than silicosis. In order to assess whether silicosis had been overlooked and under-diagnosed by physicians, the authors looked at x-rays of decedents whose underlying cause of death was listed as tuberculosis, cor pulmonale, chronic bronchitis, emphysema, or chronic airway obstruction, and whose usual industry was listed as mining, construction, plastics, soaps, glass, cement, concrete, structural clay, pottery, miscellaneous mineral/stone, blast furnaces, foundries, primary metals, or shipbuilding and repair.

Any decedent found to have evidence of silicosis on chest x-ray with a profusion score of 1/0 was considered to be a missed diagnosis. Of the 177 individuals who met study criteria, radiographic evidence of silicosis was found in 15 (8.5 percent). The authors concluded that silicosis goes undetected even when the state administers a case-based surveillance system. Goodwin *et al.* (2003, Document ID 1030) also cites mortality studies of Davis *et al.* (1983, Document ID 0999) and Hughes (1982, Document ID 0362) who reported finding decedents with past chest x-ray records showing evidence of silicosis but no mention of silicosis on the death certificate.

The Goodwin *et al.* (2003) study illustrates the importance of information about the decedent's usual occupation and usual industry on death certificates. Yet for the years 1985 to 1999, only 26 states coded this information for inclusion on death certificates. If no occupational information is available, recognizing exposure to silica, which is necessary to diagnose silicosis, becomes even more difficult, further contributing to possible underreporting.

Dr. Rosenman, a physician, epidemiologist and B-reader, testified that in his research he found silicosis recorded on only 14 percent of the death certificates of individuals with confirmed silicosis (Document ID 3425, p. 2; 3577, Tr. 854; *see also* 3756, Attachment 11). This means that as much as 86 percent of deaths related to silicosis are missing from the NIOSH WoRLD database, substantially compromising the accuracy of the surveillance information. Dr. Rosenman also found that silicosis is listed as the cause of death in a small percentage of individuals who have an advanced stage of silicosis; 18 percent in those with progressive massive fibrosis (PMF) and 10 percent in those with category 3 profusion.

As noted above, factors that contribute to underreporting by health care providers include lack of information about exposure histories and difficulty recognizing occupational illnesses that have long latency periods, like silicosis (*e.g.*, Document ID 4214, p. 13; 3584, Tr. 2557). Dr. Rosenman's testimony indicated that many physicians are unfamiliar with silicosis and this lack of recognition is one factor that contributes to the low recording rate for silicosis on death certificates (Document ID 3577, Tr. 855). In order to identify cases of silicosis, a health care provider must be informed of the patient's history of occupational exposure to dust containing respirable silica, a critical piece of information in identifying and reporting cases of silicosis. However, information on a decedent's usual occupation and/or industry is often not available at the time of death or is too general to be useful. If the physician completing the death certificate is unaware of the decedent's occupational exposure history to crystalline silica, and does not have that information available to her/him on a medical record, a diagnosis of silicosis on the death certificate is

unlikely. According to a study submitted by the Laborers' Health and Safety Fund of North America, (Wexelman *et al.*, 2010), a sample of physician residents surveyed in New York City did not believe that cause of death reporting is accurate; this was a general finding, and not specific to silicosis (Document ID 3756, Attachment 7).

The ATS and the American College of Chest Physicians commented that physicians often fail to recognize or misdiagnose silicosis as another lung disease on the death certificate, leading to under-reporting on death certificates (3577, Tr. 821, 826–827) and under-recognize and underreport cases of silicosis (Document ID 2175, p. 3). As Dr. Weissman from NIOSH responded:

> . . . it's well known that death certificates don't capture all of the people that have a condition when they pass away, and so there would be many that probably would not be captured if the silicosis didn't directly contribute to the death and depending on who filled out the death certificate, and the conditions of the death and all those kinds of things. So it's an under-representation of people who die with the condition . . . . (Document ID 3579, pp. 166–167).

Although there is little empirical evidence describing the extent to which silicosis is underreported as a cause of death, OSHA finds, based on this evidence as well as on testimony in the record, that the available silicosis surveillance data are likely to significantly understate the number of deaths that occur in the U.S. where silicosis is an underlying or contributing cause. This is in large part due to physicians and medical residents who record causes of death not being familiar or having access to the patient's work or medical history (*see* Wexelman *et al.*, 2010, Document ID 3756, Attachment 7; Al-Samarri *et al.*, Prev. Chronic Dis. 10:120210,2013). According to Goodwin *et al.* (2003, Document ID 1030, p. 310), most primary care physicians do not take occupational histories, nor do they receive formal training in occupational disease. They further stated that, since it is likely that a person would not retain the same health care provider over many years, even if the presence of silicosis in a patient might have been known by a physician who cared for them, it would not necessarily be known by another physician or resident who recorded cause of death years or decades later and who did not have access to the patient's medical or work history. OSHA finds the testimony of Dr. Rosenman compelling, who found that silicosis was not recorded as an underlying or contributing cause of death even where there was chest x-ray evidence of progressive massive fibrosis related to exposure to crystalline silica.

Some commenters stated that the decline in silicosis mortality demonstrates that there is a threshold for silicosis above the prior PEL of 100 $\mu g/m^3$ (Document ID 4224, p. 2–5; 3582, Tr. 1951–1963). OSHA finds this argument irrelevant as the threshold concept does not apply to historical surveillance data. As noted above and discussed in Section V.I, Comments and Responses Concerning Threshold for Silica-Related Diseases, OSHA believes that surveillance data should not be used for quantitative risk analysis (including determination of threshold effects) because it lacks an exposure characterization based on sampling. Thus, the surveillance data cannot demonstrate the existence of a population threshold.

There is also evidence in the record that silicosis morbidity statistics reviewed earlier in this section are underreported. This can be due, in part, to the relative insensitivity of chest roentgenograms for detecting lung fibrosis. Hnizdo *et al.* (1993) evaluated the sensitivity, specificity and predictive value of radiography by correlating radiological and pathological (autopsy) findings of silicosis. ''Sensitivity'' and ''specificity'' refer to the ability of a test to correctly identify those with the disease (true positive rate), and those without the disease (true negative). Because pathological findings are the most definitive for silicosis, findings on biopsy and autopsy provide the best comparison for determining sensitivity and specificity of chest imaging.

The study used three readers and defined a profusion score of 1/1 as positive for silicosis. Sensitivity was defined as the probability of a positive radiological reading (ILO category >1/1) given that silicotic nodules were found in the lungs at autopsy. Specificity was defined as the probability of a negative radiological reading (ILO category <1/1) given that no, or only an insignificant number of silicotic nodules were found at autopsy. The average sensitivity values were low for each of the three readers (0.39, 0.37, and 0.24), whereas the average specificity values were high (0.99, 0.97, and 0.98). For all readers, the proportion of true positive readings (*i.e.*, the sensitivity) increased with the extent of silicosis found at autopsy (Document ID 1050).

In the only published study that quantified the extent of underreporting of silicosis mortality and morbidity, Rosenman *et al.* estimated the number of new cases of silicosis occurring annually in the U.S. at between 3,600 and 7,300 based on the ratio of living to deceased persons identified and confirmed as silicotics in the Michigan surveillance data and extrapolating that ratio using the number of deaths due to silicosis for the U.S. as a whole (2003, Document ID 0420). OSHA reviewed the study in its Review of the Health Effects Literature (Document ID 1711, p. 48). Patrick Hessel, Ph.D., criticized the methods used by Dr. Rosenman, and deemed the resulting estimates unreliable, stating that the actual number of new silicosis cases arising each year is likely to be lower than the authors estimated (Document ID 2332, p. 2; 3576, Tr. 323–331).

OSHA disagrees with the criticisms that Dr. Hessel, commenting on behalf of the Chamber, offered on the study by Rosenman *et al.* (2003, Document ID 0420). Specifically, Dr. Hessel argued: (1) That the silicosis-related deaths used by Rosenman *et al.* occurred during the period 1987 through 1996, and do not reflect the declining numbers after that time period; (2) that the Michigan surveillance system relied on a single B-reader who was biased toward finding silicosis in patients who were brought to his attention for suspected silicosis; and (3) that the Michigan population was not representative of the rest of the country, since about 80 percent of the workers diagnosed with silicosis worked in foundries, which are not prevalent in most other states. Finally, in his hearing testimony, Dr. Hessel criticized the capture-recapture analysis used by Rosenman *et al.* to estimate the extent of underreporting of cases, stating that a number of underlying assumptions used in the analysis were not met (Document ID 3576, Tr. 323–332).

Dr. Rosenman addressed many of these criticisms in the study and at the rulemaking hearing. Regarding the fact that the number of silicosis-related deaths does not reflect the decline in deaths after 1996, Dr. Rosenman testified that, although the number of recorded silicosis deaths have declined since then, the ratio of cases to deaths has increased because the number of cases has not declined. ''The living to dead ratio that we reported in our published study in 2003 was 6.44. This ratio has actually increased in recent years to 15.2. A similar ratio . . . [was] found in the New Jersey surveillance data, which went from 5.97 to 11.5 times'' (Document ID 3577, Tr. 854). If one were to apply the more recent ratio from Michigan (more than double the ratio used by Rosenman *et al.*) to the more recent number of deaths in the country (about half that recorded in the mid-1990s; *see* Table V–1) to extrapolate

the number of silicosis cases for the U.S. overall, the result would be even greater than the estimate in Rosenman *et al.* (2003).

At the hearing, Dr. Rosenman testified that he was the sole B-reader of lung x-rays for the study, and that he received the x-ray films from other radiologists who suspected but did not confirm the presence of silicosis (Document ID 3577, Tr. 877–878). Dr. Rosenman, while acknowledging that there could be differences between readers in scoring x-ray films, argued that such differences in scoring—for example, whether a film is scored a 3/3, 3/2, or 2/3—did not affect this study since the study design only required that a case be identified and confirmed (diagnosis requires a chest radiograph interpretation showing rounded opacities of 1/0 or greater profusion) (Document ID 3577, Tr. 877–878; 0420, p. 142).

Dr. Rosenman also addressed the criticism that Michigan's worker population with silica exposure is significantly different from the rest of the country. In the study, Rosenman *et al.* reported that the ratio of cases to deaths was about the same for Ohio as for Michigan and, during the public hearing, Dr. Rosenman testified that the ratio of cases to deaths for New Jersey was also similar to Michigan's (11.5 vs. 15.2) (Document ID 0420, p. 146; 3577, Tr. 854). This similarity was despite the fact that New Jersey had a different industrial mix, with fewer foundries (Document ID 3577, Tr. 878). Furthermore, the estimates made by Rosenman *et al.* depended on the ratio of cases to deaths in Michigan, rather than just the number of cases in that state. The authors believed that the ratio would be unaffected by the level of industrialization in Michigan (Document ID 0420, p. 146).

Finally, regarding the capture-recapture analysis, OSHA notes that Dr. Hessel acknowledged that this technique has been used in epidemiology to estimate sizes of populations identified from multiple overlapping sources (Document ID 2332, p. 2), which is the purpose for which Rosenman *et al.* used the approach. In addition, the Rosenman *et al.* study noted that the assumptions used in capture-recapture analysis could not be fully met in most epidemiological study designs, but that the effect of violating these assumptions was either negligible or was evaluated using interaction terms in the regression models employed. The investigators also reported that the capture-recapture analysis used on Ohio state surveillance data found that the total number of cases estimated for the state was between 3.03 and 3.18 times the number of cases identified, a result that is comparable to that for Michigan (Document ID 0420, pp. 146–147). After considering Dr. Hessel's written testimony, Dr. Rosenman testified that ''. . . overall I don't think his comments make a difference in my data'' (Document ID 3577, Tr. 877).

OSHA finds all of Dr. Rosenman's responses to Dr. Hessel's criticisms to be reasonable. And based on Dr. Rosenman's comments and testimony, OSHA continues to believe that the Rosenman *et al.* (2003) analysis and resulting estimates of the number of new silicosis cases that arise each year are reasonable. Additionally, Dr. Rosenman, in updating his data for his testimony for this rulemaking, found that the ratio had increased from 6.44 in the published study to 15.2 times in more recent years (Document ID 3577, Tr. 854). The study supports OSHA's hypothesis that silicosis is a much more widespread problem than the surveillance data suggest and that OSHA's estimates of the non-fatal illnesses that will be avoided as a result of this new silica standard are not unreasonable. Regardless, even assuming commenters' criticisms have merit, they do not significantly affect OSHA's own estimates from the epidemiological evidence of the risks of silicosis.

Accordingly, after careful consideration of the available surveillance data, stakeholders' comments and testimony, and the remainder of the record as a whole, OSHA has determined that the available silicosis surveillance data are useful for providing context and an illustration of a significant general trend in the reduction of deaths associated with silicosis over the past four to five decades. As discussed above, and in large part because the data themselves are limited and incomplete, OSHA believes reliance upon them for the purpose of estimating the magnitude of the risk would be inappropriate. The Agency has chosen instead to follow its well-established practice of relying on epidemiological data to meet its burden of demonstrating that workers exposed to respirable crystalline silica at the previous PELs face a significant risk of developing silicosis and that such risk will be reduced when the new limit is fully implemented.

F. Comments and Responses Concerning Lung Cancer Mortality

OSHA received numerous comments regarding the carcinogenic potential of crystalline silica as well as the studies of lung cancer mortality that the Agency relied upon in the Preliminary Quantitative Risk Assessment (QRA). Many of these comments, particularly from the ACC, asserted that (1) OSHA should have relied upon additional epidemiological studies, and (2) the studies that the Agency did rely upon (Steenland *et al.*, 2001a, as re-analyzed in ToxaChemica, 2004; Rice *et al.*, 2001; Attfield and Costello, 2004; Hughes *et al.*, 2001; and Miller and MacCalman, 2009) were flawed or biased. In this section, OSHA presents these comments and its responses to them.

1. Carcinogenicity of Crystalline Silica

As discussed in the Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 76–77), in 1997, the World Health Organization's International Agency for Research on Cancer (IARC) conducted a thorough expert committee review of the peer-reviewed scientific literature and classified crystalline silica dust, in the form of quartz or cristobalite, as Group 1, ''carcinogenic to humans'' (Document ID 2258, Attachment 8, p. 211). IARC's overall finding for silica was based on studies of nine occupational cohorts that it considered to be the least influenced by confounding factors (Document ID 1711, p. 76). In March of 2009, 27 scientists from eight countries participated in an additional IARC review of the scientific literature and subsequently, in 2012, IARC reaffirmed that respirable crystalline silica dust is a Group 1 human carcinogen that causes lung cancer (Document ID 1473, p. 396). Additionally, in 2000, the National Toxicology Program (NTP) of HHS concluded that respirable crystalline silica is a known human carcinogen (Document ID 1164, p. 1).

The ACC, in its pre-hearing comments, questioned the carcinogenic potential of crystalline silica, asserting that IARC's 1996 recommendation that crystalline silica be classified as a Group 1 carcinogen was controversial (Document ID 2307, Attachment A, p. 29). The ACC cited Dr. Patrick Hessel's 2005 review of epidemiological studies, published after the initial IARC determination, in which he concluded that ''the silica-lung cancer hypothesis remained questionable'' (Document ID 2307, Attachment A, p. 31). The ACC reasserted this position in its post-hearing brief, contending that ''epidemiological studies have been negative as often as they have been positive'' (Document ID 4209, pp. 33–34).

After the publication of Dr. Hessel's 2005 review article, IARC reaffirmed in 2012 its earlier Group 1 classification for crystalline silica dust (Document ID 1473). As pointed out by Steenland and

Ward, IARC is one of ''2 agencies that are usually considered to be authoritative regarding whether a substance causes cancer in humans,'' the other being the NTP, which has also determined crystalline silica to be carcinogenic on two separate occasions (2013, article included in Document ID 2340, p. 5). David Goldsmith, Ph.D., who coauthored one of the first published articles linking silica exposure to lung cancer, echoed Steenland and Ward:

> It is important to recognize that evidence for silica's carcinogenicity has been reviewed three times by the International Agency for Research on Cancer, once in 1987, 1997, and 2012. It has been evaluated by California's Proposition 65 in 1988, by the National Toxicology Program in 2000 and reaffirmed in 2011, and by the National Institute for Occupational Safety and Health in 2002 (Document ID 3577, Tr. 861–862).

Multiple organizations with great expertise in this area, including the American Cancer Society, submitted comments supporting the thorough and authoritative nature of IARC's findings regarding silica's carcinogenicity (*e.g.,* Document ID 1171; 1878). OSHA likewise places great weight on the IARC and NTP classifications and, based on their findings, concludes that the carcinogenic nature of crystalline silica dust has been well established. Further support for this finding is discussed in Section V.L, Comments and Responses Concerning Causation.

2. Silicosis and Lung Cancer

In addition to debating the conclusions of IARC, Peter Morfeld, Dr. rer. medic, testifying on behalf of the ACC Crystalline Silica Panel, concluded that OSHA's risk estimates for lung cancer are ''unreliable'' because they ''ignore threshold effects and the apparent mediating role of silicosis'' (Document ID 2307, Attachment 2, p. 16). Dr. Morfeld argued that silicosis is a necessary prerequisite for silica-related lung cancer. Commenters' arguments about silicosis being a prerequisite for lung cancer and silicosis having a threshold are linked; if it were shown both that silicosis requires a certain threshold of exposure and that only persons with silicosis get lung cancer, then silica-related lung cancer would also have an exposure threshold. As discussed in Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases, commenters claimed that there is a threshold for silicosis above the previous PEL for general industry, which would make any threshold for lung cancer above that level as well. OSHA discusses these comments in detail in that section, and has determined that even if lung cancer does not occur in the absence of silicosis, the record strongly supports the conclusion that workers exposed to respirable crystalline silica would still be at risk of developing lung cancer as a result of their exposure because silicosis can develop among workers whose average and cumulative exposures are below the levels permitted by the previous PELs.

OSHA received comments from other stakeholders, including Robert Glenn, representing the Brick Industry Association, and the AFS on the possible mediating role of silicosis in the development of lung cancer (Document ID 2307, pp. 29–35; 2343, Attachment 1, pp. 42–45; 2379, Attachment 2, pp. 24–25). The ACC cited several review articles in support of its claim that ''silica exposures have not been shown to increase the risk of lung cancer in the absence of silicosis'' (Document ID 2307, Attachment A, pp. 29, 32, 35). These articles included: A 2004 review of studies by Kurihara and Wada that found that while silicosis is a risk factor for lung cancer, exposure to silica itself may not be a risk factor (Document ID 1084); a 2006 review by Pelucchi *et al.* that determined that the issue of whether silica itself increases lung cancer risk in the absence of silicosis has not been resolved (Document ID 0408); and a 2011 review by Erren *et al.* that concluded it is unclear whether silica causes lung cancer in persons who do not already have silicosis (Document ID 3873). Similarly, the AFS cited a review by the Health and Safety Executive (2003) that concluded that increased risks of lung cancer are restricted to those groups with the highest cumulative exposures, with evidence tending to show that excess lung cancer mortality is restricted to those with silicosis (Document ID 2379, Attachment 2, pp. 24–25). Having reviewed the studies cited by commenters, OSHA has come to the conclusion that none of the cited studies demonstrates that silicosis is a necessary precursor to lung cancer, but acknowledges that uncertainty remains about what percentage of lung cancers in silica-exposed workers are independent of silicosis.

Similarly, the ACC stated that none of the studies of lung cancer mortality that OSHA relied upon in the Preliminary QRA demonstrates that silica exposure causes lung cancer in the absence of silicosis (Document ID 2307, Attachment A, p. 66). During the rulemaking hearing, NIOSH scientists addressed the issue of whether silicosis is a necessary precursor to the development of lung cancer. They stated that it is a difficult issue to resolve because the two diseases may have a similar pathway, such that they can develop independently but still appear correlated. Mr. Robert Park also added that:

> [S]ilicosis isn't detectable until there's splotches on the lung that are visible in x-rays. So prior to that point, somebody could have [been] developing lung disease and you just can't see it. So, of course, people that have silicosis are going to have higher lung cancer, and it's going to look like a threshold because you didn't see the silicosis in other people that have lower lung cancer risk. To really separate those two, you'd have to do a really big study. You'd have to have some measures, independent measures of lung physiological pathology, and see what's going on with silicosis as a necessary condition for development of lung cancer (Document ID 3579, Tr. 245–247).

Similarly, David Weissman, MD, concurred that ''there's quite a bit of reason as Bob [Park] said to think that the two processes [development of silicosis and development of lung cancer] don't require each other, and it would be extraordinarily difficult to sort things out in human data'' (Document ID 3579, Tr. 247). Indeed, Checkoway and Franzblau (2000) reviewed the epidemiological literature addressing this topic, and found that the ''limitations of existing epidemiologic literature that bears on the question at hand suggest that prospects for a conclusive answer are bleak'' (Document ID 0323, p. 257). The authors concluded that silicosis and lung cancer should be treated in risk assessments as ''separate entities whose cause/effect relations are not necessarily linked'' (Document ID 0323, p. 257). Brian Miller, Ph.D., a peer reviewer of OSHA's Review of Health Effects Literature and Preliminary QRA, likewise wrote in his post-hearing comments, ''I consider this issue unanswerable, given that we cannot investigate for early fibrotic lesions in the living, but must rely on radiographs'' (Document ID 3574, p. 31).

During the public rulemaking hearing, several stakeholders pointed to a recent study of Chinese pottery workers and miners by Liu *et al.* (2013, article included in Document ID 2340) as evidence that exposure to crystalline silica is associated with lung cancer even in the absence of silicosis (Document ID 3580, Tr. 1232–1235; 3577, Tr. 803–804, 862–863). In this study, the authors excluded 15 percent of the cohort (including 119 lung cancer deaths) with radiographic evidence of silicosis and found that the risk of lung cancer mortality still increased with cumulative exposure to crystalline silica, suggesting that clinically-

apparent silicosis is not a prerequisite for silica-related lung cancer (article included in Document ID 2340, pp. 3, 7).

The ACC argued that it is ''premature to draw that conclusion,'' stating that the Liu study's conclusions are not supported by the data and raising questions about uncertainty in the exposure estimates, modeling and statistics, confounding, and the silicosis status of cohort members (Document ID 2307, Attachment A, p. 48; 4027, pp. 35–36; 4209, pp. 40–51). With regard to exposure estimates, the ACC had a number of concerns, including that conversion factors determined by side-by-side sampling in 1988–1989 were used to convert Chinese total dust concentrations to respirable crystalline silica exposures (Document ID 4209, pp. 40–41). Dr. Cox expressed concern that these conversion factors from 1988–1989 might not have been applicable to other time periods, as particle size distributions could change over time (Document ID 4027, p. 32). OSHA acknowledges this concern, but given the ''insufficient historical particle size data . . . to analyze whether there were changes in particle size distributions from the 1950s to the 1990s,'' believes that the authors were justified in making their exposure assumptions (Document ID 4027, p. 32). Dr. Cox's concerns involving modeling and statistics (*see* Document ID 4027, pp. 33–36) in the study, including the absence of model diagnostics, the use of inappropriate or misspecified models, the lack of a discussion of residual confounding and model uncertainty, and the use of inappropriate data adjustments and transformations, are discussed in detail in Section V.J, Comments and Responses Concerning Biases in Key Studies.

On the issue of confounding, the ACC noted that Liu *et al.* (2013) used a subcohort of 34,018 participants from 6 tungsten mines, 1 iron mine, and 4 potteries derived from a total cohort of 74,040 participants from 29 mines and pottery factories studied previously by Chen *et al.* (2007, Document ID 1469; 2307, Attachment A, pp. 48–50). Liu *et al.* (2013) excluded participants in the original cohort if detailed information on work history or smoking was not available, or if they worked in copper mines or tin mines where the analysis could be confounded by other exposures, namely radon and carcinogenic polycyclic aromatic hydrocarbons (PAHs) in the former and arsenic in the latter (article included in Document ID 2340, p. 2). The ACC's main concern was that Liu *et al.* (2013) did not adjust for these confounders in their analyses, but rather claimed that there were no confounding exposures in their smaller cohort on the basis of the exclusion criteria (Document ID 2307, Attachment A, p. 49).

The ACC also noted that Chen *et al.* (2007) stated that the Chinese pottery workers were exposed to PAHs, and some of the iron-copper miners were exposed to PAHs and radon progeny (Document ID 2307, Attachment A, p. 49). Chen *et al.* (2007) initially found an association between respirable silica and lung cancer mortality in the pottery workers and iron-copper miners, but it disappeared after adjusting for PAH exposures (Document ID 1469). In the tungsten miners, Chen *et al.* (2007) found no significant association for lung cancer mortality, while Liu *et al.* (2013) did. Similarly, the ACC pointed out that a subsequent study by Chen *et al.* (2012, article included in Document ID 2340) also failed to find a statistically significant increase in the hazard ratio for lung cancer, meaning that there was no significant positive exposure-response relationship between cumulative silica exposure and lung cancer mortality (Document ID 4209, p. 45). Dr. Morfeld concluded, ''Unless and until these issues are resolved, Liu *et al.* (2013) should not be used to draw conclusions regarding exposure-response relationships between RCS [respirable crystalline silica], silicosis and lung cancer risk'' (Document ID 2307, Attachment 2, pp. 15–16).

During the public hearing, counsel to the ACC asked Dr. Steenland, a co-author on the Liu *et al.* (2013) study, if he would provide measurement data on the PAH exposures in the potteries, as well as present the data from the Liu *et al.* (2013) study separately for pottery factories and tungsten mines, as they were in Chen *et al.* (2007, Document ID 1469) (Document ID 3580, Tr. 1237–1240). Dr. Steenland subsequently provided the requested data for inclusion in the rulemaking record (Document ID 3954).

With respect to the PAH data for the potteries, Dr. Weihong Chen, the study's first author, reported that, in measurements in 1987–1988 in the four potteries that were excluded from the Liu *et al.* (2013) analysis, the mean total PAHs was 38.9 μg/m^3 and the mean carcinogenic PAHs was 4.7 μg/m^3. In the four potteries that were included in the Liu *et al.* (2013) analysis, the mean total and carcinogenic PAHs, as measured in 1987–1988, were substantially lower at 11.6 and 2.5 μg/m^3, respectively. When the measurements were repeated in 2006, the mean total and carcinogenic PAHs in the four potteries included in the analysis were still lower, at 2.2 and 0.08 μg/m^3, levels that were ''not much higher than environmental PAH in many [Chinese] cities'' (Document ID 3954, p. 2). Dr. Chen also reported that, when comparing levels within six job titles, there was no significant correlation between total or carcinogenic PAHs (based on the 2006 measurements) and respirable silica dust. When the results were presented separately for the mines and potteries, in analyses using continuous cumulative exposure, the relationship between silica exposure and lung cancer mortality remained significant for the pottery factories, but not the metal mines. In the categorical analyses using quartiles of cumulative exposure, the results were mixed: The association between silica exposure and lung cancer mortality was statistically significant in some exposure quartiles for both metal mines and pottery factories (Document ID 3954, p. 2).

Based upon these subsequent data, the ACC concluded that PAHs were likely present in the potteries but not in the mines (Document ID 4209, p. 45). OSHA believes this conclusion, although plausible, to be speculative. What is known is that the potteries that were excluded had a higher average level of PAHs, and that a significant association between cumulative silica exposure and lung cancer mortality remained in the included potteries even after the analysis was separated by potteries and mines. However, the association was less clear in the metal mines.

The ACC also raised concerns about the silicosis status of lung cancer cases in the Liu cohort, asserting that some workers may not have had post-employment radiography given that social health insurance only recently began to pay for it. As such, the ACC asserted that some workers who developed lung cancer post-employment may have also had undiagnosed silicosis (Document ID 4209, pp. 49–50). OSHA acknowledges the limitations of the study, as with any retrospective study, but also notes that no evidence was put forth to indicate that workers with silicosis were misclassified in the study as workers without silicosis. Further, Dr. Goldsmith testified that the method used by Liu *et al.* for excluding workers with silicosis (x-ray findings) was ''very eminently reasonable,'' given that the only foolproof means of proving the absence of silicosis—autopsy—was not available for this particular cohort (Document ID 3577, Tr. 874–875).

Thus, OSHA concludes that the Liu *et al.* (2013) study preliminarily suggests

that silicosis is not required for the development of lung cancer; however, no one study will settle the question of the role of silicosis in the carcinogenicity of crystalline silica. As acknowledged by Dr. Cox, the Agency did not rely upon the Liu *et al.* (2013) study in its preliminary or final QRA (Document ID 2307, Attachment 4, p. 37).

Overall, after giving lengthy consideration to all evidence in the record regarding whether silicosis is a necessary precursor to the development of lung cancer, including the Liu study, the NIOSH testimony, and the mechanistic evidence for the carcinogenicity of crystalline silica discussed in Section V.H, Mechanisms of Silica-Induced Adverse Health Effects, OSHA concludes that the mediating role of silicosis in the development of lung cancer is not ''apparent,'' as suggested by Dr. Morfeld and the ACC (Document ID 2307, Attachment 2, p. 16). As such, OSHA continues to believe that substantial evidence supports the Agency's decision to consider lung cancer as a separate, independent health endpoint in its risk analysis. The Agency also notes that even if lung cancer does not occur in the absence of silicosis, the record strongly supports the conclusion that workers exposed to respirable crystalline silica would still be at risk of developing lung cancer as a result of their exposure because silicosis can develop from average and cumulative exposures below the levels allowed at the previous PEL (*see* Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases.)

3. Additional Studies

Stakeholders also suggested several additional studies that they believe OSHA should include in its QRA on lung cancer. The AFS commented that OSHA's Preliminary QRA overlooked a 2003 report by the Health and Safety Executive (HSE, Document ID 1057), asserting that over 40 percent of the references cited by HSE were omitted in OSHA's review (Document ID 4035, p. 2). OSHA disagrees with this assessment of overlooking the report, noting that the Agency reviewed and referenced the HSE report in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711, p. 77). As discussed in Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA, OSHA used a weight-of-evidence approach to evaluate the scientific studies in the literature to determine their overall quality. In so doing, OSHA thoroughly reviewed approximately 60 published, peer-reviewed primary epidemiological studies covering more than 30 occupational cohorts in over a dozen industrial sectors, as well as the IARC pooled study and several meta-analyses (Document ID 1711, pp. 75–172).

The AFS also submitted a 2011 review of 30 foundry epidemiology studies by the Industrial Industries Advisory Council (IIAC) and noted that only 7 of those 30 studies were included in OSHA's Review of Health Effects Literature and Preliminary QRA (Document ID 2379, p. 24). AFS wrote:

> The PQRA largely dismisses the foundry epidemiology studies, based on assertions of positive confounding. However, a study showing that there is no adverse effect despite a positive confounder is not only still relevant to the question, but should be more persuasive than a study without positive confounders because the data then show that even with an additive risk, there is no increase in effect at the reported exposure levels (Document ID 2379, p. 24).

In response to this comment, OSHA gathered the remaining 23 foundry studies cited in the submitted report and placed them in the rulemaking docket during the post-hearing comment period. OSHA notes, in the first instance, that most of these studies were not designed to study the effects of silica exposure on foundry workers, and did not even attempt to do so; rather, their purpose was to examine lung cancer mortality and/or morbidity in foundry work, which involves many toxic and otherwise harmful substances besides silica. Therefore, OSHA would likely be unable to suitably use these studies as a basis for a quantitative risk assessment regarding respirable crystalline silica by itself.

With respect to AFS's assertions of studies showing ''no adverse effect,'' OSHA notes that the summary section of the IIAC review report, submitted as evidence by AFS, stated that, ''The cohort mortality studies and two morbidity studies suggest an increased risk of lung cancer in foundry workers when considered overall, but do not support a doubling of risk. . . . Findings in the case-control studies, the majority of which adjust for the effects of smoking . . . tend to support those of the cohort studies'' (Document ID 3991, p. 5). As such, this review of 30 foundry epidemiology studies showed an increased excess risk of lung cancer from foundry work; the fact that the excess risk was not increased by a factor of two is irrelevant to the current proceedings. The factor of two appears to be used by the IIAC in determining whether monetary benefits should be paid to foundry workers in Great Britain and is completely unrelated to OSHA's statutory requirements for determining whether workers exposed to silica are at a significant risk of material impairment of health. Given that excess lung cancer was observed in many of these studies, OSHA rejects the AFS's assertion that, even with positive confounding, there was no increase in adverse effect (*i.e.*, lung cancer).

OSHA also notes that the IIAC's finding of an elevated risk of lung cancer in foundries is not surprising. As Dr. Mirer stated during his testimony, IARC categorized foundry work as Group 1, carcinogenic to humans, in 1987 based on observed lung cancer (Document ID 2257, Attachment 3, p. 5). IARC reaffirmed its Group 1 classification for foundry work in 2012 (Document ID 4130). However, as noted by OSHA in its Review of Health Effects Literature, the foundry epidemiology studies were profoundly confounded by the presence of exposures to other carcinogens, including PAHs, aromatic amines, and metals (Document ID 1711, p. 264). Because of this confounding, as well as the fact that most of these studies did not specifically study the effects of silica exposure on foundry workers, OSHA has decided not to include them in its QRA.

The ACC likewise cited several individual studies that it believed found no relationship between silica exposure and lung cancer risk (Document ID 2307, Attachment A, pp. 33–35). These included studies by: (1) Yu *et al.* (2007), which found no consistent exposure-response relationship between silica exposure and lung cancer death in workers with silicosis in Hong Kong (Document ID 3872); (2) Chen *et al.* (2007), which found, as mentioned in relation to the Liu *et al.* (2013) study, no relationship between silica exposure and lung cancer after adjusting for confounders in a study of Chinese tungsten miners, tin miners, iron-copper miners, and pottery workers (Document ID 1469); (3) Birk *et al.* (2009), which found the standardized mortality ratio (SMR) for lung cancer was not elevated in a subgroup of men who worked in areas of German porcelain plants with the highest likely silica exposures (Document ID 1468); (4) Mundt *et al.* (2011), which found, in a subsequent analysis of the German porcelain industry, that cumulative silica exposure was not associated with lung cancer mortality, mortality from kidney cancer, or any other cause of death other than silicosis (Document ID 1478); and (5) Westberg *et al.* (2013), which found that cumulative silica exposure was not associated with lung cancer morbidity (Document ID 4054).

Briefly, Chen *et al.* (2007) examined a cohort of male workers in 29 Chinese mines and factories, and initially found a significant trend between cumulative silica exposure and lung cancer mortality in pottery workers and tin miners; this trend was no longer significant after adjustment for occupational confounders (carcinogenic PAHs in potteries, arsenic in tin mines) (Document ID 1469, pp. 320, 323–324). On the contrary, Liu *et al.* (2013) demonstrated a statistically significant association between cumulative silica exposure and lung cancer mortality after excluding mines and factories with confounding exposures (article included in Document ID 2340). As noted previously, there are questions of how confounding exposures to radon, PAHs, and arsenic were handled in both the Chen *et al.* (2007) and Liu *et al.* (2013) studies. One important difference between the two studies, however, was the follow-up time. While Chen *et al.* (2007) had follow-up to 1994 and identified 511 lung cancer deaths in a cohort of 47,108 workers (Document ID 1469, pp. 321–322), Liu *et al.* (2013) had follow-up to 2003 and identified 546 lung cancer deaths in a cohort of 34,018 workers (article included in Document ID 2340, pp. 2–4).

OSHA discussed the Birk *et al.* (2009, Document ID 1468) and Mundt *et al.* (2011, Document ID 1478) studies of the German porcelain industry in its Supplemental Literature Review, noting several limitations that are applicable to both studies and might preclude the conclusion that there was no association between silica exposure and lung cancer (Document ID 1711, Attachment 1, pp. 6–12). One such limitation was the mean age of subjects—35 years—at the start of follow-up, making this a relatively young cohort in which to observe lung cancer. The mean follow-up period of 19 years per subject was also a limitation, given the long latency for lung cancer and the young age of the cohort at the start of follow-up; only 9.2 percent of the cohort was deceased by the end of the follow-up period. OSHA noted that Mundt *et al.* (2011) acknowledged that additional follow-up of the cohort may be valuable (Document ID 1711, Attachment 1, pp. 10–11; 1478, p. 288). In addition, Mundt *et al.* (2011) had only 74 male lung cancer deaths, some of whom had possible or probable prior silica exposure that could have resulted in cumulative exposure misclassification (Document ID 1478, pp. 285, 288). The authors also reported statistically significantly elevated lung cancer hazard ratios for some categories of average silica exposure, but did not present any trend analysis data (Document ID 1478, p. 285). It also does not appear that Mundt *et al.* performed any lagged analyses for lung cancer to account for the latency period of lung cancer.

Following the ACC's citation of the Yu *et al.* (2007) and Westberg *et al.* (2013) studies in its pre-hearing comments, OSHA obtained and reviewed these studies, and added them to the rulemaking docket (Document ID 3872; 4054). Yu *et al.* (2007) followed a cohort of 2,789 workers in Hong Kong diagnosed with silicosis between 1981 and 1998. The average follow-up time was 9 years, with 30.6 percent of the cohort deceased when the study ended in 1999. The SMR for lung cancer was not statistically significantly elevated following indirect adjustment for cigarette smoking; similarly, the authors did not find a significant exposure-response relationship between cumulative silica exposure and lung cancer mortality (Document ID 3872). Westberg *et al.* (2013) studied a group of 3,045 male Swedish foundry workers to determine lung cancer incidence and morbidity. Although the lung cancer incidence was statistically significantly elevated, the authors did not find a significant exposure-response relationship with cumulative quartz exposure (Document ID 4054, p. 499).

Regarding these studies, OSHA notes that the Westberg *et al.* (2013) study, like other foundry studies, is confounded by other carcinogenic substances present in foundries, including, as the authors pointed out, phenol, formaldehyde, furfuryl alcohols, PAHs, carbon black, isocyanates, and asbestos (Document ID 4054, p. 499). The Yu *et al.* (2007) study had an average follow-up period of only 9 years (Document ID 3872, p. 1058, Table 1), which is a short follow-up period when considering the latency period for the development of cancer. In addition, the Yu *et al.* study (2007), as described in the earlier Tse *et al.* (2007) study, used a job exposure matrix developed from expert opinion to assign estimated past levels of silica exposure to individuals based on self-reported work history; changes in exposure intensity with calendar year were not considered because of limited data (Document ID 3841, p. 88; 3872, p. 1057). OSHA notes that this exposure estimation may have included considerable misclassification due to inaccuracies in self-reported work history, the use of expert opinion to estimate past exposure levels rather than actual measurements for the subjects under study, and the failure to incorporate any changes in exposure levels over calendar time into the exposure estimates. Although these exposure estimates were used in an analysis that found a significant exposure-response for NMRD mortality among workers with silicosis (Tse *et al.,* 2007, Document ID 3841), an exposure-response for lung cancer mortality may not be as strong and may be harder to detect, requiring more accurate exposure information. OSHA also notes that NMRD mortality is likely to be a competing cause of death with lung cancer, such that some workers may have died from NMRD before developing lung cancer. The workers with silicosis in this study also had high exposures (mean cumulative exposure of 10.89 mg/m^3-yrs) (Document ID 3872, p. 1058), possibly making it difficult to detect an exposure-response for lung cancer when exposures are relatively homogenous and high. Selection effects would have been extreme in these highly-exposed workers, whose all-cause mortality was double what would be expected (853 deaths observed, 406 expected) in the general population of males in Hong Kong and whose respiratory disease mortality was an astounding six times the expected level (445 deaths observed, 75 expected) (Document ID 3872, p. 1059).

OSHA acknowledges that not every study reaches the same results and conclusions. This is typically true in epidemiology, as there are different cohorts, measurements, study designs, and analytical methods, among other factors. As a result, scientists critically examine the studies, both individually and overall, in the body of literature to draw weight-of-evidence conclusions. IARC noted, with respect to its 1997 carcinogenicity determination:

> [N]ot all studies reviewed demonstrated an excess of cancer of the lung and, given the wide range of populations and exposure circumstances studied, some non-uniformity of results had been expected. However, overall, the epidemiological findings at the time supported an association between cancer of the lung and inhaled crystalline silica (α-quartz and cristobalite) resulting from occupational exposure (Document ID 1473, p. 370).

Given IARC's re-affirmation of this finding in 2012, OSHA does not believe that the individual studies mentioned above fundamentally change the weight of evidence in the body of literature supporting the carcinogenicity of crystalline silica. The best available evidence in the rulemaking record continues to indicate that exposure to respirable crystalline silica causes lung cancer. OSHA acknowledges, however, that there is some uncertainty with respect to the exact magnitude of the

lung cancer risk, as each of the key studies relied upon provides slightly different risk estimates, as indicated in Table VI–1.

Further, the ACC focused extensively on and advocated for a study by Vacek *et al.* (2011) that found no significant association between respirable silica exposure and lung cancer mortality in a cohort of Vermont granite workers (Document ID 1486, pp. 75–81). Included in the rulemaking docket are the peer-reviewed published version of the study (Document ID 1486) and the earlier Final Report to the ACC, whose Crystalline Silica Panel funded the study (Document ID 2307, Attachment 6), as well as comments from two of the authors of Vacek *et al.* (2011) responding to OSHA's treatment of the study in its Supplemental Literature Review (Document ID 1804). The ACC stated:

> Perhaps of most interest and relevance for present purposes—because the cohort has been studied so extensively in the past and because the present PEL is based indirectly on experience in the Vermont granite industry—is the mortality study of Vermont granite workers published in 2011. While the Vermont granite workers cohort has been studied on a number of previous occasions, this is the most comprehensive mortality study of Vermont granite workers to date (Document ID 2307, Attachment A, p. 36).

The ACC criticized OSHA for rejecting the Vacek *et al.* (2011) study in its Supplemental Literature Review and instead relying upon the Attfield and Costello (2004, Document ID 0284) study of Vermont granite workers (Document ID 2307, Attachment A, pp. 36–47; 4209, pp. 34–36). The ACC asserted several differences between the studies. First, while Attfield and Costello had 5,414 workers (201 lung cancer deaths) in the cohort, Vacek *et al.* had 7,052 workers (356 lung cancer deaths) as they extended the follow-up period by 10 years to 2004. Vacek *et al.* also claimed to have more complete mortality data, finding that ''162 workers, whom Attfield assumed were alive in 1994, had died before that time and some decades earlier'' (Document ID 2307, Attachment A, p. 38). In addition, Vacek *et al.* used exposure measurements and raw data not used by Attfield and Costello; for example, Vacek *et al.* used pension records and interviews from other studies to account for gaps in employment and changes in jobs, while Attfield and Costello assumed that a person remained in the same job between chest x-rays at the Vermont Department of Industrial Health surveillance program. Different conversion factors to estimate gravimetric concentrations from particle count data were also used: Attfield and Costello used a factor of 10 mppcf = 75 $\mu g/m^3$ while Vacek *et al.* used a factor of 10 mppcf = 100 $\mu g/m^3$ (Document ID 2307, Attachment A, pp. 36–39; 1804, p. 3). OSHA notes that this discrepancy in gravimetric conversion factors should not affect the detection of an exposure-response relationship, as all exposures would differ by a constant factor.

The ACC also pointed out that Attfield and Costello's exposure estimate for sandblasters was 60 $\mu g/m^3$ prior to 1940, 50 $\mu g/m^3$ from 1940–1950, and 40 $\mu g/m^3$ after 1950, maintaining these numbers were too low compared to Vacek *et al.'s* estimates of 240, 160, and 70 $\mu g/m^3$, respectively (Document ID 2307, Attachment A, p. 39; 1486, p. 313). Attfield and Costello took these estimates for sand blasters from the Davis *et al.* (1983, Document ID 0999) study, discussed in detail below; the estimates were based on six published industrial hygiene measurement studies.

Lastly, the ACC posited that Attfield and Costello inappropriately excluded the highest exposure group, stating:

> Vacek *et al.* used all their data in evaluating potential E–R [exposure-response] trends with increasing exposure. Attfield and Costello did not. Instead, on a post hoc basis, they excluded the highest exposure category from their analysis when they discovered that the E–R trend for lung cancer was not significant if that group was included (even though the trends for non-malignant respiratory diseases were significant when all the data were used). This is an example of both data selection bias and confirmation bias (Document ID 2307, Attachment A, p. 40).

Based upon these assertions, the ACC concluded, ''In sum, when judged without a result-oriented confirmation bias, the larger, more recent, more comprehensive, and more detailed study by Vacek *et al.* (2011) must be deemed to supersede Attfield and Costello (2004) as the basis for evaluating potential silica-related lung cancer risks in the Vermont granite industry'' (Document ID 2307, Attachment A, p. 41).

OSHA initially discussed some issues surrounding the Vacek *et al.* (2011) study in its Supplemental Literature Review (Document ID 1711, Attachment 1, pp. 2–5). Specifically, OSHA noted that (1) the cumulative exposure quintiles used in the Vacek *et al.* (2011) analysis were higher than the values used in the Attfield and Costello (2004) analysis; (2) the regression models used in the Vacek *et al.* (2011) study exhibited signs of uncontrolled confounding, as workers in the second lowest cumulative exposure stratum in the models (except for silicosis) exhibited a lower risk than those in the lowest stratum, while all outcomes (except NMRD) in the highest exposure stratum showed a decline in the odds ratio (a measure of the association between silica exposure and health outcome) compared to the next lower stratum; and (3) Vacek *et al.* (2011) found a statistically significant excess of lung cancer (SMR = 1.37, with almost 100 excess lung cancer deaths) in the cohort when compared to U.S. white males (Document ID 1486, p. 315). Regarding the excess lung cancer deaths, although they were unable to obtain information on smoking for many of the cohort members, Vacek *et al.* suggested that the elevated SMR for lung cancer was due, at least in part, to the differences between the smoking habits of the cohort and reference populations (Document ID 1486, p. 317). OSHA noted that although the SMR for other NMRD was elevated, there was no significant SMR elevation for other smoking-associated diseases, including cancers of the digestive organs, larynx, and bladder, as well as bronchitis, emphysema, and asthma (Document ID 1711, Attachment 1, p. 5). Elevated SMRs for these diseases would be expected if workers in the study population smoked more than those in the reference population; in fact, for all heart disease, the mortality in the study population (SMR = 0.89) was statistically significantly lower than the reference population (Document ID 1486, p. 315). These data do not support Vacek *et al.'s* assertion that smoking was responsible for the increased lung cancer SMR in the cohort. In addition, Davis *et al.* (1983) noted that granite shed workers employed during the 1970's smoked only slightly more than U.S. white males (Document ID 0999, p. 717). OSHA also pointed out that the SMR may have been understated, as Vacek *et al.* did not account for a healthy worker effect (HWE).

The ACC did not agree with OSHA's review of the Vacek *et al.* study, noting that OSHA ''rejects Vacek *et al.* (2011) on grounds that are confusing and unfounded'' (Document ID 2307, Attachment A, p. 41). The ACC argued that the quintiles of cumulative exposure used by Vacek *et al.* were not higher than typical values for lung cancer, and that OSHA, in its Supplemental Literature Review, compared the Vacek *et al.* quintiles of cumulative exposure for silicosis with the Attfield and Costello groups used for both silicosis and lung cancer (Document ID 2307, Attachment A, pp. 41–42). OSHA acknowledges this discrepancy and, given that Vacek *et al.*

used quintiles of cumulative exposure that differed for each health endpoint, agrees that the quintiles for lung cancer used by Vacek *et al.* were not appreciably higher than the exposure groups used by Attfield and Costello, though the Agency recognizes that there may be alternative explanations for the patterns observed in the Vacek *et al.* data. Regarding uncontrolled confounding, the ACC stated that ''The Vermont granite worker cohort, after all, supposedly is free of confounding exposures,'' (Document ID 2307, Attachment A, p. 43 (citing Attfield and Costello, 2004, 0284)). Vacek *et al.* also pointed out that although the odds ratios for the second lowest exposure stratums were lower than those for the lowest categories for each of the diseases, they were not statistically significantly lower (Document ID 1804, pp. 1–2).

Although OSHA notes that this latter phenomenon, in which the odds ratio for the second lowest exposure stratum is lower than that for the lowest stratum, is commonly observed and often attributable to some form of selection confounding, the Agency recognizes that there may be alternative explanations for the patterns observed in the Vacek *et al.* data. One such explanation for the decreased odds ratios in the highest exposure group is potential attenuation resulting from a HWE.

The HWE, as defined by Stayner *et al.* (2003), has two components: (1) A healthy initial hire effect, in which bias is ''introduced by the initial selection of workers healthy enough to work . . . and the use of general population rates for the comparison group, which includes people who are not healthy enough to work,'' and (2) a healthy worker survivor effect, referring ''to the tendency of workers with ill health to drop from the workforce and the effect this dropout may have on exposure-response relationships in which cumulative exposure is the measure of interest'' (Document ID 1484, p. 318). Thus, the healthy initial hire effect occurs in the scenario in which the death rate in a worker group is compared to that in the general population; because the general population has many people who are sick, the death rate for workers may be lower, such that a direct comparison of the two death rates results in a bias. The healthy worker survivor effect occurs in the scenario in which less healthy workers transfer out of certain jobs into less labor-intensive jobs due to decreased physical fitness or illness, or leave the workforce early due to exposure-related illness prior to the start of follow-up in the study. As a result, the healthier workers accumulate the highest exposures such that the risk of disease at higher exposures may appear to be constant or decrease.

OSHA disagrees with the ACC's statement that ''the possibility of a potential HWE in this cohort could not have affected the E–R analyses'' in Vacek *et al.* (2011) (Document ID 2307, Attachment A, p. 46), and with the similar statement by study authors Pamela Vacek, Ph.D. and Peter Callas, Ph.D., both of the University of Vermont, who asserted that the HWE could not have impacted their exposure-response analyses ''because they were not based on an external reference population'' (Document ID 1804, p. 2). This explanation only considers one component of the HWE, the healthy initial hire effect. An internal control analysis, such as that performed by Vacek *et al.,* will generally minimize the healthy initial hire effect but does not address the healthy worker survivor effect (*see* Document ID 1484, p. 318 (Stayner *et al.* (2003)). Thus, the statement by the ACC that there could be no HWE in the internal case control analysis of Vacek *et al.* (2011) is incorrect, as it considered only the healthy initial hire effect and not the healthy worker survivor bias.

In contrast, Attfield and Costello's stated rationale for excluding the highest exposure group is related to the healthy worker survivor effect:

> We do know that this group is distinctive in entering the cohort with substantial exposures—83% had worked for 20 years or more in the high dust levels prevalent prior to controls. They were, therefore, a highly selected healthy worker group. A further reason may be that in the days when tuberculosis and silicosis were the main health concerns in these workers, lung cancer may have been obscured in this group as a cause of death in some cases'' (Document ID 0284, p. 136).

Support for Attfield and Costello's reasoning is provided by a study by Applebaum *et al.* (2007), which re-analyzed the data from the Attfield and Costello (2004) paper and concluded that there was a healthy worker survivor effect present (study cited by Vacek *et al.,* 2009, Document ID 2307, Attachment 6, p. 3). Applebaum *et al.* (2007) split the cohort of Vermont granite workers into two groups: (1) Those that began working before the start of the study follow-up, *i.e.*, prevalent hires; and (2) those that began working after the start of the study follow-up, *i.e.*, incident hires. The rationale for splitting the cohort into these two groups was to examine if a healthy worker survivor effect was more likely in the prevalent hire group, as this group would be affected by workers that were more susceptible to health effects and left the industry workforce prior to the start of the study follow-up (Applebaum *et al.*, 2007, pp. 681–682). Using spline models to examine exposure-response relationships without forcing a particular form (*e.g.,* linear, linear-quadratic) on the observed data, the authors found that the inclusion of prevalent hires in the analysis weakened the association between cumulative silica exposure and lung cancer because of bias from the healthy worker survivor effect. The bias can be reduced by including only incident hires, or keeping the date of hire close to the start of follow-up (Applebaum *et al.*, 2007, pp. 685–686). An alternative explanation for this trend offered by Applebaum *et al.* may be that, assuming that there was more measurement error in the older data, the prevalent hires had more exposure misclassification (2007, p. 686); in such a case, however, the inclusion of prevalent hires would still bias the results towards the null. Given the findings of the Applebaum *et al.* (2007) study, OSHA believes that Attfield and Costello (2004) had good reasons for removing the highest exposure group, which was composed mostly of prevalent workers (83 percent of workers in the highest exposure group had worked at least 20 years prior to the start of the follow-up period) (Document ID 0284, p. 136).

Vacek *et al.* (2011), on the other hand, excluded 609 workers in the design of their study cohort due to insufficient information. However, the majority of the workers excluded from the cohort were incident hires who began work after 1950 (Document ID 2307, Attachment 6, p. 12; 1486, p. 314). The final Vacek *et al.* (2011) cohort included 2,851 prevalent hires (began employment before 1950) compared to 4,201 incident hires (began employment in or after 1950) (Document ID 2307, Attachment 6, p. 12; 1486, p. 314). By composing about 40 percent of their cohort with prevalent hires and excluding many incident hires, Vacek *et al.* (2011) may have introduced additional healthy worker survivor effect bias into their study. Interestingly, Vacek *et al.* described the Applebaum *et al.* (2007) results in their 2009 report, stating, ''They [Applebaum *et al.*] found that decreasing the relative proportion of prevalent to incident hires [in the data used by Attfield and Costello] resulted in a stronger association between cumulative silica exposure and lung cancer mortality'' (Document ID

2307, Attachment 6, p. 3). Despite their acknowledgement of the Applebaum *et al.* (2007) findings, Vacek *et al.* (2011) did not conduct any analysis of only the incident hires, or use statistical methods to better determine the presence and effect of a healthy worker survivor effect in their study.

The ACC also commented on Vacek *et al.*'s suggestion that the elevated SMR observed for lung cancer in the cohort (when compared to a reference population of U.S. white males) was due to differences in the smoking habits of the cohort and reference population, which OSHA criticized in its Supplemental Literature Review (Document ID 1486, p. 317; 1711, Attachment 1, p. 5). The ACC stated, ''OSHA suggests that the lack of complete smoking data for the cohort is a problem and contends that smoking could not explain the elevated SMR for lung cancer. This criticism, as Dr. Vacek explains, is overstated, and, in any event, does not detract from the study's findings regarding the absence of an association between silica exposure and lung cancer'' (Document ID 2307, Attachment A, pp. 46–47; 1804, p. 2).

Vacek *et al.* (2011) estimated the relative smoking prevalence in the cohort to be 1.35 times that in the reference population; using this estimated relative smoking prevalence, the authors estimated that ''the expected number of lung cancer deaths in the cohort after adjusting the reference rates for smoking would be 353, yielding a [non-significant] SMR of 1.02'' (Document ID 1486, p. 317). OSHA notes that this method used by Vacek *et al.* to adjust the SMR for smoking neglects the healthy worker survivor effect (*i.e.*, smokers may leave the workforce sooner than nonsmokers because smoking is a risk factor for poor health). Absent control for the healthy worker survivor effect, smoking would (and perhaps did) become a negative confounder because long duration—high cumulative exposure—workers would tend toward lower smoking attributes. The method used by Vacek *et al.* is also inconsistent with the frequently cited Axelson (1978) method, which is used to adjust the SMR when the exposed population has a higher percentage of smokers than the reference population (Checkoway *et al.* 1997, Document ID 0326; Chan *et al.* 2000, 0983). As a result, Vacek *et al.* (2011) likely overestimated the confounding effect of smoking in this cohort.

In addition, as previously noted by OSHA, the SMRs for cancers largely attributable to smoking, such as those of the buccal cavity and pharynx (SMR = 1.01), larynx (SMR = 0.99), and esophagus (SMR = 1.15) were not significant in the Vacek *et al.* study (Document ID 1486, p. 315; 2307, Attachment 6, p. 14). The SMR of 0.94 for bronchitis, emphysema, and asthma also was not significant. If smoking were truly responsible for the highly statistically significant SMR (1.37) observed for lung cancer, the SMRs for these other diseases should be significant as well. OSHA likewise notes that other studies have found that smoking does not have a substantial impact on the association between crystalline silica exposure and lung cancer mortality (*e.g.,* Checkoway *et al.*, 1997, Document ID 0326; Steenland *et al.*, 2001a, 0452, p. 781) and that crystalline silica is a risk factor for lung cancer independent of smoking (Kachuri *et al.*, 2014, Document ID 3907, p. 138; Preller *et al.*, 2010, 4055, p. 657).

OSHA is also concerned about some features of the study design and exposure assessment in Vacek *et al.* (2011). Regarding the study design, in their nested case-control analyses, Vacek *et al.* sorted cases into risk sets based on year of birth and year of death, and then matched three controls to each risk set; from the data presented in Table 5 of the study, the actual number of controls per lung cancer case can be calculated as 2.64 (Document ID 1486, p. 316). Vacek *et al.*'s decision to use such a small number of controls per case was unnecessarily restrictive, as there were additional cohort members who could have been used as controls for the lung cancer deaths. Typically, if the relevant information is available, four or more (or all eligible) controls are used per case to increase study power to detect an association. OSHA notes that Steenland *et al.* (2001a), in their nested case-control pooled analysis, used 100 controls per case (Document ID 0452, p. 777).

In addition, Vacek *et al.* stated that for the categorical analysis, cut points on cumulative exposure were based on quintiles of the combined distribution for cases and controls (Document ID 1486, p. 314). Therefore, there should be an approximately equal total number of subjects (cases plus controls) in each group (or quintile). OSHA's examination of Table 5 in the Vacek *et al.* (2011) study shows that there is an approximately equal distribution of subjects for all endpoints except lung cancer; for example, the silicosis groups each had 43–44 subjects, the NMRD groups each had 125–130 subjects, the kidney cancer groups each had 22–23 subjects, and the kidney disease groups each had 25 subjects. However, the lung cancer groups, ranging from the lowest to the highest exposure, had 325, 232, 297, 241, and 202 subjects (Document ID 1486, p. 316). OSHA could find no explanation for this discrepancy in the text of the Vacek *et al.* (2011) study, and questions how the lung cancer groups were composed.

With respect to the different job exposure matrices, OSHA has reason to believe that the exposure data reported in the Attfield and Costello study are more accurate than the data Vacek *et al.* used. OSHA is particularly concerned that Vacek *et al.*'s pre-1940 exposure estimate of 150 $\mu g/m^3$ for one job (channel bar operator) was much lower than Attfield and Costello's estimate, from the Davis *et al.* (1983) matrix, of 1070 $\mu g/m^3$ (Document ID 1486, p. 313; 0284, p. 131). As NIOSH observed in its post-hearing comments, changing the exposure estimate for channel bar operators could have ''major consequences'' on the exposure-response analysis, as the job occurred frequently (Document ID 4233, p. 22). NIOSH then pointed out that the Attfield and Costello (2004) exposure estimate for channel bar operators was based on multiple exposure measurements conducted by Davis *et al.* (1983), whereas Vacek *et al.* based their exposure estimate ''on only three dust measurements'' in which ''only wet drilling was used. Thus, their study used not only very limited sampling data but also values that were biased towards low levels, since the samples were taken when water was being used to control dust,'' a practice that was not typically used for this occupation at the time (Document ID 4233, p. 22). In fact, photographs from Hosey *et al.* (1957) showed channel bar drilling in 1936 and 1937 with and without dust control; the caption for the photo without dust control states that the ''operator in background is barely visible through dust cloud'' (Document ID 4233, p. 24, citing 3998, Attachment 14b). As NIOSH explained,

> If there is a true [linear] relationship between exposure to silica dust and lung cancer mortality, classifying highly exposed workers incorrectly as low-exposed shifts the elevated risks to the low exposure range. The impact is to spuriously elevate risks at low exposures and lower them at high exposures, resulting in the exposure-response trend being flattened or even obscured. Ultimately, the true relationship may not be evident, or if it is, may be attenuated (Document ID 4233, p. 22, n. 1).

Vacek *et al.* reported in their study that they conducted a sensitivity analysis that did not change the exposure-response relationship between silica exposure and lung cancer risk,

even when Attfield and Costello's pre-1940 exposure estimates were used for channel bar operators (Document ID 2340, pp. 317–318; 2307, Attachment 6, p. 31). Part of the problem may be the way that channel bar operators were defined by Vacek *et al.* As noted by NIOSH, ''Leyner driller and channel bar operator or driller are synonyms'' (Document ID 4233, p. 22, n. 3). Attfield and Costello defined channel bar operators in that way, with a pre-1940 exposure estimate of 1070 μg/m^3 (Document ID 0284, p. 131). Vacek *et al.*, on the contrary, assigned channel bar operators to a category called ''channel bar (wet)'' and assigned a pre-1940 exposure estimate of 150 μg/m^3 (Document ID 2307, Attachment 6, Appendix B, pp. 7, 15). They included Leyner drillers under a general category called ''driller'' with a pre-1940 exposure estimate of 1070 μg/m^3 (Document ID 2307, Attachment 6, Appendix B, pp. 7, 15). Included in the Vacek *et al.* (2009) category of ''drillers'' were plug drillers (Document ID 2307, Attachment 6, Appendix B, p. 15); OSHA notes that Attfield and Costello used a lower pre-1940 exposure estimate of 650 μg/m^3 for plug drillers, as defined by Davis *et al.* (1983). OSHA believes that Vacek *et al.* underestimated the exposures of some channel bar operators, and overestimated the exposures of plug drillers, which may have contributed to the lack of association, and that the categorization used by Attfield and Costello, with the synonymous channel bar operators and Leyner drillers in one category, and plug drillers in a separate category, was more appropriate. Thus, even in Vacek *et al'*s sensitivity analysis, in which they used Attfield and Costello's exposure estimate of 1070 μg/m^3 for channel bar operators and drillers, the plug drillers would still have had a higher exposure estimate (1070 μg/m^3 versus Attfield and Costello's 650 μg/m^3), making the analysis different from that of Attfield and Costello.

For the reasons discussed herein, OSHA has decided not to reject the Attfield and Costello (2004) study in favor of the Vacek *et al.* (2011) study as a basis for risk assessment. OSHA maintains that it has performed an objective analysis of the Attfield and Costello (2004) and Vacek *et al.* (2011) studies. OSHA agrees with some of the ACC's criticisms regarding the Agency's initial evaluation of the exposure groupings and confounding in the Vacek *et al.* (2011) study. OSHA is concerned, however, as discussed above, about several aspects of Vacek *et al.* (2011), including a potential bias from the healthy worker survivor effect, which was shown to exist in this cohort (see Applebaum *et al.*, 2007, cited in Document ID 2307, Attachment 6, p. 3), as well as about job categorization that may have resulted in exposure misclassification for certain job categories (*e.g.,* the synonymous channel bar operators and Leyner drillers). Despite its concerns with the Vacek *et al.* study, OSHA acknowledges that comprehensive studies, such as Attfield and Costello (2004) and Vacek *et al.* (2011), in the Vermont granite industry have shown conflicting results with respect to lung cancer mortality (Document ID 0284; 1486). As discussed earlier, conflicting results are often observed in epidemiological studies due to differences in study designs, analytical methods, exposure assessments, populations, and other factors. In addition, the exposure-response relationship between silica and lung cancer may be easily obscured by bias, as crystalline silica is a comparably weaker carcinogen (*i.e.*, the increase in risk per unit exposure is smaller) than other well-studied, more potent carcinogens such as hexavalent chromium (Steenland *et al.*, 2001, Document ID 0452, p. 781). Although OSHA believes that the Attfield and Costello (2004) study is the most appropriate Vermont granite study to use in its QRA, the Agency notes that, even in the absence of the Attfield and Costello (2004) study, the risk estimates for lung cancer mortality based on other studies still provide substantial evidence that respirable crystalline silica poses a significant risk of serious health conditions to exposed workers.

4. Comments on Specific Studies Relied Upon by OSHA in Its QRA

a. Attfield and Costello (2004)

As stated above, OSHA disagrees with the ACC's contention that Vacek *et al.* provides a more reliable scientific basis for estimating risk than Attfield and Costello. While it is true that the final risk estimate (54 deaths per 1,000 workers) derived from the Attfield and Costello study for an exposure level of 100 μg/m^3 is the highest when compared to the other studies, it is not true that the final risk estimate (22 deaths per 1,000 workers) derived from the Attfield and Costello study is the highest for the final rule's PEL of 50 μg/m^3. In fact, it is within the range of risk estimates derived from the ToxaChemica (2004) pooled analysis of 16 to 23 deaths per 1,000 workers at the final PEL. Thus OSHA has decided to retain its reliance on the Attfield and Costello (2004) study and, again, notes that, even without the Attfield and Costello (2004) study, all of the other studies in the Final QRA demonstrate a clearly significant risk of lung cancer mortality (11 to 54 deaths per 1,000 workers) at an exposure level of 100 μg/m^3, with a reduced, albeit still significant, risk (5 to 23 deaths per 1,000 workers) at an exposure level of 50 μg/m^3 (see Table VI–1 in Section VI, Final Quantitative Risk Assessment and Significance of Risk). Excluding Attfield and Costello (2004), in other words, would not change OSHA's final conclusion regarding the risk of death from lung cancer.

b. Miller and MacCalman (2009)

According to the ACC, OSHA's risk estimates based on the Miller and MacCalman (2009, Document ID 1306) study are ''more credible than the others—because [the study] involved a very large cohort and was of higher quality in terms of design, conduct, and detail of exposure measurements,'' and also adjusted for smoking histories (Document ID 2307, Attachment A, p. 73). Although the risk estimates generated from the Miller and MacCalman data were the lowest of the lung cancer mortality estimates, the ACC next asserted that they were biased upwards for several reasons. First, the ACC stated that exposure information was lacking for cohort members after the mines closed in the mid-1980's, and quoted OSHA as stating, ''Not accounting for this exposure, if there were any, would bias the risk estimates upwards'' (Document ID 2307, Attachment A, p. 74 (quoting 1711, p. 289)). OSHA, however, does not believe there to have been additional substantial quartz exposures. As the study authors wrote, ''Because of the steep decline of the British coal industry, the opportunities for further extensive coal mine exposure were vanishingly small'' (Document ID 1306, p. 11). Thus OSHA believes it to be unlikely that the risk estimates are biased upwards to any meaningful degree based on lack of exposure information at the end of the study period.

The ACC also stated that the unrestricted smoking of cohort members after the closure of the mines would have resulted in risk estimates that were biased upwards (Document ID 2307, Attachment A, p. 74). OSHA has no reason to believe, nor did the ACC submit any evidence in support of its contention, that unrestricted smoking occurred, however, and notes that the authors stated that the period after the mines closed was one of ''greater anti-

smoking health promotion campaigns'' (Document ID 1306, p. 11).

Finally, the ACC noted that Miller and MacCalman did not adjust significance levels for the multiple comparisons bias with respect to lag selection that Dr. Cox alleged affected their study (Document ID 2307, Attachment A, p. 74). Dr. Cox claimed that trying multiple comparisons of alternative approaches, such as different lag periods, and then selecting a final choice based on the results of these multiple comparisons, leads to a multiple comparisons bias that could result in false-positive associations (Document ID 2307, Attachment 4, p. 28; see Section V.J, Comments and Responses Concerning Biases in Key Studies). He argued that the authors should have reduced the significance level (typically p = 0.05) at which a result is considered to be significant. ''Lag'' refers to the exclusion of the more recent years of exposure (*e.g.,* 10-year lag, 15-year lag) to account for the fact that diseases like cancer often have a long latency period (*i.e.,* that the cancer may not be detected until years after the initiating exposure, and exposures experienced shortly before detection probably did not contribute to the development of disease). ''Lag selection,'' therefore, refers to the choice of an appropriate lag period. As addressed later in the Section V.J, Comments and Responses Concerning Biases in Key Studies, OSHA does not necessarily believe such an adjustment of significance levels to be appropriate, based upon the testimony of Mr. Park of NIOSH, nor is it typically performed in the occupational epidemiology literature (Document ID 3579, Tr. 151–152). Similarly, the ACC stated that the confidence intervals are overly narrow because they ignore model uncertainty, and that multiple imputation of uncertain exposure values should have been performed (Document ID 2307, Attachment A, p. 75). OSHA rejects this assertion on the grounds that the authors used detailed exposure estimates that the ACC recognized raised the credibility of the study; the ACC wrote, regarding the study, ''it involved a very large cohort and was of higher quality in terms of design, conduct, and detail of exposure measurements'' (Document ID 2307, Attachment A, p. 73). Lastly, the ACC argued that an exposure threshold should have been examined (Document ID 2307, Attachment A, p. 75). OSHA discusses at length this issue of thresholds, and the difficulty in ruling them in or out at low exposures, in Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases.

In summary, OSHA notes that the ACC has not provided any non-speculative evidence to support its claims that the risk estimates derived from the Miller and MacCalman (2009) study are biased upwards. As stated in the Review of Health Effects Literature and Preliminary QRA, and acknowledged by the ACC (Document ID 2307, p. 73), OSHA believes these risk estimates to be very credible, as the study was based on well-defined union membership rolls with good reporting, had over 17,000 participants with nearly 30 years of follow-up, and had detailed exposure measurements of both dust and quartz, as well as smoking histories (Document ID 1711, pp. 288–289).

c. Steenland (2001a) and ToxaChemica (2004)

OSHA also received several comments on the ToxaChemica (2004, Document ID 0469) analysis, which was based on the Steenland *et al.* (2001a, Document ID 0452) pooled analysis. First, the ACC claimed that there is significant heterogeneity in the exposure-response coefficients, derived from the individual studies. Because the risk estimates based on these coefficients differ by almost two orders of magnitude, the ACC suggested that these models are misspecified for the data (Document ID 2307, Attachment A, pp. 75–76). Essentially, the ACC claimed that the exposure-response coefficients differ too much among the individual studies, and asserted that it is therefore inappropriate to use the pooled models. Dr. Cox wrote: ''Steenland et al. did not address the heterogeneity, but artificially suppressed it by unjustifiably applying a log transformation. This is not a valid statistical approach for exposure estimates with substantial estimation errors'' (Document ID 2307, Attachment 4, p. 75). During the public hearing, however, Dr. Steenland explained to OSHA's satisfaction how the data in his study was transformed, using accepted statistical methods. Specifically, referring to his use of a log transformation to address the heterogeneity, Dr. Steenland testified:

> [I]t reduces the effect of the very highest exposures being able to drive an exposure-response curve because those exposures are often [skewed] way out—skewed to the right, because occupational exposure data is often log normal. With some very high exposures, they are sort of extreme, and that can drive your exposure-response curve. And you take the log, it pulls them in, and so therefore gives less influence to those high data points. And I think those high data points are often measured with more error (Document ID 3580, Tr. 1265–1266).

OSHA finds this testimony to be persuasive and, therefore, believes that Dr. Steenland's use of a log transformation to address the heterogeneity was appropriate. The log transformation also permits a better model fit when attenuation of the response is observed at high cumulative exposures.

Dr. Morfeld commented that Steenland et al. did not take into account smoking, which could explain the observed excess lung cancer of 20 percent (SMR = 1.2). Dr. Morfeld stated, ''Thus, lung cancer excess risks were demonstrated only under rather high occupational exposures to RCS dust, and, even then, an upward bias due to smoking and a necessary intermediate role for silicosis could not be ruled out'' (Document ID 2307, Attachment 2, p. 10). Dr. Steenland addressed the concern about a potential smoking bias during his testimony:

> We concluded that this positive exposure response was not likely due to different smoking habits between high exposed and low exposed workers. And the reason we did that was twofold. First, workers tend to smoke similar amounts regardless of their exposure level in general. We often worry about comparing workers to the general population because workers tend to smoke more than the general population. But, in internal analyses, we don't have this problem very often. When we have smoking data, we see that it is not related to exposure, so a priori we don't think it is likely to be a strong confounder in internal analyses. Secondly, a number of the studies we used in our pool[ed] cohort had smoking data, either for the whole cohort or partially. And when they took that into account, their results did not change. In fact, they also found that smoking was not related to exposure in their studies, which means that it won't affect the exposure-disease relationship because if it is going to do that, it has to differ between the high exposed and the low exposed, and it generally did not (Document ID 3580, Tr. 1227–1228).

In addition, Brown and Rushton (2009), in their review article submitted to the rulemaking record by Dr. Morfeld, appeared to agree with Dr. Steenland, stating, ''This [Steenland *et al.*] internal analysis removed the possibility of confounding by smoking'' (Document ID 3573, Attachment 5, p. 150). Thus, OSHA rejects Dr. Morfeld's assessment that the risk estimates may be biased upwards due to smoking.

The ACC also commented that exposure misclassification due to uncertain exposure estimates in Steenland's pooled cohort could have created the appearance of a monotonic relationship, in which the response

increases with the exposure, even if the true response was not monotonic (Document ID 2307, Attachment A, p. 76). The ACC, along with Dr. Borak (representing the U.S. Chamber of Commerce) and others, likewise cited OSHA's statement from the Review of Health Effects Literature and Preliminary QRA, in which the Agency acknowledged that uncertainty in the exposure estimates that underlie each of the 10 studies in the pooled analysis was likely to represent one of the most important sources of uncertainty in the risk estimates (Document ID 1711, p. 292; 2376, p. 16). Dr. Borak also quoted Mannetje et al. (2002), who developed quantitative exposure data for the pooled analysis, as stating, ''While some measurement error certainly occurred in our estimates, a categorical analysis based on broad exposure groups should not be much affected by the resulting level of misclassification'' (Document ID 2376, p. 17, quoting 1090, p. 84). From this statement, Dr. Borak concluded that the researchers themselves believed the data were only adequate for ''categorical analyses which might lead to qualitative conclusions'' (Document ID 2376, p. 17).

OSHA disagrees with Dr. Borak's interpretation of the Mannetje *et al.* statement, as categorical analyses are typically quantitative in nature, with the data being used to draw quantitative conclusions. However, OSHA recognized the possibility for uncertainty in the exposure estimates, and it is for this reason that OSHA commissioned a quantitative analysis of uncertainty in Steenland's pooled study (ToxaChemica, 2004, Document ID 0469). This analysis suggested that exposure misclassification had little effect on the pooled exposure coefficient (and the variance around that estimate) for the lung cancer risk model (Document ID 1711, pp. 313–314). Given this analysis, OSHA also disagrees with the ACC's statement that ''it is virtually certain that substantial exposure estimation error infused the pooled analysis, resulting in exposure misclassification that would create a false appearance of a monotonically increasing exposure-response even where none exists'' (Document ID 2307, Attachment A, p. 78). OSHA notes that this statement is not supported with any evidence from the Steenland et al. (2001) study. In addition, as discussed at length in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis, exposure estimation error can also bias results towards the null (weaken or obscure the exposure-response relationship) (Document ID 3580, Tr. 1266–67; 3576, Tr. 358–359; 3574, p. 21). Other criticisms from the ACC concerning alleged modeling errors and biases in the Steenland study and the alleged threshold for the health effects of silica exposure are discussed generally in Section V.J, Comments and Responses Concerning Biases in Key Studies, and Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases. Dr. Cox's and Dr. Morfeld's criticisms of the uncertainty analysis performed by Toxachemica are addressed in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis. For the reasons stated in those sections, OSHA is unpersuaded by these criticisms.

The ACC concluded:

> For all these reasons, the pooled analysis by Steenland *et al.* (2001) does not yield credible or reliable estimates of silica-related lung cancer risk. But, even if risk estimates based on Steenland *et al.* (2001) were not so problematic, that study would not demonstrate that reducing the PEL from 0.1 mg/m^3 [100 μg/m^3] to 0.05 mg/m^3 [50 μg/m^3] will result in a substantial reduction in the risk of lung cancer (Document ID 2307, Attachment A, p. 81).

The ACC then discussed the ToxaChemica report (2004), which the ACC claimed shows that ''under the spline model (which the authors prefer over the log cumulative model because of biological plausibility)'' reducing the PEL from 100 μg/m^3 to 50 μg/m^3 would negligibly reduce the excess risk of lung cancer mortality from 0.017 (17/1,000) to 0.016 (16/1,000), ''risk values that are indistinguishable given the overlapping confidence limits of the two estimates'' (Document ID 2307, Attachment A, p. 81). In addition, the ACC noted that the excess risk at 150 μg/m^3 and 250 μg/m^3 in the spline model is the same as the excess risk at 50 μg/m^3, while that at 200 μg/m^3 is lower. ''Estimates of lung cancer risk in the neighborhood of the current general industry PEL are hugely uncertain—with the data suggesting that a greater reduction in lung cancer risk could be achieved by doubling the PEL to 200 μg/m^3 than by cutting it in half to a level of 50 μg/m^3'' (Document ID 2307, Attachment A, pp. 81–82).

OSHA notes that these risk estimates cited by the ACC were the original estimates for the spline model provided to OSHA by ToxaChemica in its 2004 report (Document ID 0469). These are not the risk estimates used by OSHA. Instead, to estimate the risks published in this final rule, the Agency used the exposure-response coefficients from the study in an updated life table analysis using background all-cause mortality and lung cancer mortality rates from 2006 and 2011, respectively. The risk estimates using the 2011 background data are the most updated numbers with which to make the comparisons ACC has suggested. With the 2011 background data, the estimated excess risk is 20 deaths per 1,000 workers at 100 μg/m^3, and 16 deaths per 1,000 workers at 50 μg/m^3, a reduction of 4 deaths. OSHA's estimated excess risk at 250 μg/m^3 is 24 deaths per 1,000 workers, an increase in 8 deaths when compared to 50 μg/m^3. Thus it is not the case, as ACC suggested, that increasing the PEL would cause a reduction in lung cancer mortality risk.

In addition, the linear spline model employed by Steenland et al. (2001) was only one of three models used by OSHA to estimate quantitative risks from the pooled analysis. OSHA also used the log-linear model with log cumulative exposure as well as the linear model with log cumulative exposure (see Section VI, Final Quantitative Risk Assessment and Significance of Risk). OSHA notes that all three models indicated a reduction in risk when comparing an exposure level of 100 μg/m^3 to 50 μg/m^3.

In summary, OSHA disagrees with the ACC's assertion that the Steenland et al. pooled analysis does not yield credible risk estimates for lung cancer mortality. Dr. Morfeld's assertion that the risk estimates were biased upwards due to smoking is quite unlikely to be true, given that the study was an internal (worker to worker) analysis. The ACC's claim that exposure estimation error resulted in false exposure-response relationships was not supported by any actual data; as discussed in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis, exposure estimation error can also bias results towards the null (weaken or obscure the exposure-response relationship) (Document ID 3580, Tr. 1266–67; 3576, Tr. 358–359; 3574, p. 21). For these reasons, OSHA rejects the ACC's claims that the Steenland study of lung cancer mortality does not yield credible risk estimates. Rather, based upon its review, OSHA believes this pooled analysis to be of high quality. As Dr. Steenland testified during the informal public hearings, this pooled analysis, with its more than 60,000 workers and 1,000 lung cancer deaths, involved ''a rich dataset with high statistical power to see anything, if there was anything to see'' (Document ID 3580, Tr. 1227). In fact, OSHA believes the Steenland *et al.* (2001a) study to be among the best available studies in the peer-reviewed literature on the topic of

silica exposure and its relationship to lung cancer mortality.

d. Rice *et al.* (2001)

The ACC also commented on the Rice *et al.* (2001, Document ID 1118) study of diatomaceous earth workers, which found a significant risk of lung cancer mortality that increased with cumulative silica exposure in a cohort of diatomaceous earth workers. The ACC claimed that it had a high likelihood of exposure misclassification. Dr. Cox contended that the practice of ''[a]ssigning each worker a single estimated cumulative exposure based on estimated mean values produces biased results and artificially narrow confidence intervals (and hence excess false-positive associations)'' (Document ID 2307, Attachment 4, p. 76). OSHA notes that Rice *et al.* (2001) described the exposure estimation procedure in their paper. There were more than 6,000 measurements of dust exposure taken from 1948–1988; particle count data were converted to gravimetric data using linear regression modeling. Cumulative exposures to respirable crystalline silica were then estimated for each worker using detailed employment records (Document ID 1118, p. 39). OSHA concludes it is highly unlikely that the exposure estimates are biased to such an extent, as Dr. Cox suggests, that they would produce false-positive associations.

The ACC also noted that the mean crystalline silica exposure in the diatomaceous earth worker cohort was 290 $\mu g/m^3$, approximately three times the former PEL for general industry (Document ID 2307, Attachment A, p. 83). OSHA, however, believes that the cumulative respirable crystalline silica dust concentration is the metric of concern here, as that is what was used in the regression models. The mean cumulative respirable crystalline silica dust concentration in the study was 2.16 mg/m^3-yrs, which is a very realistic cumulative exposure for many workers (Document ID 1118, p. 39).

The ACC also stated that the results of the Rice study were confounded by smoking and possibly asbestos exposure (Document ID 2307, Attachment A, p. 83). OSHA previously addressed the possible confounding in this cohort in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 139–143). Rice *et al.* (2001) used the same cohort originally reported on by Checkoway *et al.* (1993, Document ID 0324; 1996, 0325; 1997, 0326). The Rice study discussed the smoking confounding analysis performed by Checkoway *et al.* (1997), in which the Axelson method (1978) was used to make a worst case estimate (assuming 20 times greater lung cancer risk in smokers compared to non-smokers) and indirectly adjust the relative risk (RR) estimates for lung cancer for differences in smoking rates (Document ID 1118, pp. 40–41). With exposures in the Checkoway study lagged 15 years to account for the latency period, the worst case effect was to reduce the RR for lung cancer in the highest exposure group from 2.15 to 1.67. Checkoway *et al.* concluded that the association between respirable silica exposure and lung cancer was unlikely to be confounded by cigarette exposure (Document ID 0326, pp. 684, 687). Regarding confounding by asbestos exposure, Rice *et al.* (2001) stated:

> Checkoway *et al.* found no evidence that exposure to asbestos accounted for the observed association between mortality from lung cancer and cumulative exposure to silica. Our analyses of their data also found no evidence of confounding by asbestos in the Poisson regression or Cox's proportional hazards models regardless of lag period; therefore, exposure to asbestos was not included in the models presented in this paper (Document ID 1118, p. 41).

Based upon these analyses, OSHA rejects the ACC's unsupported assertion that the results of Rice *et al.* (2001) were confounded by smoking and asbestos exposure.

Lastly, Dr. Cox asserted that there were several biases in Rice *et al.* (2001), including multiple-testing bias from testing multiple lag periods, exposure groupings, and model forms; model specification bias; and a lack of model diagnostics (Document ID 2307, Attachment 4, pp. 63–64, 77). OSHA addressed these issues generally in Section V.J, Comments and Responses Concerning Biases in Key Studies, and rejects these assertions for the same reasons. OSHA also discussed regression diagnostics at length in the same section. In summary, despite the criticisms directed at the Rice *et al.* study by the ACC, OSHA continues to believe that the quantitative exposure-response analysis by Rice *et al.* (2001) is of high quality and appropriate for inclusion in the QRA (Document ID 1711, p. 143).

e. Hughes *et al.* (2001)

The ACC, through the comments of Dr. Cox, presented a similar critique of the study of North American industrial sand workers by Hughes *et al.* (2001, Document ID 1060). This study found a statistically significant association (increased odds ratios) between lung cancer mortality and cumulative silica exposure as well as average silica concentration (Document ID 1060). In this study, according to Dr. Cox, ''The selected model form guarantees a monotonic exposure-response relation, independent of the data. Model uncertainty and errors in exposure estimates have both been ignored, so the slope estimate from Hughes *et al.* (2001), as well as the resulting excess risk estimates, are likely to be biased and erroneous'' (Document ID 2307, Attachment 4, p. 85). The ACC also noted that this cohort had incomplete smoking information, with the proportion of ''ever smokers'' significantly higher in cases than in controls. In addition, the ACC asserted that asbestos exposure may have also occurred, as three death certificates listed mesothelioma as the cause of death (Document ID 2307, Attachment A, pp. 85–86).

OSHA discussed the Hughes *et al.* (2001, Document ID 1060) study in its Review of Health Effects Literature and Preliminary QRA, highlighting as strengths the individual job, exposure, and smoking histories that were available (Document ID 1711, p. 285). Exposure levels over time were estimated via a job exposure matrix constructed by Rando *et al.* (2001, Document ID 0415) utilizing substantial exposure data, including 14,249 respirable dust and silica samples taken from 1974 to 1998 in nine plants (Document ID 1711, pp. 88, 124–128; 1060, 202). Smoking data were collected from medical records supplemented by information from next of kin or living subjects for 91 percent of cases and controls (Document ID 1060, p. 202). OSHA believes these smoking histories allowed the authors to adequately control for confounding by smoking in their analyses. Regarding the three death certificates listing mesothelioma, McDonald *et al.* (2001) explained that two were for workers not included in the case/control study because they were hired at or after age 40 with less than 10 years of work time; the third was for a worker hired at age 19 who then accumulated 32 years of experience in maintenance jobs (Document ID 1091, p. 195). As such, OSHA does not believe it likely that asbestos exposure was a large source of confounding in typical industrial sand operations in this study. OSHA also notes that the positive findings of this study were consistent with those of other studies of workers in this cohort, including Steenland and Sanderson (2001, Document ID 0455) and McDonald *et al.* (2005, Document ID 1092).

The ACC also noted that there was no consistent correlation in Hughes *et al.* (2001) between employment duration

and lung cancer risk (Document ID 2307, Attachment A, p. 86), with Dr. Cox suggesting that model specification error was to blame (Document ID 2307, Attachment 4, p. 86). OSHA believes that cumulative exposure is a more appropriate metric for determining risk than is duration of exposure because the cumulative exposure metric considers both the duration and intensity of exposure. For example, some workers may have been employed for a very long duration with low exposures, whereas others may have been employed for a short duration but with high exposures; both groups could have similar cumulative exposures.

In summary, OSHA considers the Hughes *et al.* (2001) study to be of high enough quality to provide risk estimates for excess lung cancer from silica exposure, as the study is unlikely to be substantially confounded. For these reasons, the Agency finds the assertion that the risk estimates based on this study are erroneous to be unconvincing.

Overall, regarding all of the studies upon which OSHA relied in its Preliminary QRA, the ACC concluded, ''In sum, none of the studies on which OSHA relies is inconsistent with a concentration threshold above 100 μg/m^3 for any risk of silica-related lung cancer; none demonstrates an increased lung cancer risk in the absence of silicosis; and none provides a sound basis for estimating lung cancer risks at RCS [respirable crystalline silica] exposure levels of 100 μg/m^3 and below'' (Document ID 2307, Attachment A, p. 87).

OSHA is not persuaded that the evidence presented by the ACC supports these conclusions. On the contrary, as OSHA discussed in the Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases, demonstrating the absence of a threshold is not a feasible scientific pursuit, and some models produce threshold estimates well below the PELs. Similarly, the ACC has not put forward any study that has proven that silicosis must be a precursor for lung cancer and, as discussed in Section V.H, Mechanisms of Silica-Induced Adverse Health Effects, some studies have shown genotoxic mechanisms by which exposure to crystalline silica may lead to lung cancer. The strong epidemiological evidence for carcinogenicity, supported by evidence from experimental animal and mechanistic studies, allowed IARC to conclude on multiple occasions that respirable crystalline silica is a Group I carcinogen. OSHA places great weight on this conclusion given IARC's authority and standing in the international scientific community. In addition, all of the lung cancer studies relied upon by OSHA used models that allow for the estimation of lung cancer risks at crystalline silica exposure levels of 100 μg/m^3 and below. OSHA believes these studies (Steenland *et al.*, 2001a, Document ID 0452, as re-analyzed in ToxaChemica, 2004, 0469; Rice *et al.*, 2001, 1118; Attfield and Costello, 2004, 0284; Hughes *et al.*, 2001, 1060; and Miller and MacCalman, 2009, 1306) are of high quality and contain well-supported findings. Thus, OSHA continues to rely upon these studies for deriving quantitative risk estimates in its QRA and continues to believe that workers exposed to respirable crystalline silica at levels at or near the previous and new PELs are faced with a significant risk of dying from lung cancer. As such, the Agency believes it would be irresponsible as a scientific matter, and inconsistent with its statutory obligations to issue standards based on the best available evidence after conducting an extensive rulemaking, to retain the regulatory status quo.

G. Comments and Responses Concerning Renal Disease Mortality

OSHA estimated quantitative risks for renal disease mortality (Document ID 1711, pp. 314–316) using data from a pooled analysis of renal disease, conducted by Steenland *et al.* (2002a, Document ID 0448). As illustrated in Table VI–1, the lifetime renal disease mortality risk estimate for 45 years of exposure to the previous general industry PEL (100 μg/m^3 respirable crystalline silica) is 39 deaths per 1,000 workers. However, for the final PEL (50 μg/m^3), it is 32 deaths per 1,000 workers. Although OSHA acknowledges that there are considerably less data for renal disease mortality, and thus the risk findings based on them are less robust than those for silicosis, lung cancer, and non-malignant respiratory disease (NMRD) mortality, the Agency believes the renal disease risk findings are based on credible data. Indeed, the Steenland *et al.* pooled analysis had a large number of workers from three cohorts with sufficient exposure data, and exposure matrices for the three cohorts had been used in previous studies that showed positive exposure-response trends for silicosis morbidity or mortality, thus tending to validate the underlying exposure and work history data (*see* Document ID 1711, pp. 215–216). Nevertheless, OSHA received comments that were critical of its risk estimates for renal disease mortality. Based upon its review of the best available evidence, OSHA finds that these comments do not alter its overall conclusions on renal disease mortality. In addition, OSHA notes that even if the risk of renal disease mortality is discounted, there would remain clearly significant risks of lung cancer mortality, silicosis and NMRD mortality, and silicosis morbidity, with more robust risk estimates based upon a larger amount of data from numerous studies (*see* Table VI–1).

OSHA received several comments from the ACC regarding the Agency's quantitative risk estimates for renal disease mortality. Specifically, the ACC argued that: (1) The pooled study (Steenland *et al.*, 2002a, Document ID 0448) that OSHA relied upon did not provide sufficient data to estimate quantitative risks; (2) the individual studies included in the pooled study had several limitations; and (3) most epidemiological studies have not demonstrated a statistically significant association between silica exposure and renal disease mortality (Document ID 2307, Attachment A, pp. 139–157; 4209, pp. 92–96). As explained below, and as stated above, although the Agency acknowledges there is greater uncertainty in the risk estimates related to renal disease than other silica-related diseases, the best available evidence is of sufficient quality to quantify the risk of renal disease in the final risk assessment.

1. Pooled Study

Some commenters expressed concern about the Steenland *et al.* (2002a, Document ID 0448) pooled study of renal disease mortality, which OSHA and its contractor, ToxaChemica, used to calculate quantitative risk estimates. Specifically, the ACC questioned why the analysis only used three studies (Homestake, North Dakota gold miners, Steenland and Brown, 1995a, Document ID 0450; U.S. industrial sand workers, Steenland *et al.*, 2001b, Document ID 0456; Vermont granite workers, Costello and Graham, 1988, Document ID 0991) out of the ten originally used in the pooled study of lung cancer mortality (Steenland *et al.*, 2001a, Document ID 0452). Peter Morfeld, Dr. rer. medic., representing the ACC, wrote in his written testimony that although Steenland *et al.* (2002a, Document ID 0448) indicated that the three studies were selected because they were the only ones to have information on multiple cause mortality, all 10 studies had information on renal disease as an underlying cause of death (Document ID 2308, Attachment 4, pp. 24–25). Since ToxaChemica focused on underlying cause results in their discussion, Dr. Morfeld argued that not having used all

10 studies in the pooled analysis ''raises a suspicion of study selection bias'' (Document ID 2308, Attachment 4, pp. 24–25).

OSHA finds this assertion of study selection bias by the ACC and Dr. Morfeld to be unpersuasive because Steenland *et al.*'s explanation (2002a) for including only three studies in the pooled analysis was sound. The authors reported in their pooled study that both underlying cause and multiple cause mortality were available for only three cohorts of silica-exposed workers, and ''multiple cause (any mention on the death certificate) was of particular interest because renal disease is often listed on death certificates without being the underlying cause'' (Document ID 0448, p. 5). The authors likewise cited a study (Steenland *et al.*, 1992), indicating that the ratio of chronic renal disease mortality shown anywhere on a U.S. death certificate versus being shown as an underlying cause is 4.75 (Document ID 0453, Table 2, pp. 860–861). Indeed, in their pooled analysis of renal disease mortality, Steenland *et al.* noted that there were 51 renal disease deaths when using underlying cause, but 204 when using multiple cause mortality (Document ID 0448, p. 5). As renal disease is a serious disabling disease, the use of multiple cause mortality gives a much better sense of the burden of excess disease than does the use of underlying cause of death as an endpoint. As such, Steenland *et al.* calculated odds ratios by quartile of cumulative silica exposure for renal disease in a nested case-control analysis that considered any mention of renal disease on the death certificate as well as underlying cause. For multiple-cause mortality, the exposure-response trend was statistically significant for both cumulative exposure ($p = 0.004$) and log cumulative exposure ($p = 0.0002$); whereas for underlying cause mortality, the trend was statistically significant only for log cumulative exposure ($p = 0.03$) (Document ID 1711, p. 315). Thus, OSHA believes that Steenland *et al.* (2002a, Document ID 0448) were justified in including only the three cohorts with all-cause mortality in their pooled analysis.

Concern was also expressed about the model selection in the pooled analysis. Dr. Morfeld noted that a statistically significant association between exposure to crystalline silica and renal disease mortality was only found in the underlying cause analysis in which the model was logged ($p = 0.03$) (Document ID 2308, Attachment 4, p. 25). Dr. Morfeld commented, ''The authors stated that the log-model fit better, but evidence was not given (*e.g.,* information criteria), and it is unclear whether the results are robust to other transformations'' (Document ID 2308, Attachment 4, p. 25).

OSHA disagrees with this criticism because a log transformation of the cumulative exposure metric is reasonable, given that exposure variables are often lognormally distributed in epidemiological studies, as discussed in Section V.J, Comments and Responses Concerning Biases in Key Studies. Also, while it is true that Steenland *et al.* (2002a) only found a statistically significant association in the continuous underlying cause analysis when the cumulative exposure metric was logged ($p = 0.03$), OSHA notes that the authors also found a statistically significant association in the highest quartile of unlogged cumulative silica exposure (1.67 + mg/m^3-yr) in the categorical underlying cause analysis (95% confidence interval: 1.31–11.76) (Document ID 0448, Table 2, p. 7). Thus, for the highest cumulative exposures, there was a significant association with renal disease mortality even without a log transformation of the exposure metric. Dr. Morfeld also failed to mention that Steenland *et al.* (2002a) found statistically significant associations in the continuous analyses (for both untransformed and log-transformed cumulative exposure) using any mention of renal disease on the death certificate, which adds weight to the study's findings that exposure to respirable crystalline silica is associated with renal disease mortality (Document ID 0448, Table 2, p. 7). In light of this, OSHA concludes that Dr. Morfeld's criticism of the pooled analysis is without merit.

The ACC also noted that the authors of this study, Drs. Kyle Steenland and Scott Bartell, acknowledged the limitations of the data in their 2004 ToxaChemica report to OSHA. Specifically, in reference to the 51 renal deaths (underlying cause) and 23 renal cases in the pooled study, Drs. Steenland and Bartell wrote, ''This amount of data is insufficient to provide robust estimates of risk'' (Document ID 2307, Attachment A, p. 139, citing 0469, p. 27). Given this acknowledgement, the ACC concluded that OSHA's inclusion of the renal disease mortality risk estimates in the significant risk determination and calculation of expected benefits was speculative (Document ID 2307, Attachment A, pp. 139–140). During the hearing, Dr. Steenland further explained, ''I think there is pretty good evidence that silica causes renal disease. I just think that there is not as big a database as there is for lung cancer and silicosis. And so there is more uncertainty'' (Document ID 3580, Tr. 1245). OSHA agrees with Dr. Steenland and acknowledges, as it did in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711, p. 357), that its quantitative risk estimates for renal disease mortality have more uncertainty and are less robust than those for the other health effects examined (*i.e.*, lung cancer mortality, silicosis and NMRD mortality, and silicosis morbidity). However, OSHA disagrees with the ACC's suggestion that the Agency's renal disease risk estimates are ''rank speculation'' (Document ID 4209, pp. 95–96), as these estimates are based on the best available evidence in the form of a published, peer-reviewed pooled analysis (Steenland *et al.* 2002a, Document ID 0448) that uses sound epidemiological and statistical methods. Thus, OSHA believes that it is appropriate to present the risk estimates along with the associated uncertainty estimate (*e.g.*, 95% confidence intervals) (*see* Document ID 1711, p. 316).

2. Individual Studies in the Pooled Study

The ACC also identified limitations in each of the three epidemiological studies included in the Steenland *et al.* (2002a, Document ID 0448) pooled study. First, with respect to the Steenland and Brown (1995a, Document ID 0450) study of North Dakota gold miners, the ACC noted there was a significantly elevated standardized mortality ratio (SMR) for chronic renal disease only in the men hired prior to 1930. It noted that there were no silica exposure measurement data available for this early time period, such that Steenland and Brown (1995a, Document ID 0450) instead estimated a median exposure (150 μg/m^3) that was seven times higher for men hired prior to 1930, versus men hired after 1950 (20 μg/m^3) (Document ID 2307, Attachment A, p. 147). The ACC maintained that these exposure estimates were likely to be understated and not credible, while also suggesting ''the existence of an average exposure threshold ≥150 μg/m^3 for any risk of silica-related renal disease mortality'' (Document ID 2307, Attachment A, p. 147).

OSHA finds the ACC's suggestion of a threshold to be unpersuasive, as the ACC provided no analysis to indicate a threshold in this study. OSHA addresses the Steenland and Brown (1995a, Document ID 0450) exposure assessment in Section V.D, Comments and Responses Concerning Silicosis and Non-Malignant Respiratory Disease Mortality and Morbidity. The ACC also

ignored the alternative explanation, that elevated chronic renal disease mortality may have only been seen in the workers hired prior to 1930 because they had a higher cumulative exposure than workers hired later, not because there was necessarily a threshold.

The ACC had a similar criticism of the Steenland *et al.* (2001b, Document ID 0456) study of North American industrial sand workers. The ACC posited that the exposure estimates were highly uncertain and likely to be understated (Document ID 2307, Attachment A, p. 149). The ACC noted that these exposure estimates, developed by Sanderson *et al.* (2000, Document ID 0429), were considerably lower than those developed by Rando *et al.* (2001, Document ID 0415) for another study of North American industrial sand workers (Document ID 2307, Attachment A, p. 149). After discussing several differences between these two exposure assessments, the ACC pointed to OSHA's discussion in the lung cancer section of the preamble to the Proposed Rule (78 FR at 56302) in which the Agency acknowledged that McDonald *et al.* (2001, Document ID 1091), Hughes *et al.* (2001, Document ID 1060) and Rando *et al.* (2001, Document ID 0415) had access to smoking histories, plant records, and exposure measurements that allowed for the development of a job exposure matrix, while Steenland and Sanderson (2001, Document ID 0455) had limited access to plant facilities, less detailed historic exposure data, and used MSHA enforcement records for estimates of recent exposure (Document ID 2307, Attachment A, pp. 149–151). The ACC then noted that the McDonald *et al.* study (2005, Document ID 1092), using the Rando *et al.* (2001, Document ID 0415) exposure assessment, found no association between end-stage renal disease or renal cancer and cumulative silica exposure (Document ID 2307, Attachment A, pp. 149, 152).

The ACC also noted that, based on underlying cause of death, the SMR for acute renal death in the Steenland *et al.* (2001b, Document ID 0456) study was not significant (95% confidence interval: 0.70–9.86), and the SMR for chronic renal disease was barely significant (95% confidence interval: 1.06–4.08) (Document ID 2307, Attachment A, p. 151). In light of this, the ACC maintained that Steenland *et al.* based their exposure-response analyses on multiple-cause mortality data, using all deaths with any mention of renal disease on the death certificate even if it was not listed as the *underlying cause*. The ACC asserted that ''only the underlying cause data involve actual deaths from renal disease'' (Document ID 2307, Attachment A, p. 152).

OSHA does not find this criticism persuasive. For regulatory purposes, multiple-cause mortality data is, if anything, more relevant because renal disease constitutes the type of material impairment of health that the Agency is authorized to protect against through regulation regardless of whether it is determined to be the underlying cause of a worker's death. Moreover, the discrepancy in the renal disease mortality findings is a moot point, as only the model in the pooled study with renal disease as an underlying cause was used to estimate risks in the Preliminary QRA (Document ID 1711, p. 316). In any event, OSHA notes an important difference between the Steenland *et al.* study (2001b, Document ID 0456) and the McDonald study (2005, Document ID 1092): They did not look at the same cohort of North American industrial sand workers. Steenland *et al.* (2001b) examined a cohort of 4,626 workers from 18 plants; the average year of first employment was 1967, with follow-up through 1996 (Document ID 0456, pp. 406–408). McDonald *et al.* (2005) examined a cohort of 2,452 workers employed between 1940 and 1979 at eight plants, with follow-up through 2000 (Document ID 1092, p. 368). Although there was overlap of about six plants in the studies (Document ID 1711, p. 127), these were clearly two fairly different cohorts of industrial sand workers. These differences in the cohorts might explain the discrepancy in the studies' results. In addition, OSHA notes that McDonald *et al.* (2005, Document ID 1092) observed statistically significant excess mortality from nephritis/nephrosis in their study that was not explained by the findings of their silica exposure-response analyses (Document ID 1092, p. 369).

The ACC further argued that the Steenland *et al.* (2002a, Document ID 0448) pooled study is inferior to the Vacek *et al.* (2011, Document ID 2340) study of Vermont granite workers, which found no association between cumulative silica exposure and mortality from either kidney cancer or non-malignant kidney disease and which it contended has better mortality and exposure data (Document ID 2307, Attachment A, p. 154) (citing Vacek *et al.* (2011, Document ID 2340). In particular, it argued that the Vacek *et al.* study is more reliable for this purpose than the unpublished Attfield and Costello data (2004, Document ID 0285) on Vermont granite workers, which Steenland *et al.* relied on in finding an association between silica exposure and renal disease.

OSHA notes that Steenland *et al.* acknowledged in their pooled study that that unpublished data had not undergone peer review (Document ID 0448, p. 5). Despite this limitation, OSHA is also unpersuaded that the Vacek *et al.* study, although it observed no increased kidney disease mortality (Document ID 2340, Table 3, p. 315), negates Steenland *et al.*'s overall conclusions. OSHA discussed several substantial differences between these two studies in Section V.F, Comments and Responses Concerning Lung Cancer Mortality.

3. Additional Studies

The ACC also submitted to the record several additional studies that did not show a statistically significant association between exposure to crystalline silica and renal disease mortality. These included the aforementioned studies by McDonald *et al.* (2005, Document ID 1092) and Vacek *et al.* (2011, Document ID 2340), as well as studies by Davis *et al.* (1983, Document ID 0999), Koskela *et al.* (1987, Document ID 0363), Cherry *et al.* (2012, article included in Document ID 2340), Birk *et al.* (2009, Document ID 1468), Mundt *et al.* (2011, Document ID 1478), Steenland *et al.* (2002b, Document ID 0454), Rosenman *et al.* (2000, Document ID 1120), and Calvert *et al.* (2003, Document ID 0309) (Document ID 2307, Attachment A, pp. 140–145). In light of its assertions on the limitations of the three studies in the pooled analysis, and because the three studies ''run counter to a larger number of studies in which a causal association between silica exposure and renal disease was not found,'' the ACC concluded that ''the three studies relied on by OSHA do not provide a reliable or supportable basis for projecting any risk of renal disease mortality from silica exposure'' (Document ID 4209, p. 94). Similarly, the AFS argued that renal disease was only ''found in a couple of selected studies and not observed in most others,'' including no foundry studies (Document ID 2379, Attachment 1, pp. 1–3).

In light of the analysis contained in the Review of Health Effects Literature and Preliminary QRA, and OSHA's confirmation of its preliminary findings through examination of the record, OSHA finds these claims to be lacking in merit (Document ID 1711, pp. 211–229). In the Review of Health Effects Literature and Preliminary QRA, OSHA presented a comprehensive analysis of several studies that showed an association between crystalline silica

and renal disease, as well as discussing other studies that did not (Document ID 1711, pp. 211–229). Based upon its overall analysis of the literature, including the negative studies, OSHA concluded that there was substantial evidence suggesting an association between exposure to crystalline silica and increased risks of renal disease. This conclusion was supported by a number of case reports and epidemiological studies that found statistically significant associations between occupational exposure to silica dust and chronic renal disease (Calvert *et al.*, 1997, Document ID 0976), subclinical renal changes (Ng *et al.*, 1992c, Document ID 0386), end-stage renal disease morbidity (Steenland *et al.*, 1990, Document ID 1125), end-stage renal disease incidence (Steenland *et al.* 2001b, Document ID 0456), chronic renal disease mortality (Steenland *et al.*, 2002a, 0448), and granulomatosis with polyangitis (Nuyts *et al.*, 1995, Document ID 0397). In other findings, silica-exposed individuals, both with and without silicosis, had an increased prevalence of abnormal renal function (Hotz *et al.*, 1995, Document ID 0361), and renal effects were reported to persist after cessation of silica exposure (Ng *et al.*, 1992c, Document ID 0386). While the mechanism of causation is presently unknown, possible mechanisms suggested for silica-induced renal disease included a direct toxic effect on the kidney, deposition in the kidney of immune complexes (IgA) following silica-related pulmonary inflammation, or an autoimmune mechanism (Calvert *et al.*, 1997, Document ID 0976; Gregorini *et al.*, 1993, 1032).

From this review of the studies on renal disease, OSHA concluded that there were considerably less data, and thus the findings based on them were less robust, than the data available for silicosis and NMRD mortality, lung cancer mortality, or silicosis morbidity. Nevertheless, OSHA concluded that the Steenland *et al.* (2002a, Document ID 0448) pooled study had a large number of workers and validated exposure information, such that it was sufficient to provide useful estimates of risk of renal disease mortality. With regard to the additional negative studies presented by the ACC, OSHA notes that it discussed the Birk *et al.* (2009, Document ID 1468) and Mundt *et al.* (2011, Document ID 1478) studies in the Supplemental Literature Review of the Review of Health Effects Literature and Preliminary QRA, noting the short follow-up period as a limitation, which makes it unlikely to observe the presence of renal disease (Document ID 1711, Supplement, pp. 6–12). OSHA likewise discussed the Vacek *et al.* (2011, Document ID 2340) study earlier in this section, and notes that Cherry *et al.* reported a statistically significant excess of non-malignant renal disease mortality in the cohort for the period 1985–2008, with an unexplained cause (2012, p. 151, article included in Document ID 2340). Although these latter two studies did not find a significant association between silica exposure and renal disease mortality, OSHA does not believe that they substantially change its conclusions on renal disease mortality from the Preliminary QRA, given the number of positive studies presented and the limitations of those two studies.

Thus, OSHA recognizes that the renal risk estimates are less robust and have more uncertainty than those for the other health endpoints for which there is a stronger case for causality (*i.e.*, lung cancer mortality, silicosis and NMRD mortality, and silicosis morbidity). But, for the reasons stated above, OSHA believes that the evidence supporting causality regarding renal risk outweighs the evidence casting doubt on that conclusion. Scientific certainty is not the legal standard under which OSHA acts. OSHA is setting the standard based upon the clearly significant risks of lung cancer mortality, silicosis and NMRD mortality, silicosis morbidity, and renal disease mortality at the previous PELs; even if the risk of renal disease mortality is discounted, the conclusion would not change that regulation is needed to reduce the significant risk of material impairment of health (*see Society of the Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301, 1308 (2d Cir. 1975)).

H. Mechanisms of Silica-Induced Adverse Health Effects

In this section, OSHA describes the mechanisms by which silica exposure may cause silica-related health effects, and responds to comments criticizing the Agency's analysis on this topic. In the proposal as well as this final rule, OSHA relied principally on epidemiological studies to establish the adverse health effects of silica exposure. The Agency also, however, reviewed animal studies (in vivo and in vitro) as well as in vitro human studies that provide information about the mechanisms by which respirable crystalline silica causes such effects, particularly silicosis and lung cancer. OSHA's review of this material can be found in the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment (QRA), which provided background and support for the proposed rule (Document ID 1711, pp. 229–261).

As described in the Review of Health Effects Literature, OSHA performed an extensive evaluation of the scientific literature pertaining to inhalation of respirable crystalline silica (Document ID 1711, pp. 7–265). Due to the lack of evidence of health hazards from dermal or oral exposure, the Agency focused solely on the studies addressing the inhalation hazards of respirable crystalline silica. OSHA determined, based on the best available scientific information, that several cellular events, such as cytotoxicity (*i.e.*, cellular damage), oxidative stress, genotoxicity (*i.e.*, damage to cellular DNA), cellular proliferation, and inflammation can contribute to a range of neoplastic (*i.e.*, tumor-forming) and non-neoplastic health effects in the lung. While the exact mechanisms have yet to be fully elucidated, they are likely initiated by damage to lung cells from interaction directly with the silica particle itself or through silica particle activation of alveolar macrophages following phagocytosis (*i.e.*, engulfing particulate matter in the lung for the purpose of removing or destroying foreign particles). The crystalline structure and unusually reactive surface properties of the silica particle appear to cause the early cellular effects. Silicosis and lung cancer share common features that arise from these early cellular interactions but OSHA, in its Review of Health Effects Literature and Preliminary QRA, ''preliminarily conclude[d] that available animal and in vitro studies have not conclusively demonstrated that silicosis is a prerequisite for lung cancer in silica-exposed individuals'' (Document ID 1711, p. 259). Although the health effects associated with inhalation of respirable crystalline silica are seen primarily in the lung, other observed health effects include kidney and immune dysfunctions.

Below, OSHA reviews the record evidence and responds to comments it received on the mechanisms underlying respirable crystalline silica-induced lung cancer and silicosis. The Agency also addresses comments regarding the use of animal studies to characterize adverse health effects in humans caused by exposure to respirable crystalline silica.

1. Mechanisms for Silica-Related Health Effects

In 2012, IARC reevaluated the available scientific information regarding respirable crystalline silica and lung cancer and reaffirmed that crystalline silica is carcinogenic to

humans, *i.e.*, a Group 1 carcinogen (Document ID 1473, p. 396). OSHA's review of all the evidence now in the rulemaking record, including the results of IARC's reevaluation, indicates that silica may lead to increased risk of lung cancer in humans by a multistage process that involves a combination of genotoxic (*i.e.*, causing damage to cellular DNA) and non-genotoxic (*i.e.*, not involving damage to DNA) mechanisms. Respirable crystalline silica may cause genotoxicity as a result of reactive oxygen species (ROS) produced by activated alveolar macrophages and other lung cells exposed to crystalline silica particles during phagocytosis. ROS have been shown to damage DNA in human lung cells in vitro (*see* Document ID 1711, pp. 236–239). This genotoxic mechanism is believed to contribute to neoplastic transformation and silica-induced carcinogenesis. ROS is not only produced during the early cellular interaction with crystalline silica but also produced by PMNs (polymorphonuclear leukocytes) and lymphocytes recruited during the inflammatory response to crystalline silica. In addition to genotoxicity contributed by ROS, it is also plausible that reactive molecules on the surface of crystalline silica itself may bind directly to DNA and result in genotoxicity (Document ID 1711, p. 236). It should be noted that the mechanistic evidence summarized above suggests that crystalline silica may cause early genotoxic events that are independent of the advanced chronic inflammatory response and silicosis (Document ID 1473, pp. 391–392).

Non-genotoxic mechanisms are also believed to contribute to the lung cancer caused by respirable crystalline silica. Phagocytic activation as well as silica-induced cytotoxicity trigger release of the aforementioned ROS, cytokines (*e.g.*, TNFα), and growth factors (see Document ID 1711, pp. 233–235). These agents are able to cause cellular proliferation, loss of cell cycle regulation, activation of oncogenes (genes that have the potential to cause cancer), and inhibition of tumor suppressor genes, all of which are non-genotoxic mechanisms known to promote the carcinogenic process. It is plausible that these mechanisms may be involved in silica-induced tumorigenesis. The biopersistence and cytotoxic nature of crystalline silica leads to a cycle of cell death (*i.e.*, cytotoxicity), activation of alveolar macrophages, recruitment of inflammatory cells (*e.g.*, PMNs, leukocytes), and continual release of the non-genotoxic mediators (*i.e.*, ROS, cytokines) able to promote carcinogenesis. The non-genotoxic mechanisms caused by early cellular responses (*e.g.*, phagocytic activation, cytotoxicity) are regarded, along with genotoxicity, as important potential pathways that lead to the development of tumors (Document ID 1711, pp. 232–239; 1473, pp. 394–396).

The same non-genotoxic processes that may cause lung cancer from respirable crystalline silica exposure are also believed to lead to chronic inflammation, lung scarring, fibrotic lesions, and eventually silicosis. This would occur when inflammatory cells move from the alveolar space through the interstitium of the lung as part of the clearance process. In the interstitium, respirable crystalline silica-laden cells—macrophages and neutrophils—release ROS and TNF-α, as well as other cytokines, stimulating the proliferation of fibroblasts (*i.e.*, the major lung cell type in silicosis). Proliferating fibroblasts deposit collagen and connective tissue, inducing the typical scarring that is observed with silicosis. Alternatively, alveolar epithelial cells containing respirable crystalline silica die and may be replaced by fibroblasts due to necrosis of the epithelium. This allows for uninhibited growth of fibroblasts and formation of connective tissue where scarring proliferates (*i.e.*, silicosis). As scarring increases, there is a reduction in lung elasticity concomitant with a reduction of the lung surface area capable of gas exchange, thus reducing pulmonary function and making breathing more difficult (Document ID 0314; 0315). It should be noted that silicosis involves many of the same mechanisms that occur during the early cellular interaction with crystalline silica. Therefore, it is plausible that development of silicosis may also potentially contribute to silica-induced lung cancer. However, the relative contributions of silicosis-dependent and silicosis-independent pathways are not known.

Although it is clear that exposure to respirable crystalline silica increases the risk of lung cancer in exposed workers (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk), some commenters claimed that such exposure cannot cause lung cancer independently of silicosis (*i.e.*, only those workers who already have silicosis can get lung cancer) (Document ID 2307, Attachment A, p. 53). This claim is inconsistent with the credible scientific evidence presented above that genotoxic and non-genotoxic mechanisms triggered by early cellular responses to crystalline silica prior to development of silicosis may contribute to crystalline silica-induced carcinogenesis. OSHA finds, based on its review of all the evidence in the rulemaking record, that workers without silicosis, as well as those with silicosis, are at risk of lung cancer if regularly exposed to respirable crystalline silica at levels permitted under the previous and new PELs. The Agency also emphasizes that, regardless of the mechanism by which respirable crystalline silica exposure increases lung cancer risk, the fact remains that workers exposed to respirable crystalline silica continue to be diagnosed with lung cancer at a higher rate than the general population. Therefore, as discussed in section VI, Final Quantitative Risk Assessment and Significance of Risk, OSHA has met its burden of proving that workers exposed to previously allowed levels of respirable crystalline silica are at significant risk, by one or more of these mechanisms, of serious and life-threatening health effects, including both silicosis and lung cancer.

2. Relevance of Animal Models to Humans

Animal data has been used for decades to evaluate hazards and make inferences regarding causal relationships between human health effects and exposure to toxic substances. The National Academies of Science has endorsed the use of well-conducted animal studies to support hazard evaluation in the risk assessment process (Document ID 4052, p. 81) and OSHA's policy has been to rely on such studies when regulating carcinogens. In the case of respirable crystalline silica, OSHA has used evidence from animal studies, along with human epidemiology and other relevant information, to establish that occupational exposure is associated with silicosis, lung cancer, and other non-malignant respiratory diseases, as well as renal and autoimmune effects (Document ID 1711, pp. 261–266). Exposure to various forms of respirable crystalline silica by inhalation and intratracheal instillation has consistently caused lung cancer in rats (IARC, 1997, Document ID 1062, pp. 150–163). These results led IARC and NTP to conclude that there is sufficient evidence in experimental animals to demonstrate the carcinogenicity of crystalline silica in the form of quartz dust. IARC also concluded that there is sufficient evidence in human studies for the carcinogenicity of crystalline silica in the form of quartz or cristobalite.

In its pre-hearing comments and post-hearing brief, the ACC noted that increased lung cancer risks from exposure to respirable crystalline silica have not been found in animal species other than rats, and questioned the relevance of the rat model for evaluating potential lung carcinogenicity in humans (Document ID 2307, Attachment A, p. 30; 4209, p. 32). Specifically, the ACC highlighted studies by Holland (1995) and Saffiotti *et al.* (1996) indicating that bioassays in respirable crystalline silica-exposed mice, guinea pigs, and Syrian hamsters have not found increased lung cancer (Document ID 2307, Attachment A, p. 30, f. 51).

The ACC proposed that the increased lung cancer risk in respirable crystalline silica-exposed rats is due to a particle overload phenomenon, in which lung clearance of nonfibrous durable particles initiates a non-specific response that results in intrapulmonary lung tumors (Document ID 2307, Attachment A, p. 30, n. 51). Dr. Cox, on behalf of the ACC, citing Mauderly (1997, included in Document ID 3600), Oberdorster (1996, Document ID 3969), and Nikula *et al.* (1997, included in Document ID 3600), likewise commented that rats are ''uniquely sensitive to particulate pollution, for species-specific reasons that do not generalize to other rodents or mammals, including humans'' (Document ID 2307, Attachment 4, p. 83). OSHA reviewed the three studies referenced by Dr. Cox and notes that two actually appear to support the use of the rat model and the third does not reject it. Mauderly (1997) noted that the rat model was the only one to correctly predict carcinogenicity after inhalation exposure to several types of asbestos, and highlighted the shortcomings of other models, such as those using hamsters, which are highly insensitive to particle-induced lung cancers (article included in Document ID 3600, pp. 1339–1343). While Mauderly (1997) advised caution when using the rat because it is the most sensitive rodent species for lung cancer, he concluded that ''there is evidence supporting continued use of rats in exploration of carcinogenic hazards of inhaled particles,'' and that the other test species are problematic because they provide too many false negatives to be predictive (article included in Document ID 3600, p. 1343). Similarly, Oberdorster (1996), in discussing particle parameters used in the evaluation of exposure-dose-relationships of inhaled particles, stated that ''the rat model should not be dismissed prematurely'' (Document ID 3969, p. 73). Oberdorster (1996) postulated that humans and rats have very similar responses to particle-induced effects when analyzing the exposure-response relationship using particle surface area, rather than particle mass, as the exposure metric. Oberdorster concluded that there simply was not enough known regarding exact mechanisms to reject the model outright (Document ID 3969, pp. 85–87). The remaining paper cited by Dr. Cox, Nikula *et al.* (1997), evaluated the anatomical differences between primate and rodent responses to inhaled particulate matter and the role of clearance patterns and physiological responses to inhaled toxicants. The study noted that the differences between primate clearance patterns and rat clearance patterns may play a role in the pathogenesis from inhaled poorly soluble particles but did not dismiss the rat model as irrelevant to humans (Nikula, 1997, included in Document ID 3600, pp. 83, 93, 97).

Thus, OSHA finds that the Mauderly (1997) and Oberdorster (1996) articles generally support the rat as an appropriate model for qualitatively assessing the hazards associated with particle inhalation. OSHA likewise notes that the rat model is a common and well-accepted toxicological model used to assess human health effects from toxicant inhalation (ILSI, 2000, Document ID 3906, pp. 2–9). OSHA evaluated the available studies in the record, both positive and non-positive, and believes that it is appropriate to regard positive findings in experimental studies using rats as supportive evidence for the carcinogenicity of crystalline silica. This determination is consistent with that of IARC (Document ID 1473, p. 388) and NTP (Document ID 1164, p. 1), which also regarded the significant increases in incidence of malignant lung tumors in rats from multiple studies by both inhalation and intratracheal instillation of crystalline silica to be sufficient evidence of carcinogenicity in experimental animals and, therefore, to contribute to the evidence for carcinogenicity in humans.

3. Hypothesis That Lung Cancer Is Dependent on Silicosis

The ACC asserted in its comments that ''if it exists at all, silica-related carcinogenicity most likely arises through a silicosis pathway or some other inflammation-mediated mechanism, rather than by means of a direct genotoxic effect'' (Document ID 2307, Attachment A, p. 52; 4209, p. 51; 2343, Attachment 1, pp. 40–44). It explained that the ''silicosis pathway'' means that lung cancer stems from chronic inflammatory lung damage, which in turn, ''implies that there is a threshold for any causal association between silica exposure and risk of lung cancer'' (Document ID 2307, Attachment A, pp. 52–53). The ACC went on to state that a mechanism that involves ROS, growth factors, and inflammatory cytokines from alveolar macrophages is ''most consistent'' with development of advanced chronic inflammation (*e.g.*, epithelial hyperplasia, lung tissue damage, fibrosis, and silicosis). According to this hypothesis, silica-related lung cancer is restricted to people who have silicosis (Document ID 2307, Attachment 2, p. 7). Regarding this hypothesis, the ACC concluded, ''[t]his view of the likely mechanism for silica-related lung cancer is widely accepted in the scientific community, including by OSHA's primary source of silica-related health risk estimates, Dr. Kyle Steenland. OSHA appears to share this view as well'' (Document ID 2307, Attachment A, p. 54).

The ACC statement regarding acceptance by OSHA and the scientific community is inaccurate. It implies scientific consensus, as well as OSHA's concurrence, that the chronic inflammation from silicosis is the only mechanism by which crystalline silica exposure results in lung cancer. The ACC has over-simplified and neglected the findings of the mechanistic studies that show activation of phagocytic and epithelial cells to be an early cellular response to crystalline silica prior to chronic inflammation (*see* Document ID 1711, pp. 234–238). As discussed previously, alveolar macrophage activation leads to initial production of ROS and release of cytokine growth factors that could contribute to silica-induced carcinogenicity through both genotoxic and non-genotoxic mechanisms. The early cellular response does not require chronic inflammation and silicosis to be present, as postulated by the ACC. It is possible that the early mechanistic influences that increase cancer risk may be amplified by a later severe chronic inflammation or silicosis, if such a condition develops. However, as Brian Miller, Ph.D., stated ''this issue of silicosis being a precursor for lung cancer is unanswerable, given that we cannot investigate for early fibrotic lesions in the living, but must rely on radiographs.'' (Document ID 3574, Tr. 31).

In pre-hearing comments the ACC commented, as proof of silicosis being linked to lung cancer, that fibrosis was linked to adenocarcinomas (Document ID 2307, Attachment A, p. 61). This statement is misleading. As explained

earlier, silicosis results from stimulation of fibroblast cells that cause lung fibrosis. Adenocarcinomas, a hallmark tumor type in respirable crystalline silica-induced lung cancer, are tumors that arise not from fibroblasts, but exclusively from lung epithelial cells (IARC, 2012, Document ID 1473, pp. 381–389, 392). These tumors may be linked to the genotoxic and non-genotoxic mechanisms that occur prior to fibrosis, not secondary to the fibrotic process itself.

OSHA also received some comments that questioned the existence of a direct genotoxic mechanism. Jonathan Borak, M.D., on behalf of the U.S. Chamber of Commerce, commented, ''there is no direct evidence that silica causes cancer by means of a directly DNA-reactive mechanism'' (Document ID 2376, p. 21). Dr. Peter Morfeld, on behalf of the ACC, as well as Peter Valberg, Ph.D., and Christopher M. Long, Sc.D., of Gradient Corporation, on behalf of the U.S. Chamber of Commerce, cited a scientific article by Borm *et al.* (2011, included in Document ID 3573) which reported finding evidence against a genotoxic mechanism and in favor of a mechanism secondary to chronic inflammation (Document ID 3458, pp. 5–7; 4016, pp. 5–6; 4209, p. 51). Borm *et al.* (2011, included in Document ID 3573) analyzed 245 published studies from 1996 to 2008 identified using the search terms ''quartz'' and 'toxicity'' in conjunction with ''surface,'' ''inflammation,'' ''fibrosis,'' and ''genotoxicity.'' The authors then estimated the lowest dose (in units of micrograms per cell surface area) to consistently induce DNA damage or induce markers of inflammation (*e.g.*, IL–8 upregulation) in in vitro studies. They adjusted the in vitro doses for the lung surface area encountered in vivo and found the crystalline silica dose that produced primary genotoxicity was 60–120 times higher than the dose that produced inflammatory cytokines (Borm *et al.*, 2011, included in Document ID 3573, p. 762). Drs. Valberg and Long concluded that Borm *et al.* demonstrated that genotoxicity was a secondary response to chronic inflammation, except at very high exposures at which genotoxicity independent of inflammation might occur. They also maintained that lung cancer as a secondary response to chronic inflammation is considered to have a threshold (Document ID 4016, p. 6).

OSHA reviewed the Borm *et al.* study (2011, Document ID 3889), and notes several limitations. The authors examined the findings from various genotoxic assays (comet assay, 8–OH–dG, micronucleus test) (Borm *et al.*, 2011, 3889, p. 758). They reported that 40 $\mu g/cm^2$ was the lowest dose in vitro to produce significant direct DNA damage from crystalline silica. This genotoxic dose appears to be principally obtained from a study of a specific quartz sample (*i.e.*, DQ12) in a single human alveolar epithelial cell line (*i.e.*, A549 cells), even though Appendix Table 3 cited in vitro studies using other cells (*e.g.*, fibroblasts) and other types of quartz (*e.g.*, MinUsil) that produced direct genotoxic effects at lower doses (Borm *et al.*, 2011, Document ID 3889, pp. 760, 769–770). This is especially pertinent since Borm *et al.* state that in vitro systems utilizing single-cell cultures are generally much less sensitive than in vivo systems, especially if attempting to determine oxidative stress-induced effects, since many cell culture systems use reagents that can scavenge ROS (Borm *et al.* 2011, Document ID 3889, p. 760). There was no indication that the authors accounted for this deficiency. They go on to conclude that their work shows a large-scale variation in hazard across different forms of quartz with regard to effects such as DNA breakage (*e.g.*, genotoxicity) and inflammation (Borm *et al.* 2011, Document ID 3889, p. 762).

The extreme variation in response along with reliance on an insensitive genotoxicity test system could overestimate the appropriate genotoxic dose in human lung cells in vivo. In addition, Borm *et al.* used the dose sufficient to initiate production of an inflammatory cytokine (*i.e.*, IL–8) in the A549 cell-line as the threshold for inflammation. It is not clear that an early cellular response, such as IL–8 production necessarily reflects a sustained inflammatory response. In summary, OSHA finds inconsistencies in this analysis, leaving some questions regarding the study's conclusion that silica induces genotoxicity only as a secondary response to an inflammation-driven mechanism. While the in vitro dose comparisons in this study fail to demonstrate that genotoxicity is secondary to the inflammatory response, the study findings do indicate that cellular responses to crystalline silica that drive inflammation may also lead to tumorigenesis through both genotoxic and non-genotoxic mechanisms.

Dr. Morfeld, in his hearing testimony on behalf of the ACC, referred to the paper by Borm *et al.* (2011) as reaching the conclusion that the mechanism of silica-related lung cancer is secondary inflammation-driven genotoxicity. As summarized by the ACC in post-hearing comments, he observed that ''there are no crystalline silica particles found in the nucleus of the cells. There is nothing going on with particles in the epithelial cells inside the lung'' (Document ID 4209, p. 52). In hearing testimony, however, Dr. Morfeld acknowledged that the Borm paper had limitations on extrapolating from in vitro to in vivo and cited a study by Donaldson *et al.* (2009), which discussed some of the limitations and the need for caution in extrapolating from in vitro to in vivo (Document ID 3582, Tr. 2076–2077; 3894, pp. 1–2). In considering this testimony, OSHA notes that the Donaldson *et al.* (2009) study, which includes the same authors as the Borm *et al.* (2011) study, acknowledged that direct interaction between respirable crystalline silica and epithelial cellular membranes induces intracellular oxidative stress which is capable of being genotoxic (Document ID 3894, p. 3). This is consistent with the OSHA position as well as the most recent IARC reevaluation of the cancer hazard from crystalline silica dust. As IARC stated in its most recent evaluation of the carcinogenicity of respirable crystalline silica under a section on direct genotoxicity and cell transformation (Document ID 1473, section 4.2.2, pp. 391–393):

> Reactive oxygen species are generated not only at the particle surface of crystalline silica, but also by phagocytic and epithelial cells exposed to quartz particles. . . . Oxidants generated by silica particles and by the respiratory burst of silica-activated phagocytic cells may cause cellular and lung injury, including DNA damage (Document ID 1473, p. 391).

Given the IARC determination as well as the animal and in vitro studies reviewed herein, OSHA finds that there is no conclusive evidence that silica-related lung cancer only occurs as a secondary response to chronic inflammation, or that silicosis is a necessary prerequisite for lung cancer. Instead, OSHA finds support in the scientific literature for a conclusion that tumors may form through genotoxic as well as non-genotoxic mechanisms that result from respirable crystalline silica interaction with alveolar macrophages and other lung cells prior to onset of silicosis.

4. Hypothesis That Crystalline Silica-Induced Lung Disease Exhibits a Threshold

It is well established that silicosis arises from an advanced chronic inflammation of the lung. As noted above, a common hypothesis is that pathological conditions that depend on chronic inflammation may have a threshold. The exposure level at which silica-induced health effects might begin

to appear, however, is poorly characterized in the literature (*see* Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases). The threshold exposure level required for a sustained inflammatory response is dependent upon multiple pro- and anti-inflammatory factors that can be quite variable from individual to individual and from species to species (Document ID 3896).

Discounting or overlooking the evidence that respirable crystalline silica may be genotoxic in the absence of chronic inflammation, Drs. Valberg and Long commented that crystalline silica follows a threshold paradigm for poorly soluble particles (PSPs). PSPs are defined generally as nonfibrous particles of low acute toxicity, which are not directly genotoxic (ILSI, 2000, Document ID 3906, p. 1). Specifically, Drs. Valberg and Long stated:

> Mechanisms whereby lung cells respond to retention of a wide variety of PSPs, including crystalline silica, follow a generally accepted threshold paradigm, where the initiation of a chronic inflammatory response is a necessary step in the disease process, and the inflammatory response does not become persistent until particle retention loads become sufficient to overwhelm lung defense mechanisms. This overall progression from increased but controlled pulmonary inflammation across a threshold exposure that leads to lung damage has been described by a number of investigators (Mauderly and McCunney, 1995; ILSI, 2000; Boobis *et al.*, 2009; Porter *et al.* 2004) (Document ID 2330, p. 19).

Similarly, Dr. Cox, in his post-hearing comments, discussed his 2011 article describing a quantifiable exposure-response threshold for lung diseases induced by inhalation of respirable crystalline silica (Document ID 4027, p. 29). Dr. Cox hypothesized the existence of an exposure threshold such that exposures to PSPs, which he described as including titanium dioxide, carbon black, and crystalline silica, must be intense enough and last long enough to disrupt normal homeostasis (*i.e.*, normal cellular functions) and overwhelm normal repair processes. Under the scenario he described, a persistent state of chronic, unresolved inflammation results in a disruption of macrophage and neutrophil ability to clear silica and other foreign particles from the lung (Document ID 1470, pp. 1548–1551, 1555–1556).

OSHA disagrees with these characterizations about exposure thresholds because, among other reasons, respirable crystalline silica is not generally considered to be in the class of substances defined as PSPs.[7] Specifically, regarding the comments of Drs. Valberg and Long, OSHA notes that the two cited documents (Mauderly and McCunney, 1995, and ILSI, 2000) summarizing workshops on PSPs did not include crystalline silica in the definition of PSP and the lung ''overload'' concept, instead highlighting silica's cytotoxic and genotoxic mechanisms. Mauderly and McCunney (1995) stated, ''[i]t is generally accepted that the term 'overload' should be used in reference to particles having low cytotoxicity, which overload clearance [mechanisms] by virtue of the mass, volume, or surface area of the deposited material (Morrow, 1992)'' (p. 3, article cited in Document ID 2330, p. 19). Mauderly specifically cited quartz as a cytotoxic particle that may fall outside this definition (p. 24, article cited in Document ID 2330, p. 19). The International Life Science Institute's (ILSI) Workshop Report (2000) intended only to address particles of ''low acute toxicity,'' such as carbon black, coal dust, soot, and titanium dioxide (Document ID 3906, p. 1). OSHA believes that the cytotoxic nature of crystalline silica would exclude it from the class of rather nonreactive, non-toxic particles mentioned above. Therefore, the Agency concludes that most scientific experts would not include crystalline silica in the class of substances known as PSPs, nor intend for findings regarding PSPs to be extrapolated to crystalline silica.

During the public hearing, OSHA questioned Dr. Morfeld about the relevance of the rat overload response and whether he considered crystalline silica to be like other PSPs such as carbon black. Dr. Morfeld replied that he was well aware of the literature and indicated that crystalline silica was not considered one of the PSPs (specifically not like carbon black) that these reports reviewed (Document ID 3582, Tr. 2072–2074). OSHA also notes a report of the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), which was cited by the ACC (Document ID 4209, p. 32) and stated that ''particles exhibiting significant surface related (cyto)toxicity like crystalline silica (quartz) and/or other specific toxic properties do not fall under this definition [of PSPs]'' (Document ID 3897, p. 5).

Respirable crystalline silica differs from PSPs because it does not require particle overload to induce the same response typical of PSPs. ''Overload'' refers to the consequence of exposure that results in a retained lung burden of particles that is greater than the steady-state burden predicted from deposition rates and clearance kinetics (Document ID 4174, p. 20). This is a result of a volumetric over-exposure of dust in the lung, which overwhelms macrophage function. Respirable crystalline silica does not operate on this mechanism since macrophage function is inhibited by the cytotoxic nature of respirable crystalline silica rather than a volumetric overload (Oberdorster, 1996, Document ID 3969). Therefore, respirable crystalline silica does not require particle overload to induce the same response. Studies have found that the respirable crystalline silica exposure levels required to induce tumor formation in some animal studies are similar to those observed in human studies, whereas studies involving PSPs tend to show responses at much higher levels of exposure (Muhle *et al.*, 1991, Document ID 1284; Muhle *et al.*, 1995, 0378; Saffiotti and Ahmed, 1995, 1121).

A study by Porter *et al.* (2004) demonstrated that pulmonary fibrosis induction does not require silica particle overload (Document ID 0410, p. 377). The ACC cited this study in its post-hearing brief, stating, ''Porter . . . noted that the response of the rat lung to inhaled crystalline silica particles is biphasic, with a below-threshold phase characterized by increased but controlled pulmonary inflammation'' (Document ID 4209, p. 52). OSHA notes that this biphasic response is due in part to the cytotoxic nature of crystalline silica, which disrupts macrophage clearance of silica particles leading to a chronic inflammatory response at less than overload conditions. While there are some mechanistic similarities, OSHA believes that the argument that crystalline silica operates on the basis of lung overload is erroneous and based on false assumptions that ignore toxicological properties unique to crystalline silica, such as cytotoxicity and the generation of intracellular ROS (Porter *et al.*, 2002, Document ID 1114; Porter *et al.*, 2004, 0410). As previously discussed, the generation of ROS could

[7] OSHA notes that crystalline silica has many mechanistic features in common with asbestos. They are both durable, biopersistent mineral forms where there is sufficient evidence of an association with lung cancer (*i.e.*, IARC Group 1 carcinogens), chronic lung inflammation, and severe pulmonary fibrosis (*i.e.*, silicosis and asbestosis) in humans. Like crystalline silica, asbestos has reactive surfaces or other physiochemical properties able to hinder phagocytosis and activate macrophages to release reactive oxygen species, cytokines, and growth factors that lead to DNA damage, cytotoxicity, cell proliferation and an inflammatory response responsible for the disease outcomes mentioned above (*see* IARC 2012, Document ID 1473, pp. 283–290). Crystalline silica and asbestos can trigger phagocytic activation well below the high mass burdens required to ''overload'' the lung and impair pulmonary clearance that is typical of carbon black and other low acute-toxicity PSPs.

potentially damage cellular DNA by a genotoxic mechanism that may not exhibit a threshold.

OSHA thoroughly reviewed Dr. Cox's 2011 article (Document ID 1470), in which he proposed a threshold for crystalline silica, in its Supplemental Literature Review (Document ID 1711, Attachment 1, pp. 37–39). OSHA concluded that the evidence used to support Cox's assertion that the OSHA PEL was below a threshold for lung disease in humans was not supported by the evidence presented (Document ID 1470, p. 1543; 1711, Attachment 1). Specifically, Cox (2011) modelled a threshold level for respirable crystalline silica using animal studies of PSPs. This approach, according to the ILSI report (2000) and ECETOC report (2013), is clearly not appropriate since the cytotoxic nature of crystalline silica is not consistent with the low-toxicity PSPs (Document ID 3906, p. 1; 3897, p. 5). Dr. Cox (2011) categorized crystalline silica incorrectly as a PSP and ignored the evidence for cytotoxicity and genotoxicity associated with crystalline silica. He further failed to consider or include studies indicating a tumor response at exposure levels below that leading to an excessive chronic inflammatory response, such as Porter *et al.* (2002) and Muhle *et al.* (1995) (Document ID 1114; 0378). Thus, OSHA considers the threshold model designed by Dr. Cox (2011, Document ID 1470) and referenced by Drs. Valberg and Long (Document ID 2330) to be contradicted by the best available evidence regarding the toxicological properties of respirable crystalline silica. Although OSHA acknowledges the possible existence of a threshold for an inflammatory response, the Agency believes that the threshold is likely much lower than that advocated by industry representatives such as the ACC and the Chamber of Commerce (*see* Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases).

OSHA concludes that a better estimate of a threshold effect for inflammation and carcinogenesis was done by Kuempel *et al.* (2001, Document ID 1082). These researchers studied the minimum human exposures necessary to achieve adverse functional and pathological evidence of inflammation. They employed a physiologically-based lung dosimetry model, included more relevant studies, and considered a genotoxic effect for lung cancer (Kuempel *et al.*, 2001, Document ID 1082; *see* 1711, pp. 231–232). Briefly, Kuempel *et al.* evaluated both linear and nonlinear (threshold) models and determined that the average minimum critical quartz lung burden (M_{crit}) in rats associated with reduced pulmonary clearance and increased neutrophil inflammation was 0.39 mg quartz/g lung tissue. M_{crit} is based on the lowest observed adverse effect level in a study in rats (Kuempel, 2001, Document ID 1082, pp. 17–23). A human lung dosimetry model, developed from respirable coal mine dust and quartz exposure and lung burden data in UK coal miners (Tran and Buchanan, 2001, Document ID 1126), was then used to estimate the human-equivalent working lifetime exposure concentrations associated with lung doses. An 8-hour time-weighted average (TWA) concentration of 0.036 mg/m^3 (36 $\mu g/m^3$) over a 45-year working lifetime was estimated to result in a human-equivalent lung burden to the average M_{crit} in rats (Document ID 1082, pp. 24–26). OSHA peer reviewer Gary Ginsburg, Ph.D., summarized, ''the Kuempel *et al.* (2001, 2001b) rat analysis of lung threshold loading and extrapolation to human dosimetry leads to the conclusion that in the median case this threshold is approximately 3 times below the current [now former] OSHA PEL'' (Document ID 3574, pp. 23). This estimated threshold would be significantly below the final PEL of 50 $\mu g/m^3$.

In pre-hearing comments, ACC stated that some health organizations suggested a silicosis-dependent threshold exists for lung cancer (ACC, Document ID 2307, Attachment A, pp. 60–62). Specifically, ACC cited Environment and Health Canada as stating:

> Although the mechanism of induction for the lung tumours has not been fully elucidated, there is sufficient supportive mode of action evidence from the data presented to demonstrate that a threshold approach to risk assessment is appropriate based on an understanding of the key events in the pathogenesis of crystalline silica induced lung tumours (pp. 49–51 as cited by ACC, Document ID 2307, p. 62).

In addition to the statement submitted by ACC, Environment and Health Canada also stated that:

> While there is sufficient evidence to support key events in a threshold mode of action approach for lung tumours, the molecular mechanism is still not fully elucidated. Also, despite the fact that the effects seen in rats parallel the effects observed in human studies, additional mechanistic studies could further clarify why lung tumours are not seen in all experimental animals . . . Thus, the question of whether silica exposure, in the absence of silicotic response, results in lung tumours remains unanswered.'' (pp. 51–52 as cited by ACC, Document ID 2307, pp. 59–61).

It should be noted that the Environment and Health Canada report was to determine general population risk of exposure to respirable crystalline silica as a fraction of PM_{10}. Environment and Health Canada found that levels 0.1–2.1 $\mu g/m^3$ respirable crystalline silica were sufficiently protective for the general population because they represented a margin of exposure (MOE) 23–500 times lower than the 50 $\mu g/m^3$ quartz concentration associated with silicosis in humans (pp. 50–51 as cited by ACC, Document ID 2307, pp. 59–61).

A report by Mossman and Glenn (2013) reviewed the findings from several international OEL setting panels (Document ID 4070). The report cites findings from the European Commission's Scientific Committee on Occupational Exposure Limits for respirable crystalline silica. The findings ''acknowledged a No Observed Adverse Exposure Level (NOAEL) for respirable crystalline silica in the range below 0.020 mg/m^3, but stated that a clear threshold for silicosis could not be identified'' (Mossman and Glen, 2013; Document ID 4070, p. 655). The report went on to state that SCOEL (2002) recommended that an OEL should lie below 50 $\mu g/m^3$ (Document ID 4070, p. 655). Therefore, even if silica-induced lung cancer were limited only to a mechanism that involved an inflammation-dependent threshold, OSHA concludes that exposure threshold would likely be lower than the final PEL.

5. Renal Disease and Autoimmunity

While mechanistic data is limited, other observed health effects from inhalation of respirable crystalline silica include kidney and autoimmune effects. Translocation of particles through the lymphatic system and filtration through the kidneys may induce effects in the immune and renal systems similar to the types of changes observed in the lung (Miller, 2000, Document ID 4174, pp. 40–45). A review of the available literature indicates that respirable crystalline silica most likely induces an oxidative stress response in the renal and immune cells similar to that described above (Donaldson *et al.*, 2009, Document ID 3894).

6. Conclusion

OSHA has reviewed and responded to the comments received on the mechanistic studies of respirable crystalline silica-induced lung cancer and silicosis, as well as comments that the mechanistic data imply the existence of an exposure threshold. OSHA concludes that: (1) Lung cancer likely results from both genotoxic and non-genotoxic mechanisms that arise during early cellular responses as well

as during chronic inflammation from exposure to crystalline silica; (2) there is not convincing data to demonstrate that silicosis is a prerequisite for lung cancer; (3) experimental studies in rats are relevant to humans and provide supporting evidence for carcinogenicity; (4) crystalline silica does not behave like PSPs such as titanium dioxide; and (5) any threshold for an inflammatory response to respirable crystalline silica is likely several times below the final PEL of 50 μg/m³. Thus, the best available evidence on this issue supports OSHA's findings that respirable crystalline silica increases the risk of lung cancer in humans, even in the absence of silicosis, and that lung cancer risk can be increased by exposure to crystalline silica at or below the new OSHA PEL of 50 μg/m³.

I. Comments and Responses Concerning Thresholds for Silica-Related Diseases

In this section, OSHA discusses comments focused on the issue of exposure-response thresholds for silica exposure. In the comments received by OSHA on this topic, an exposure-response ''threshold'' for silica exposure typically refers to a level of exposure such that no individual whose exposure is below that level would be expected to develop an adverse health effect. Commenters referred to thresholds both in terms of concentration and cumulative exposure (*i.e.*, a level of cumulative exposure below which an individual would not be expected to develop adverse health effects). In addition to individual thresholds, some commenters referred to a ''population average threshold,'' that is, the mean or median value of individual thresholds across a population of workers. There is significant scientific controversy over whether any such thresholds exist for silicosis and lung cancer, as well as the cumulative exposure level or concentration at which a threshold effect may occur and whether certain statistical modeling approaches can be used to identify threshold effects.

OSHA has reviewed the evidence in the record pertaining to thresholds, and has determined that the best available evidence supports the Agency's use of non-threshold exposure-response models in its risk assessments for silicosis and lung cancer. The voluminous scientific record accrued by OSHA in this rulemaking supports lowering the existing PEL to 50 μg/m³. Rather than indicating a threshold of risk that starts above the previous general industry PEL, the weight of this evidence, including OSHA's own risk assessment models, supports a conclusion that there continues to be significant, albeit reduced, risk at the 50 μg/m³ exposure limit. OSHA's evaluation of the best available evidence on thresholds indicates that there is considerable uncertainty about whether there is any threshold below which silica exposure causes no adverse health effects; but, in any event, the weight of evidence supports the view that, if there is a threshold of exposure for the health effects caused by respirable crystalline silica, it is likely lower than the new PEL of 50 μg/m³. Commenters have not provided convincing evidence of a population threshold (*e.g.*, an exposure level safe for all workers) above the revised PEL. In addition, OSHA's final risk assessment demonstrates that achieving this limit—which OSHA separately concludes is overall the lowest feasible level for silica-generating operations—will result in significant reductions in mortality and morbidity from occupational exposure to respirable crystalline silica.

1. Thresholds—General

In the Preliminary Quantitative Risk Assessment (QRA) (Document ID 1711, pp. 275, 282–285), OSHA reviewed evidence on thresholds from a lung dosimetry model developed by Kuempel *et al.* (2001, Document ID 1082) and from epidemiological analyses conducted by Steenland and Deddens (2002, Document ID 1124). As discussed in the Preliminary QRA, Kuempel *et al.* (2001) used kinetic lung models for both rats and humans to relate lung burden of crystalline silica and estimate a minimum critical lung burden (M_{crit}) of quartz above which particle clearance begins to decline and lung inflammation begins to increase (early steps in the process of developing silica-related disease). The M_{crit} would be achieved by a human equivalent airborne exposure to 36 μg/m³ for 45 years, based on the authors' rat-to-human lung model conversion. Exposures below this level would not lead to an excess lung cancer risk in the average individual, if it were assumed that cancer is strictly a secondary response to persistent inflammation. OSHA notes, however, that if some of the silica-related lung cancer risk occurs as a result of direct genotoxicity from early cellular interaction with respirable silica particles, then this threshold value may not be applicable. Since silicosis is caused by persistent lung inflammation, this exposure level could be viewed as a possible average threshold level for that disease as well (Document ID 1711, p. 284). As 36 μg/m³ is well below the previous general industry PEL of 100 μg/m³ and below the final PEL of 50 μg/m³, the Kuempel *et al.* study showed no evidence of an exposure-response threshold high enough to impact OSHA's choice of PEL.

Steenland and Deddens (2002, Document ID 1124) examined a pooled lung cancer study originally conducted by Steenland *et al.* (2001a). They found that a threshold model based on the log of cumulative dose (15-year lag) fit better than a no-threshold model, with the best threshold at 4.8 log mg/m³-days (representing an average exposure of 10 μg/m³ over a 45-year working lifetime). OSHA preliminarily concluded that, in the Kuempel et al. (2001) study and among the studies evaluated by Steenland *et al.* (2001a) in the pooled analysis, there was no empirical evidence of a threshold for lung cancer in the exposure range represented by the previous and final PELs (*i.e.*, at 50 μg/m³ or higher) (Document ID 1711, pp. 275, 284). Thus, based on these two studies, workers exposed at or below the new PEL of 50 μg/m³ over a working lifetime still face a risk of developing silicosis and lung cancer because their exposure would be above the supposed exposure threshold.

In its prehearing comments, the ACC argued that OSHA's examination of the epidemiological evidence, along with animal studies and mechanistic considerations, ''has not shown that reducing exposures below currently permitted exposure levels would create any additional health benefits for workers. OSHA's analysis and the studies on which it relies have not demonstrated the absence of an exposure threshold above 100 μg/m³ for the various adverse health effects considered in the QRA'' (Document ID 2307, Attachment A, p. 26; also 2348, Attachment 1, p. 33). According to the ACC, an exposure threshold above OSHA's previous general industry PEL of 100 μg/m³ means that workers exposed below that level will not get sick, negating the need to lower the PEL (Document ID 2307, Attachment A, p. 91).

Members of OSHA's peer review panel for the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment (Document ID 1711) rejected the ACC's comments as unsupportable. Peer reviewer Mr. Bruce Allen stated: ''it is essentially impossible to distinguish between dose-response patterns that represent a threshold and those that do not'' in epidemiological data (Document ID 3574, p. 8). Peer reviewer Dr. Kenneth Crump similarly commented:

> OSHA is on very solid ground in the [Preliminary QRA's] statement that ''available information cannot firmly establish a threshold exposure for silica-

related effects'' . . . the hypothesis that a particular dose response does not have a threshold is not falsifiable. Similarly, the hypothesis that a particular dose response does have a threshold is not falsifiable (Document ID 3574, p. 17).

Dr. Cox, representing the ACC, agreed with Dr. Crump that ''it's impossible to prove a negative, empirically . . . you could never rule out that possibility'' of a threshold at a low level of exposure (Document ID 3576, Tr. 402). However, he contended that it is possible to rule out a threshold in the higher-level range of observed exposures based on observed illness: ''I think that there are plenty of chemicals for which the hypothesis of a threshold exist[ing] at or above current standards could be ruled out because you see people getting sick at current levels'' (Document ID 3576, Tr. 403). Other commenters stated their belief that workers recently diagnosed with silicosis must have had exposures above the previous general industry PEL and, based on this supposition, concluded that OSHA has not definitively proven risk to workers exposed below the previous general industry PEL (Document ID 4224, pp. 2–5; Tr. 3582, pp. 1951–1963).

OSHA agrees with Dr. Cox that observation of workers ''getting sick at current levels'' can rule out a threshold effect at those levels. As is discussed below, there is evidence that workers exposed to silica at cumulative or average exposure levels permitted under the previous PELs have become ill and died as a result of their exposure. OSHA thus strongly disagrees with any implication from commenters that the Agency should postpone reducing a PEL until it has extensive documentation of sick and dying workers to demonstrate that the current PEL is not sufficiently protective (*see* Section II, Pertinent Legal Authority, and Section VI, Final Quantitative Risk Assessment and Significance of Risk).

The ACC's and Chamber's comments on this issue essentially argue that the model OSHA used to assess risk was inadequate to assess whether a threshold of risk exists and, if one does exist, at what level (Document ID 2307, Attachment A, pp. 52–65; 2376, pp. 20–22; 2330, pp. 17–21). According to OSHA peer reviewer Dr. Crump, however, the analytical approach taken by OSHA in the Preliminary QRA was appropriate. Considering the inherent limitations of epidemiological data:

an attempt to distinguish between threshold and non-threshold dose responses is not even a scientific exercise . . . The best that can be done is to attempt to place bounds on the amount of risk at particular exposures consistent with the available data, which is what OSHA had done in their risk assessment (Document ID 3574, p. 17).

A further source of uncertainty in investigating thresholds was highlighted by Dr. Mirer, on behalf of the AFL–CIO (Document ID 3578, Tr. 988–989) and by peer reviewer Dr. Andrew Salmon, who stated:

[m]any of the so-called thresholds seen in epidemiological studies represent thresholds of observability rather than thresholds of disease incidence . . . studies (and anecdotal observations) with less statistical power and shorter post-exposure followup (or none) will necessarily fail to see the less frequent and later-appearing responses at lower doses. This creates an apparent threshold which is higher in these studies than the apparent threshold implied by studies with greater statistical power and longer follow-up (Document ID 3574, p. 37).

Peer reviewer Dr. Gary Ginsberg suggested that, recognizing these inherent limitations, OSHA should characterize the body of evidence and argument surrounding thresholds by discussing the following factors related to whether a threshold for silica-related health effects exists at exposure levels above the previous general industry PEL:

the choices relative to the threshold concept for the silica dose response . . . [including] specific dose response datasets that are consistent with a linear or a threshold-type model, if a threshold seems likely, where was it seen relative to the current and proposed PEL, and a general discussion of mechanism of action, measurement error and population variability as concepts that can help us understand silica dose response for cancer and non-cancer endpoints (Document ID 3574, p. 24).

Following Dr. Ginsberg's suggestion, OSHA has, in its final health and risk analysis, considered the epidemiological evidence relevant to possible threshold effects for silicosis and lung cancer. As discussed below, first in ''Thresholds—Silicosis and NMRD'' and then in ''Thresholds—Lung Cancer,'' OSHA has carefully considered comments about statistical methods, exposure measurement uncertainty, and variability as they pertain to threshold effects. The discussion addresses the epidemiological evidence with respect to both cumulative and concentration thresholds. For reference, a working lifetime (45 years) of exposure to silica at the previous general industry PEL (100 µg/m^3) and the final PEL (50 µg/m^3) yield cumulative exposures of 4.5 mg/m^3-yrs and 2.25 mg/m^3-yrs, respectively. Other sections with detailed discussions pertinent to threshold issues include Section V.H, Mechanisms of Silica-Induced Adverse Health Effects, and Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis.

2. Thresholds—Silicosis and NMRD

OSHA has determined that the studies most relevant to the threshold issue in this rulemaking are those of workers who have cumulative exposures or average exposure concentrations below the levels associated with the previous general industry PEL (100 µg/m^3, or cumulative exposure of 4.5 mg/m^3-yrs). Contrary to comments that OSHA only relied on studies involving exposures far above the levels of interest to OSHA in this rulemaking, and then extrapolated exposure-response relationships down to relevant levels (*e.g.*, Document ID 2307, Attachment A, pp. 94–95; 4226, p. 2), a number of silicosis studies included workers who were exposed at levels close to or below the previous OSHA PEL for general industry. For example, four of the six cohorts of workers in the pooled silicosis mortality risk analysis conducted by Mannetje *et al.* (2002) had median cumulative exposures below 2.25 mg/m^3-yrs., and three had median silica concentrations below 100 µg/m^3 (Mannetje *et al.*, 2002, Document ID 1089, p. 724). Other silicosis studies with significant numbers of relatively low-exposed workers include analyses of German pottery workers (Birk *et al.,* 2009, Document ID 4002, Attachment 2; Mundt *et al.*, 2011, 1478; Morfeld *et al.*, 2013, 3843), Vermont granite workers (Attfield and Costello, 2004, Document ID 0285; Vacek *et al.*, 2011, 1486), and industrial sand workers (McDonald *et al.*, 2001, Document ID 1091; Hughes *et al.*, 2001, 1060; McDonald *et al.*, 2005, 1092). In this section, OSHA will discuss each of them in relationship to whether they suggest the existence of a threshold above 100 µg/m^3, the previous PEL for general industry.

a. Mannetje *et al.* Pooled Study and Related Analyses

Mannetje *et al.* (2002b, Document ID 1089) estimated excess lifetime risk of silicosis based on six of the ten cohorts that were part of the IARC multi-center exposure-response study (Steenland *et al.*, 2001a, Document ID 0452). The six cohorts were U.S. diatomaceous earth (DE) workers, Finnish granite workers, U.S. granite workers, U.S. industrial sand workers, U.S. gold miners, and Australian gold miners. Together, the cohorts included 18,634 subjects and 170 silicosis deaths. All cohorts except the Finnish granite workers and Australian gold miners had significant numbers of workers with median

cumulative and/or average exposures below the levels associated with OSHA's previous general industry PEL. Checking for nonlinearities in their exposure-response model, Mannetje *et al.* found that a five-knot cubic spline model (which allows for deviations, such as thresholds, from a linear relationship) did not fit the data better than the linear model used in their main analysis. The result of this attempt to check for nonlinearities suggests that there is no threshold effect in the relationship between cumulative silica exposure and silicosis risk in the study. Significantly, NIOSH stated that the results of Mannetje *et al.'s* analysis ''suggest the absence of threshold at the lowest [cumulative] exposure analyzed . . . in fact, the trend for silicosis mortality risk extends down almost linearly to the lowest cumulative exposure stratum'', in which ''the average cumulative exposure is the equivalent of 45 years of exposure at 11.1 μg/m^3 silica'' (Document ID 4233, pp. 34–35). This level is significantly below the new OSHA PEL of 50 μg/m^3.

As discussed in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis, OSHA commissioned Drs. Kyle Steenland and Scott Bartell to examine the potential effects of exposure measurement error on the mortality risk estimates derived from the pooled studies of lung cancer (Steenland *et al.*, 2001, Document ID 0452) and silicosis (Mannetje *et al.*, 2002b, Document ID 1089). Their analysis of the pooled data, using a variety of standard statistical techniques (*e.g.*, regression analysis), also found the data either consistent with the absence of a threshold or inconsistent with the existence of a threshold [8] (Document ID 0469). Thus, neither Mannetje et al. nor Steenland and Bartell's analyses of the pooled cohorts suggested the existence of a cumulative exposure threshold effect; in fact, they suggested the absence of a threshold. Given the predominance in these studies of cohorts where at least half of the workers had cumulative exposures below 4.5 mg/m^3-yrs, OSHA believes these results constitute strong evidence against an exposure threshold above the level of cumulative exposure resulting from long-term exposure at the previous PEL of 100 μg/m^3.

b. Vermont Granite Workers

As discussed in the Supplemental Literature Review of Epidemiological Studies, Vacek *et al.* (2011, Document ID 1486) examined exposures from 1950 to 1999 for a group of 7,052 workers in the Vermont granite industry (Document ID 1711, Attachment 1, pp. 2–5). The exposure samples show relatively low exposures for the worker population. For the period 1950 to 2004, Verma *et al.* (2012), who developed the job exposure matrix used by Vacek *et al.*, estimated that average exposure concentrations in 21 of 22 jobs were below 100 μg/m^3, and 11 of the 22 job classes were at 50 μg/m^3 or below. The remaining job category, laborer, had an estimated average exposure concentration of exactly 100 μg/m^3 (Verma *et al.*, 2011, Document ID 1487, p. 75).

Six of the 5,338 cohort members hired in or after 1940, when Vermont's dust control program was in effect, were identified as having died of silicosis by the end of the follow-up period (Vacek *et al.*, Document ID 1486, p. 314). The frequency of observed silicosis mortality in the population is significant by OSHA standards (1.1 per 1,000 workers), and may be underestimated due to under-reporting of silicosis as a cause of death (*see* Section V.E, Comments and Responses Concerning Surveillance Data on Silicosis Morbidity and Mortality). This observed silicosis mortality shows that deaths from silicosis occurred among workers hired after silica concentrations were reduced below OSHA's previous general industry PEL. It therefore demonstrates that a threshold for silicosis above 100 μg/m^3 is unlikely.

In terms of morbidity, Graham *et al.*'s study of radiographic evidence of silicosis among retired Vermont granite workers found silicosis in 5.7 percent of workers hired after 1940 (equivalent to 57/1,000 workers) (Graham *et al.*, 2004, Document ID 1031, p. 465). OSHA concludes that these studies of low-exposed workers in the Vermont granite industry show significant risk of silicosis—both mortality and morbidity—at concentrations below the previous PELs. These studies also indicate that a threshold at an exposure concentration significantly above the previous PEL for general industry, as posited by industry representatives, is unlikely.

c. U.S. Industrial Sand Workers

In an exposure-response study of 4,027 workers in 18 U.S. industrial sand plants, Steenland and Sanderson (2001) reported that approximately three-quarters of the workers with complete work histories had cumulative exposures below 1.28 mg/m^3-yrs, well below the cumulative exposure of 2.25 mg/m^3-yrs associated with a working lifetime of exposure at the final PEL of 50 μg/m^3 (Document ID 0455, p. 700). The study identified fourteen deaths from silicosis and unspecified pneumoconiosis (~3.5 per 1,000 workers) (Document ID 0455, p. 700), of which seven occurred among workers with cumulative exposures below 1.28 mg/m^3-yrs. As with other reports of silicosis mortality, this figure may underestimate the true rate of silicosis mortality in this worker population.

Hughes *et al.* (2001) reported 32 cases of silicosis mortality in a cohort of 2,670 workers at nine North American industrial sand plants (~12 per 1,000) (Document ID 1060, p. 203). The authors developed a job-exposure matrix based on exposure samples collected by the companies and by MSHA between 1973 and 1994, along with the 1946 exposure survey used by Steenland and Sanderson (2001, Document ID 0455; 2307, Attachment 7, p. 6). Job histories were available for 29 workers who died of silicosis. Of these, fourteen had estimated cumulative exposure less than or equal to 5 mg/m^3-yrs, and seven had cumulative exposures less than or equal to 1.5 mg/m^3-yrs (Document ID 1060, p. 204). Both studies clearly showed silicosis risk among workers whose cumulative exposures were comparable to those that workers could experience under the final PEL (Document ID 0455, p. 700; 1060, p. 204), indicating that a threshold above this level of cumulative exposure is unlikely.

d. German Porcelain Workers

A series of papers by Birk *et al.* (2009, Document ID 4002, Attachment 2; 2010, Document ID 1467), Mundt *et al.* (2011, Document ID 1478), and Morfeld *et al.* (2013, Document ID 3843) examined silicosis mortality and morbidity in a population of over 17,000 workers in the German porcelain industry. Cohort members' annual average concentrations of respirable quartz dust were reconstructed from detailed work histories and dust measurements collected in the industry from 1951 onward (Birk *et al.*, 2009, Document ID 4002, Attachment 2, pp. 374–375). Morfeld *et al.* observed 40 silicosis morbidity cases (ILO profusion category 1/1 or greater), and noted that additional

[8] This analysis included a log-cumulative logistic regression model, as well as a categorical analysis and five-knot restricted cubic spline analysis using log-cumulative exposure. Had the spline analysis shown a better-fitting model with a flat exposure-response at low cumulative exposure levels, it might have suggested a threshold effect for cumulative exposure. However, no significant difference was observed between the parametric model and the two other models, which had greater flexibility in the shape of the exposure-response (Document ID 0469, p. 50, Figure 5).

follow-up of the cohort might be necessary due to the long latency period of silicosis (2013, Document ID 3843, p. 1032).

Follow-up time is a critical factor for detection of silicosis, which has a typical latency of 20–30 years (*see* Morfeld *et al.*, 2013, Document ID 3843, p. 1028). As stated in Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA, the disease latency for silicosis can extend to around 30 years. Follow-up was extremely limited in the German porcelain workers silicosis morbidity analysis, with a mean of 7.5 years of follow up for the study population (Document ID 3843). Despite the limited follow-up time, the cohort showed evidence of silicosis morbidity among low-exposed workers: 17.5 percent of cases occurred among workers whose highest average silica exposure in any year (''highest annual'') was estimated by the authors to be less than 250 μg/m^3, and 12.5 percent of cases occurred among workers whose highest annual silica exposure was estimated at less than 100 μg/m^3 (Document ID 3843).

The lead author of the study, Dr. Peter Morfeld, testified at the public hearings on behalf of the ACC Crystalline Silica Panel. In his post-hearing comments, Dr. Morfeld stated that ''[m]echanistic considerations imply that we should not expect to see a threshold for cumulative exposure'' in silicosis, but that the question of whether a threshold concentration level may exist remains (Document ID 4003, p. 3). The study by Morfeld *et al.* ''focused on the statistical estimation of a concentration threshold . . . [and] simultaneously took into account the cumulative exposure to respirable crystalline silica dust as a driving force of the disease'' (Document ID 4003, p. 3). Morfeld *et al.* applied a technique developed by Ulm *et al.* (1989, 1991) to estimate a concentration threshold. In this method a series of candidate exposure concentration values are subtracted from the estimated annual mean concentration data. Using the recalculated exposure estimates for the study population, regression analyses for each candidate are run to identify the best fitting model, using the Akaike Information Criterion (AIC) to evaluate model fit (Document ID 3843, p. 1029). According to Morfeld, the best fitting model in their study estimated a threshold concentration of 250 μg/m^3 (AIC = 488.3) with a 95 percent confidence interval of 160 to 300 μg/m^3. A second model with very similar fit (AIC = 488.8) estimated a threshold concentration of 200 μg/m^3 with a 95 percent confidence interval of 57 μg/m^3 to 270 μg/m^3. A third model with a poorer fit (AIC=490.6) estimated a threshold concentration of 80 μg/m^3 with a 95 percent confidence interval of 0.2 μg/m^3 to 210 μg/m^3 (Document ID 3843, Table 3, p. 1031).

In the Final Peer Review Report, Dr. Crump stated that Morfeld *et al.*'s modeling approach, like ''all such attempts statistically to estimate a threshold,'' is ''not reliable because the threshold estimates so obtained are highly unstable'' (Document ID 3574, p. 17). Dr. Morfeld's co-author, Dr. Mundt, stated in the public hearings:

> I'll be the first one to tell you there is a lot of imprecision and, therefore, say confidence intervals or uncertainty should be respected, and that the—I'm hesitant to just focus on a single point number like the .25 [250 μg/m^3], and prefer that you encompass the broader range that was reported in the Morfeld, on which I was an author and consistently brought this point to the table (Document ID 3577, Tr. 645).

NIOSH submitted post-hearing comments on the analysis in Morfeld *et al.* (2013). NIOSH pointed out that the exposure measurements in the analysis were based on German dust samplers, which for pottery have been shown to collect approximately twice as much dust as U.S. samplers. Therefore, ''when Dr. Morfeld cited 0.15 mg/m^3 (150 μg/m^3) as the lower 95% confidence limit for the threshold, that would convert to 0.075 mg/m^3 (75 μg/m^3) in terms of equivalent measurements made with a U.S. sampler'' (Document ID 4233, p. 21). Similarly, the U.S. equivalent of each of the other threshold estimates and confidence limits presented in Morfeld *et al.*'s analysis would be about half the reported exposure levels. NIOSH also commented that Morfeld *et al.*'s analysis appears to be consistent with both threshold and non-threshold models (Document ID 4233, p. 55). Furthermore, NIOSH observed that Morfeld *et al.* did not account for uncertainty in the values of one of their model parameters (ε); therefore their reported threshold confidence limits of 0.16–0.30 are too narrow (Document ID 4233, p. 56). More generally, NIOSH noted that Morfeld *et al.* did not quantitatively evaluate how uncertainty in exposure estimates may have impacted the results of the analysis; Morfeld agreed that he had not performed a ''formal uncertainty analysis'' (Document ID 4233, p. 58; 3582, Tr. 2078–2079). NIOSH concluded, ''it is our firm recommendation to discount results based on the model specified in [Morfeld *et al.* Eq. 3] . . . including all results related to a threshold'' (Document ID 4233, p. 58). OSHA has evaluated NIOSH's comments on the analysis and agrees that the issues raised by NIOSH raise serious questions about Morfeld *et al.*'s conclusions regarding a silica threshold.

OSHA's greater concern with Dr. Morfeld's estimate of 250 μg/m^3 as a threshold concentration for silicosis is the fact that a substantial proportion of workers with silicosis in Dr. Morfeld's study had no estimated exposure above the threshold suggested by the authors; this threshold was characterized by commenters, including the Chamber of Commerce (Chamber), as a concentration ''below which the lung responses did not progress to silicosis'' (Document ID 4224, Attachment 1, p. 3). This point was emphasized by Dr. Brian Miller in the Final Peer Review Report (Document ID 3574, p. 57) and by NIOSH (Document ID 4233, p. 57). In the study, 17.5 percent of workers with silicosis were classified as having no exposure above Morfeld *et al.*'s estimated threshold of 250 μg/m^3, (Document ID 3843, p. 1031) and 12.5 percent of these workers were classified as having no exposure above 100 μg/m^3. OSHA believes the presence of these low-exposed workers with silicosis clearly contradicts the authors' estimate of 250 μg/m^3 as a level of exposure below which no worker will develop silicosis (*see* Document ID 4233, p. 57).

In a post-hearing comment, Dr. Morfeld offered a different interpretation of his results, describing his threshold estimate as a ''population average'' which would not be expected to characterize risk for all individuals in a population. Rather, according to Dr. Morfeld ''we expect to see differences in response thresholds among subjects'' (Document ID 4003, p. 5). OSHA agrees with this interpretation, which was similarly expressed in several comments from OSHA's peer reviewers on the subject of thresholds (*e.g.*, Document ID 3574, pp. 13, 21–22). Consistent with its peer reviewers' opinions, OSHA draws the conclusion from the data and discussion concerning population averages that these ''differences in response thresholds among subjects'' support setting the PEL at 50 μg/m^3 in order to protect the majority of workers in the population of employees exposed to respirable crystalline silica. OSHA's review of the Morfeld *et al.* data on German porcelain workers thus reinforces its view that reducing exposures to this level will benefit the many workers who would develop silicosis at exposure levels below that of the ''average'' worker.

Dr. Morfeld's discussion of his estimate as a ''population average'' among workers with different individual responses to silica exposure

echoes several comments from OSHA's peer reviewers on the subject of thresholds. In the Final Peer Review Report, Dr. Ginsberg observed that a linear exposure-response model may reflect a distribution of individual ''thresholds,'' such that ''the population can be characterized as having a distribution of vulnerability. This distribution may be due to differences in levels of host defenses that come with differences in age, co-exposure to other chemicals, the presence of interacting background disease processes, non-chemical stressors, and a variety of other host factors'' (Document ID 3574, p. 21). Given the number of factors that may influence vulnerability to certain diseases in a population of workers, Dr. Ginsberg continued:

> it is logical for OSHA to strongly consider inter-subject variability . . . as the reason for linearly-appearing regression slopes in silica-related non-cancer and cancer studies. This explanation does not imply an artifact [that is, a false appearance of linear exposure-response] but that the linear (or log linear) regression coefficient extending down to low dose reflects the inherent variability in susceptibility such that the effect of concern . . . may occur in some individuals at doses well below what might be a threshold in others (Document ID 3574, pp. 21–22).

Peer reviewer Mr. Bruce Allen agreed that ''[i]t makes no sense to discuss a single threshold value . . . Given, then, that thresholds must be envisioned as a distribution in the population, then there is substantial population-level risk even at the mean threshold value, and unacceptably high risk levels at exposures far below the mean threshold.'' He further stated:

> It is NOT, therefore, inappropriate to model the population-level observations using a non-threshold model . . . In fact, I would claim that it is inappropriate to include ANY threshold models (*i.e.*, those that assume a single threshold value) when modeling epidemiological data. A non-threshold model for characterizing the population dose-response behavior is theoretically and practically the optimal approach (Document ID 3574, p. 13).

OSHA concludes that this German porcelain workers cohort shows evidence of silicosis among workers exposed at levels below the previous PELs, and that continued follow-up of this cohort would be likely to show greater silicosis risk among low-exposed workers due to the short follow-up time. Furthermore, the Chamber's characterization of Dr. Morfeld's result as ''a threshold concentration of 250 μg/m^3 below which the lung responses did not progress to silicosis'' (Document ID 4224, p. 3) is plainly inaccurate, as the estimated exposures of a substantial proportion of the workers with silicosis in the data set did not exceed this level.

e. Park *et al.* (2002)

The ACC submitted comments on the Park *et al.* (2002, Document ID 0405) study which examined silicosis and lung disease other than cancer (*i.e.*, NMRD) in a cohort of diatomaceous earth workers. The ACC's comments on this study are discussed in detail in Section V.D, Comments and Responses Concerning Silicosis and Non-Malignant Respiratory Disease Mortality and Morbidity, including comments relating to exposure-response thresholds in this study. Briefly, the ACC claimed that the Park *et al.* (2002) study is ''fully consistent'' with Morfeld's estimate of a threshold above the 100 μg/m^3 concentration for NMRD, including silicosis, mortality (Document ID 2307, Attachment A, p. 107). However, NIOSH explained in its post-hearing brief that categorical analysis for NMRD indicated no threshold existed at or above a cumulative exposure corresponding to 25 μg/m^3 over 40 years of exposure, which is below the cumulative exposure equivalent to the new PEL over 45 years (Document ID 4233, p. 27). Park *et al.* did not attempt to estimate a threshold below that level because the data lacked the power needed to discern a threshold (Document ID 4233, p. 27). OSHA agrees with NIOSH's assessment, which indicates that, if there is a cumulative exposure threshold for NMRD, including silicosis, it is significantly below the final PEL of 50 μg/m^3.

f. Conclusion—Silicosis and NMRD

OSHA concludes that the body of epidemiological literature clearly demonstrates risk of silicosis and NMRD morbidity and mortality among workers who have been exposed to cumulative exposures or average exposure concentrations at or below the levels associated with the previous general industry PEL (100 μg/m^3, or cumulative exposure of 4.5 mg/m^3-yrs). Thus, OSHA does not agree with commenters who have stated that the previous general industry PEL is fully protective and that reducing it will yield no health benefits to silica-exposed workers (*e.g.*, Document ID 4224, p. 2–5; Tr. 3582, pp. 1951–1963). Instead, the Agency finds that the evidence is at least as consistent with a finding that no threshold is discernible as it is with a finding that a threshold exists at some minimal level of exposure. The best available evidence also demonstrates silicosis morbidity and mortality below the previous PEL of 100 μg/m^3, indicating that any threshold for silicosis (understood as an exposure level below which no one would develop disease), if one exists, is below that level. Even if the conclusion reached by Dr. Morfeld that a population average threshold exists above the level of the previous PEL is accurate, there will still be a substantial portion of the population who will develop silicosis from exposures below the identified ''threshold.'' These findings support OSHA's action in lowering the PEL to 50 μg/m^3.

3. Thresholds—Lung Cancer

OSHA's Preliminary QRA and supplemental literature review included several studies that provide information on possible threshold effects for lung cancer. OSHA has determined that the epidemiological studies most relevant to the threshold issue are those with workers who have cumulative exposures or average exposure concentrations below the levels associated with the previous general industry PEL (100 μg/m^3, or cumulative exposure of 4.5 mg/m^3-yrs). As with the silicosis studies previously discussed, contrary to comments that OSHA only relied on studies involving exposures far above the levels of interest to OSHA in this rulemaking (*e.g.*, Document ID 2307, Attachment A, pp. 94–95; 4226, p. 2), a number of lung cancer studies included workers who were exposed at levels close to or below the previous general industry PEL. Five of the 10 cohorts of workers in the pooled lung cancer risk analysis conducted by Steenland *et al.* (2001a) had median cumulative exposures below 4.5 mg/m^3-yrs (the cumulative level associated with a working lifetime of exposure at the previous general industry PEL); four were also below 2.25 mg/m^3-yrs (the cumulative level associated with a working lifetime of exposure at the revised PEL) and three had median silica concentrations below 100 μg/m^3 (Document ID 0452, p. 775). Other lung cancer studies with significant numbers of relatively low-exposed workers include analyses of the Vermont granite workers (Attfield and Costello, 2004, Document ID 0285; Vacek *et al.*, 2011, 1486) and industrial sand workers (McDonald *et al.*, 2001, Document ID 1091; Hughes *et al.*, 2001, 1060; McDonald *et al.*, 2005, 1092) described in the previous discussion on silicosis. In addition to the epidemiological studies discussed here, in Section V.H, Mechanisms of Silica-Induced Adverse Health Effects, OSHA discussed studies that have shown direct genotoxic mechanisms by which exposure to crystalline silica at any level, with no threshold effect, may lead to lung cancer.

a. Steenland *et al.* Pooled Lung Cancer Study and Related Analyse

Steenland *et al.* (2001a) estimated excess lifetime risk of lung cancer based on a 10-cohort pooled study, which included several cohorts with significant numbers of workers with median cumulative and average exposures below those allowed by the previous general industry PEL (Document ID 0452). Results indicated that 45 years of exposure at 0.1 mg/m^3 (100 μg/m^3) would result in a lifetime risk of 28 excess lung cancer deaths per 1,000 workers (95% confidence interval (CI) 13–46 per 1,000). An alternative (non-linear) model yielded a lower risk estimate of 17 per 1,000 (95% CI 2–36 per 1,000).

A follow-up letter by Steenland and Deddens (2002, Document ID 1124) addressed the possibility of an exposure threshold effect in the pooled lung cancer analysis conducted by Steenland *et al.* in 2001. According to Dr. Steenland, ''We further investigated whether there was a level below which there was no increase in risk, the so-called threshold. So we fit models that had a threshold versus those that didn't, and we explored various thresholds that might apply'' (Document ID 3580, Tr. 1229). Threshold models using average exposure and cumulative exposure failed to show a statistically significant improvement in fit over models without a threshold. However, the authors found that when they used the log of cumulative exposure (a transformation commonly used to reduce the influence of high exposure points on a model), a threshold model with a 15-year lag fit better than a no-threshold model. The authors reported the best threshold estimate at 4.8 log mg/m^3-days (Document ID 1124, p. 781), or an average exposure of approximately 10 μg/m^3 over a 45-year working lifetime, one-fifth of the final PEL. Dr. Steenland explained what his analysis indicated regarding a cumulative exposure threshold for lung cancer: ''we found, in fact, that there was a threshold model that fit better than a no-threshold model, not enormously better but better statistically, but that threshold was extremely low . . . far below the . . . silica standard proposed by OSHA'' (Document ID 3580, Tr. 1229).

In response to comments from ACC Panel members Dr. Valberg and Dr. Long that the analysis presented by Steenland *et al.* showed a clear threshold at a level of cumulative exposure high enough to bear on OSHA's choice of PEL (Document ID 2330, p. 20), Dr. Steenland explained that their conclusion was based on a misreading of an illustration in his study:

> [I]f you look at the figure, you see that the curve of the spline [a flexible, nonlinear exposure-response model] starts to go up around four on the log scale of microgram per meter cubed days. And if you transform that from the log to the regular scale, that is quite consistent with the threshold we got when we did a formal analysis using the log transform model [discussed above] (Document ID 3580, Tr. 1255).

The ACC representatives' comments do appear to be based on a misunderstanding of the figure in question, due to an error in Dr. Steenland's 2001 publication in which the axis of the figure under discussion was incorrectly labeled. This error was later corrected in an erratum (Document ID 3580, Tr. 1257; Steenland *et al.*, 2002, Erratum. Cancer Causes Control, 13:777).

In addition, at OSHA's request, Drs. Steenland and Bartell (ToxaChemica, 2004, Document ID 0469) conducted a quantitative uncertainty analysis to examine the effects of possible exposure measurement error on the pooled lung cancer study results (*see* Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis). These analyses showed no evidence of a threshold effect for lung cancer at the final or previous PELs. Based on Dr. Steenland's work, therefore, OSHA believes that no-threshold models are appropriate for evaluating the exposure-response relationship between silica exposure and lung cancer. Even if commenters are correct that threshold models are preferable, the threshold is likely at a level of cumulative exposure significantly below what a worker would accumulate in 45 years of exposure at the final PEL, and is therefore immaterial to this rulemaking (*see* Document ID 1124, p. 781).

b. Vermont Granite Workers

In the Preliminary QRA and supplemental literature review, OSHA reviewed several studies on lung cancer among silica-exposed workers in the Vermont granite industry, whose exposures were reduced to relatively low levels due to a program for dust control initiated in 1938–1940 by the Vermont Division of Industrial Hygiene (Document ID 1711, pp. 97–102; 1711, Attachment 1, pp. 2–5; 1487, p. 73). As discussed above, Verma *et al.* (2012) reported that all jobs in the industry had average exposure concentrations at or below 100 μg/m^3—most of them well below this level—in the time period 1950–2004 after implementation of exposure controls (Document ID 1487, Table IV, p. 75).

Attfield and Costello (2004) examined a cohort of 5,414 Vermont granite workers, including 201 workers who died of lung cancer (Document ID 0285, pp. 130, 134). In this study, cancer risk was elevated at cumulative exposure levels below 4.5 mg/m^3-yrs, the amount of exposure that would result from a 45-year working lifetime of exposure at the previous PEL. The authors reported elevated lung cancer in all exposure groups, observing statistically significant elevation among workers with cumulative exposures between 0.5 and 1 mg/m^3-yrs ($p < 0.05$), cumulative exposures between 2 and 3 mg/m^3-yrs ($p < 0.01$), and cumulative exposures between 3 and 6 mg/m^3-yrs ($p < 0.05$) (Document ID 0285, p. 135). These findings indicate that a threshold in exposure-response for lung cancer is unlikely at cumulative exposure levels associated with 45 years of exposure at the previous PEL and below.

Vacek *et al.* (2011) examined a group of 7,052 men, overlapping with the Attfield and Costello cohort, who worked in the Vermont granite industry at any time between January 1, 1947 and December 31, 1998 (Document ID 1486). Like Attfield and Costello, Vacek *et al.* reported significantly elevated lung cancer ($p < 0.01$) (Document ID 1486, p. 315). Most of the lung cancer cases in Vacek *et al.* (305/356) had cumulative exposures less than or equal to 4.1 mg/m^3-yrs (Document ID 1486, p. 316), below the cumulative exposure level of 4.5 mg/m^3-yrs associated with 45 years of exposure at the previous PEL and below. However, unlike Attfield and Costello, Vacek *et al.* did not find a statistically significant relationship of increasing lung cancer risk with increasing silica exposure, leading Vacek *et al.* to conclude that increased lung cancer mortality in the cohort may not have been due to silica exposure (Document ID 1486, p. 312).

The strengths and weaknesses of both studies and the differences between them that could account for their conflicting conclusions were discussed in great detail in Section V.F, Comments and Responses Concerning Lung Cancer Mortality. For the purpose of evaluating the effects of low concentrations of silica exposure, as well as whether a threshold exposure exists, OSHA believes the Attfield and Costello study may merit greater weight than Vacek *et al.* As discussed in Section V.F, Comments and Responses Concerning Lung Cancer Mortality, OSHA believes Attfield and Costello's choice to exclude the highest exposure group from their analysis likely improved their study's

estimate of the exposure-response relationship at lower exposures; by making this choice, they limited the influence of highly uncertain exposure estimates at higher levels and helped to reduce the impact of the healthy worker survivor effect. The Agency acknowledges the strengths of the Vacek *et al.* analysis as well, including longer follow-up of workers.

In conclusion, OSHA does not find compelling evidence in these studies of Vermont granite workers of a cumulative exposure threshold for lung cancer in the exposure range below the previous general industry PEL. This conclusion is based on the statistically significant elevations in lung cancer reported in both cohorts described above, which were composed primarily of workers whose cumulative exposures were below the level associated with a working lifetime of exposure. However, OSHA acknowledges that a strong conclusion regarding a threshold is difficult to draw from these studies, due to the disagreement between Attfield and Costello and Vacek *et al.* regarding the likelihood that excess lung cancer among Vermont granite workers was due to their silica exposures.

c. Industrial Sand Workers

OSHA's Preliminary QRA (Document ID 1711, pp. 285–287) evaluated a 2001 case-control analysis of industrial sand workers including 2,640 men employed before 1980 for at least three years in one of nine North American sand-producing plants. One of the sites was a large associated office complex where workers' exposures were lower than those typically experienced by production workers (Hughes *et al.*, 2001, Document ID 1060). A later update by McDonald *et al.* (2005, Document ID 1091) eliminated one plant, following 2,452 men from the 8 remaining U.S. plants. Both cohorts overlapped with an earlier industrial sand cohort, including 4,626 workers at 18 plants, which was included in Steenland *et al.*'s pooled analysis (2001a, Document ID 0452). OSHA noted that these studies (Hughes *et al.*, 2001, Document ID 1060; McDonald *et al.*, 2005, 1092; Steenland and Sanderson, 2001, 0455) showed similar exposure-response patterns of increased lung cancer mortality with increased exposure.

In the Final Peer Review Report, Dr. Ginsberg commented on the relevance of the industrial sand cohort studies, which included low-exposed workers with exceptionally well-characterized exposures, for threshold issues:

> With respect to the body of silica epidemiology literature, perhaps the case with the least amount of measurement error is of US industrial sand workers wherein many measurements were made with filter samples and SRD determination of crystalline silica and in which there was very careful estimation of historical exposure for both silica and smoking (MacDonald *et al.* 2005; Steenland and Sanderson 2001; Hughes *et al.* 2001) (Document ID 3574, pp. 22–23).

OSHA agrees with Dr. Ginsberg's assessment of these studies and has found them to be particularly high quality. Thus, the Agency was especially interested in the studies' findings, which showed that cancer risk was elevated at cumulative exposure levels below 4.5 mg/m^3-yrs, the amount of exposure that would result from a 45-year working lifetime of exposure at the previous PEL. OSHA believes these results provide strong evidence against a threshold in cumulative exposure at any level high enough to impact OSHA's choice of PEL. Dr. Ginsberg agrees with OSHA's conclusion (Document ID 3574, p. 23).

d. Other Studies

Comments submitted by the ACC briefly mentioned several epidemiological studies that, they claim, ''suggest the existence of a threshold for any increased risk of silica-related lung cancer,'' including studies by Sogl *et al.* (2012), Mundt *et al.* (2011), Pukkala *et al.* (2005), Calvert *et al.* (2003), Checkoway *et al.* (1997), and Steenland *et al.* (2001a). OSHA previously reviewed several of these studies in the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment, and the Supplemental Literature Review, though not with specific attention to their implications for exposure-response thresholds (Document ID 1711, pp. 139–155; 1711, Attachment 1, pp. 6–12). The studies cited by ACC are discussed below, with the exception of Steenland *et al.* (2001a), which was previously reviewed in this section.

e. German Porcelain Workers

OSHA reviewed Mundt *et al.* (2011, Document ID 1478) in its Supplemental Literature Review (Document ID 1711, Attachment 1, pp. 6–12). As discussed there, Mundt *et al.* examined the risks of silicosis morbidity and lung cancer mortality in a cohort of 17,644 German porcelain manufacturing workers who had participated in medical surveillance programs for silicosis between 1985 and 1987. This cohort was also examined in a previous paper by Birk *et al.* (2009, Document ID 4002, Attachment 2).

Quantitative exposure estimates for this cohort showed an average annual exposure of 110 μg/m^3 for workers hired prior to 1960 and an average of 30 μg/m^3 for workers hired after 1960. More than 40 percent of the cohort had cumulative exposures less than 0.5 mg/m^3-yrs at the end of follow-up, and nearly 70 percent of the cohort had average annual exposures less than 50 μg/m^3 (Mundt *et al.*, 2011, Document ID 1478, pp. 283–284).

The lung cancer mortality hazard ratios (HRs) associated with average annual exposure were statistically significant in two of the four average annual exposure groups: 2.1 (95% CI 1.1–4.0) for average annual exposure group >50–100 μg/m^3 and 2.4 (95% CI 1.1–5.2) for average annual exposure group >150–200 μg/m^3, controlling for age, smoking, and duration of employment. In contrast, the HRs for lung cancer mortality associated with cumulative exposure were not statistically elevated after controlling for age and smoking.

The authors suggested the possibility of a threshold for lung cancer mortality. However, no formal threshold analysis for lung cancer was conducted in this study or in the follow-up threshold analysis conducted on this population by Morfeld *et al.* for silicosis (2013, Document ID 4175). Having reviewed this study carefully, OSHA believes it is inconclusive on the issue of thresholds due to the elevated risk of lung cancer seen among low-exposed workers (for example, those with average exposures of 50–100 μg/m^3), which is inconsistent with the ACC's claim that a threshold exists at or above the previous PEL of 100 μg/m^3, and due to several limitations which may preclude detection of a relationship between cumulative exposure and lung cancer in this cohort. As discussed in the Preliminary QRA, these include: (1) A strong healthy worker effect observed for lung cancer; (2) Mundt *et al.* did not follow the typical convention of considering lagged exposures to account for disease latency; and (3) the relatively young age of this cohort (median age 56 years old at time of silicosis determination) (Document ID 1478, p. 288) and limited follow-up period (average of 19 years per subject) (Birk *et al.* 2009, Document ID 4002, Attachment 2, p. 377). Only 9.2 percent of the cohort was deceased by the end of the follow up period. Mundt *et al.* (2011) acknowledged this limitation, stating that the lack of increased risk of lung cancer was a preliminary finding (Document ID 1478, p. 288).

f. German Uranium Miners

In pre-hearing comments, Dr. Morfeld described a study of 58,677 German uranium miners by Sogl *et al.* (2012,

Document ID 3842; 2307, Attachment 2, p. 11). Dr. Morfeld noted that the study was based on a detailed exposure assessment of respirable crystalline silica (RCS) dust. According to Dr. Morfeld, Sogl *et al.* ''showed that no lung cancer excess risk was observed at RCS dust exposure levels below 10 mg/m^3-years'' (Document ID 2307, Attachment 2, p. 11). OSHA's review of this publication confirmed that the authors reported a spline function with a single knot at 10 mg/m^3-yrs, which Morfeld interprets to suggest a threshold for lung cancer of approximately 250 µg/m^3 average exposure concentration for workers exposed over the course of 40 years. However, the authors also noted that an increase in risk below this level could not be ruled out due to strong confounding with radon, resulting in possible over-adjustment (Sogl *et al.*, Document ID 3842, p. 9). That is, because workers with high exposures to silica would also have had high exposures to the lung carcinogen radon, the models used by Sogl *et al.* may have been unable to detect a relationship between silica and lung cancer in the presence of radon. As described previously, excess lung cancer has been observed among workers with lower cumulative exposures than the Sogl *et al.* ''threshold'' in other studies which do not suffer from confounding from potent lung carcinogens other than silica (for example, industrial sand workers), and which are, therefore, likely to provide more reliable evidence on the issue of thresholds. OSHA concludes that the Sogl *et al.* study does not provide convincing evidence of a cumulative exposure threshold for lung cancer.

g. U.S. Diatomaceous Earth Workers

Checkoway *et al.* (1997) investigated the risk of lung cancer among diatomaceous earth (DE) workers exposed to respirable cristobalite (a type of silica found in DE) (Document ID 0326; 1711, pp. 139–143). Exposure samples were collected primarily at one of the two plants in the study by plant industrial hygienists over a 40-year timeframe from 1948 to 1988 and used to estimate exposure for each individual in the cohort (Seixas *et al.*, 1997, Document ID 0431, p. 593). Based on 77 deaths from cancer of the trachea, lung, and bronchus, the standardized mortality ratios (SMR) were 129 (95% CI 101–161) and 144 (95% CI 114–180) based on rates for U.S. and local county males, respectively (Document ID 0326, pp. 683–684). The authors found a positive, but not monotonic, exposure-response trend for lung cancer. The risk ratios for lung cancer with increasing quintiles of respirable crystalline silica exposure were 1.00, 0.96, 0.77, 1.26 and 2.15 with a 15-year exposure lag. Lung cancer mortality was thus elevated for workers with cumulative exposures greater than 2.1 mg/m^3-yrs, but was only statistically significantly elevated for the highest exposure category (RR = 2.15; 95% CI 1.08–4.28) (Document ID 0326, p. 686). OSHA notes that this highest exposure category includes cumulative exposures only slightly higher than 4.5 mg/m^3-yrs, the level of cumulative exposure resulting from a 45-year working lifetime at the previous PEL of 100 µg/m^3. OSHA does not believe that the appearance of a statistically significantly elevated lung cancer risk in the highest category should be interpreted as evidence of an exposure-response threshold, especially in light of the somewhat elevated risk seen at lower exposure levels. OSHA believes it is more likely to reflect limited power to detect excess risk at lower exposure levels, a common issue in epidemiological studies which was emphasized by peer reviewer Dr. Andrew Salmon in relation to purported thresholds (Document ID 3574, p. 37).

h. Finnish Nationwide Job Exposure Matrix

OSHA reviewed Pukkala *et al.* (2005, Document ID 0412) in the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment (Document ID 1711, pp. 153–154). As discussed there, Pukkala *et al.* (2005) evaluated the occupational silica exposure among all Finns born between 1906 and 1945 who participated in a national population census on December 31, 1970. Follow-up of the cohort was through 1995. Between 1970 and 1995, there were 30,137 cases of incident lung cancer among men and 3,527 among women. Exposure data from 1972 to 2000 was collected by the Finnish Institute of Occupational Health (FIOH). Cumulative exposure categories for respirable quartz were defined as: <1.0 mg/m^3-yrs (low), 1.0–9.9 mg/m^3-yrs (medium) and >10 mg/m^3-yrs (high). For men, over 18 percent of the 30,137 lung cancer cases worked in occupations with potential exposure to silica dust. The cohort showed statistically significantly increased lung cancer among men in the lowest occupationally exposed group (those with less than 1.0 mg/m^3-yrs cumulative silica exposure), as well as for men with exposures in the two higher groups (1.0–9.9 mg/m^3-yrs and >10 mg/m^3-yrs). For women, the cohort showed statistically significantly increased lung cancer among women with at least 1.0 mg/m^3-yrs cumulative silica exposure. Given these results, it is unclear why ACC stated that Pukkula's results suggest that ''excess risk of lung cancer is mainly attributable to . . . cumulative exposure exceeding 10 mg/m^3-years'' (Document ID 4209, p. 54). Indeed, Pukkula's analysis appears to show excess risk of lung cancer among men with any level of occupational exposure and among women whose cumulative exposures were quite low (at least equivalent to about 25 µg/m^3 over 45 years). It does not support the ACC's contention that lung cancer is seen primarily in workers with exposures greater than 200 µg/m^3 (Document ID 4209, p. 54), but rather suggests that any threshold for lung cancer risk would likely be well below 100 µg/m^3.

i. U.S. National (27 states) Case-Control Study

As discussed in the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment (Document ID 1711, pp. 152–153), Calvert *et al.* (2003, Document ID 3890) conducted a case-control study using 4.8 million death certificates from the National Occupational Mortality Surveillance data set. Death certificates were collected from 27 states covering the period from 1982 to 1995. Cases were persons who had died from any of several diseases of interest: Silicosis, tuberculosis, lung cancer, chronic obstructive pulmonary disease (COPD), gastrointestinal cancers, autoimmune-related diseases, or renal disease. Worker exposure to crystalline silica was categorized as no/low, medium, high, or super-high based on their industry and occupation. The authors acknowledged the potential for confounding by higher smoking rates for cases compared to controls, and partially controlled for this by eliminating white-collar workers from the control group in the analysis. Following this adjustment, the authors reported weak, but statistically significantly elevated, lung cancer mortality odds ratios (OR) of 1.07 (95% CI 1.06–1.09) and 1.08 (95% CI 1.01–1.15) for the high- and super-high exposure groups, respectively (Calvert *et al.*, 2003, Document ID 3890, p. 126). Upon careful review of this study, OSHA maintains its position that it should not be used for quantitative risk analysis (including determination of threshold effects) because it lacks an exposure characterization based on sampling. Any determination regarding the existence or location of a threshold based on Calvert *et al.* (2003) must, therefore, be considered highly speculative.

j. Conclusion—Lung Cancer

In conclusion, OSHA has determined that the best available evidence on the issue of a threshold for silica-related lung cancer does not support the ACC's contention that an exposure-response threshold, below which respirable crystalline silica exposure is not expected to cause cancer, exists at or above the previous general industry PEL of 100 μg/m³. While there are some studies that claim to point to thresholds above the previous general industry PEL, multiple studies contradict this evidence, most convincingly through evidence that cohort members with low cumulative silica exposures suffered from lung cancer as a result of their exposure. These studies indicate that there is either no threshold for silica-related lung cancer, or that this threshold is at such a low level that workers cumulatively exposed at or below the level allowed by the new PEL of 50 μg/m³ will still be at risk of developing lung cancer. Thus, OSHA does not agree with commenters who have stated that the previous general industry PEL is fully protective and that reducing it will yield no health benefits to silica-exposed workers (*e.g.*, Document ID 4224, p. 2–5; Tr. 3582, pp. 1951–1963).

4. Exposure Uncertainty and Thresholds

In his pre-hearing comments, Dr. Cox stated that the observation of a positive and monotonic exposure-response relationship in epidemiological studies ''does not constitute valid evidence against the hypothesis of a threshold,'' and that OSHA's findings of risk at exposures below the previous PEL for general industry ''could be due simply to exposure misclassification'' in studies of silica-related health effects in exposed workers (Document ID 2307, Attachment 4, pp. 41–42). His statements closely followed his analyses from a 2011 paper, in which Cox presented a series of simulation analyses designed to show that common concerns in epidemiological analyses, such as uncontrolled confounding, errors in exposure estimates, and model specification errors, can obscure evidence of an exposure-response threshold, if such a threshold exists (Document ID 3600, Attachment 7). Dr. Cox concluded that the currently available epidemiological studies ''do not provide trustworthy information about the presence or absence of thresholds in exposure-response relations'' with respect to an exposure concentration threshold for lung cancer (Document ID 3600, Attachment 7, p. 1548).

OSHA has reviewed Dr. Cox's comments and testimony, and concludes that uncertainty about risk due to exposure estimation and confounding cannot be resolved through the application of the statistical procedures recommended by Dr. Cox. (Similar comments from Dr. Cox about alleged biases in the studies relied upon are addressed in the next section, where OSHA reaches similar conclusions). A reviewer on the independent peer review panel, Dr. Ginsberg, commented that:

> epidemiology studies will always have issues of exposure misclassification or other types of error that may create uncertainty when it comes to model specification. However, these types of error will also bias correlations to the null such that if they were sufficiently influential to obscure a threshold they may also substantially weaken regression results and underestimate the true risk (Document ID 3574, p. 23).

OSHA agrees with Dr. Ginsberg. As discussed in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis, a ''gold standard'' exposure sample is not available for the epidemiological studies in the silica literature, so it is not possible to determine the direction or magnitude of the effects of exposure misclassification on OSHA's risk estimates. The silica literature is not unique in this sense. As stated by Mr. Robert Park of NIOSH, ''modeling exposure uncertainty as described by Dr. Cox . . . is infeasible in the vast majority of retrospective observational studies. Nevertheless, mainstream scientific thought holds that valid conclusions regarding disease causality can still be drawn from such studies'' (Document ID 4233, p. 32).

For the reasons discussed throughout this analysis of the scientific literature, OSHA concludes that, even acknowledging a variety of uncertainties in the studies relied upon, these uncertainties are, for the most part, typical or inherent in these types of studies. OSHA therefore finds that the weight of evidence in these studies, representing the best available evidence on the health effects of silica exposure, strongly supports the findings of significant risk from silicosis, NMRD, lung cancer, and renal disease discussed in this section and in the quantitative risk assessment that follows in the next section (*see Benzene*, 448 U.S. at 656 (''OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. Although the Agency's findings must be supported by substantial evidence, 29 U.S.C. 655(f), 6(b)(5) specifically allows the Secretary to regulate on the basis of the 'best available evidence.' '')).

5. Conclusion

In summary, OSHA acknowledges that common issues with epidemiological studies limit the Agency's ability to determine whether and where a threshold effect exists for silicosis and lung cancer. However, as shown in the foregoing discussion, there is evidence in the epidemiological literature that workers exposed to silica at concentrations and cumulative levels allowable under the previous general industry PEL not only develop silicosis, but face a risk of silicosis high enough to be significant (>1 per 1,000 exposed workers). Although the evidence is less clear for lung cancer, studies nevertheless show excess cases of lung cancer among workers with cumulative exposures in the range of interest to OSHA. Furthermore, the statistical model-based approaches proposed in public comments do not demonstrate the existence or location of a ''threshold'' level of silica exposure below which silica exposure is harmless to workers. The above considerations lead the Agency to conclude that any possible exposure threshold is likely to be at a low level, such that some workers will continue to suffer the health effects of silica exposure even at the new PEL of 50 μg/m³.

There is a great deal of argument and analysis directed at the question of thresholds in silica exposure-response relationships, but nothing like a scientific consensus about the appropriate approach to the question has emerged. If OSHA were to accept the ACC's claim that exposure to 100 μg/m³ silica is safe for all workers (due to a threshold at or above an exposure concentration of 100 μg/m³) and set a PEL at 100 μg/m³ for all industry sectors, and if that claim is in fact erroneous, the consequences of that error to silica-exposed workers would be grave. A large population of workers would remain at significant risk of serious occupational disease despite feasible options for exposure reduction.

J. Comments and Responses Concerning Biases in Key Studies

OSHA received numerous comments and testimony, particularly from representatives of the ACC, regarding biases in the data that the Agency relied upon to conduct its Preliminary Quantitative Risk Assessment (Preliminary QRA). In this section, OSHA focuses on these comments regarding biases, particularly with respect to how such biases may have affected the data and findings from the

key peer-reviewed, published studies that OSHA relied upon in its Preliminary QRA.

The data utilized by OSHA to conduct its Preliminary QRA came from published studies in the peer-reviewed scientific literature. When developing health standards, OSHA is not required or expected to conduct original research or wait for better data or new studies (*see* 29 U.S.C. 655(b)(5); *e.g., United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1266 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981)). Generally, OSHA bases its determinations of significant risk of material impairment of health on the cumulative evidence found in a number of studies, no one of which may be conclusive by itself (*see Public Citizen Health Research Group* v. *Tyson,* 796 F.2d 1479, 1495 (D.C. Cir. 1986) (reviewing courts do not ''seek a single dispositive study that fully supports the Administrator's determination . . . Rather, [OSHA's] decision may be fully supportable if it is based . . . on the inconclusive but suggestive results of numerous studies.''). OSHA's critical reading and interpretation of scientific studies is thus appropriately guided by the instructions of the Supreme Court's Benzene decision that ''so long as they are supported by a body of reputable scientific thought, OSHA is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection'' (*Industrial Union Dep't* v. *American Petroleum Inst.,* 448 U.S. 607, 656 (1980)).

Since OSHA is not a research agency, it draws from the best available existing data in the scientific literature to conduct its quantitative risk assessments. In most cases, with the exception of certain risk and uncertainty analyses prepared for OSHA by its contractor ToxaChemica, OSHA had no involvement in the data generation or analyses reported in those studies. Thus, in calculating its risk estimates, OSHA used published regression coefficients or equations from key peer-reviewed, published studies, but had no control over the actual published data; nor did the Agency have access to the raw data from such studies.

As discussed throughout Section V of this preamble, the weight of scientific opinion indicates that respirable crystalline silica is a human carcinogen that causes serious, life-threatening disease at the previously-permitted exposure levels. Under its statutory mandate, the Agency can and does take into account the potential for statistical and other biases to skew study results in either direction. However, the potential biases of concern to the commenters are well known among epidemiologists. OSHA therefore believes that the scientists who conduct the studies and subject them to peer review before publication have taken the potential for biases into account in evaluating the quality of the data and analysis. As discussed further below, OSHA heard testimony from David Goldsmith, Ph.D., describing how scientists use ''absolutely the best evidence they can lay their hands on'' and place higher value on studies that are the least confounded by other factors that, if unaccounted for, could contribute to the effect (*e.g.,* lung cancer mortality). (Document ID 3577, Tr. 894–895). Dr. Goldsmith also testified that many of the assertions of biases put forth in the rulemaking docket are speculative in nature, with no actual evidence presented (Document ID 3577, Tr. 901). Thus, while taking seriously the critiques of the ''body of reputable scientific thought'' OSHA has used to support this final silica standard, the Agency finds no reason, as discussed below, to consider discredited in any material way its key conclusions regarding causation or significant risk of harm.

In his pre-hearing comments, Dr. Cox, on behalf of the ACC, claimed that the Preliminary QRA did not address a number of sources of potential bias:

> The Preliminary QRA and the published articles that it relies on do not correct for well-known biases in modeling statistical associations between exposures and response. (These include study, data, and model selection biases; model form specification and model over-fitting biases; biases due to residual confounding, *e.g.,* because age is positively correlated with both cumulative exposure and risk of lung diseases within each age category (typically 5 or more years long); and biases due to the effects of errors in exposure estimates on shifting apparent thresholds to lower concentrations). As a result, OSHA has not demonstrated that there is any non-random association between crystalline silica exposure and adverse health responses (*e.g.,* lung cancer, non-malignant respiratory disease, renal disease) at exposure levels at or below 100 [$\mu g/m^3$]. The reported findings of such an association, *e.g.,* based on significantly elevated relative risks or statistically significant positive regression coefficients for exposed compared to unexposed workers, are based on unverified modeling assumptions and on ignoring uncertainty about those assumptions (Document ID 2307, Attachment 4, pp. 1–2).

These biases, according to Dr. Cox, nearly always result in false positives, i.e., finding that an exposure-response relationship exists when there really is no such relationship (Document ID 3576, Tr. 380). Although his comments appear to be directed to all published, peer-reviewed studies relied upon by OSHA in estimating risks, Dr. Cox admitted at the hearing that his statements about false positives were based on his review of the Preliminary QRA with relation to lung cancer only, and that he ''[didn't] really know'' whether the same allegations of bias he directed at the lung cancer studies are relevant to the studies of silica's other health risks (Document ID 3576, Tr. 426). In his comments, Dr. Cox discussed each source of bias in detail; OSHA will address them in turn. The concerns expressed by commenters, including Dr. Cox, about exposure uncertainty—another potential source of bias—are addressed in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis.

1. Model Specification Bias

Dr. Cox stated that model specification error occurs when the model form, such as the linear absolute risk model, does not correctly describe the data (Document ID 2307, Attachment 4, p. 21). Using a simple linear regression example from Wikipedia, Dr. Cox asserted that common indicators of goodness-of-fit, including sum of square residuals and correlation coefficients, can be weak in identifying ''nonlinearities, outliers, influential single observations, and other violations of modeling assumptions'' (Document ID 2307, Attachment 4, pp. 52–53). He advocated for the use of diagnostic tests to check that a model is a valid and robust choice, stating, ''[u]nfortunately, OSHA's Preliminary QRA and the underlying papers and reports on which it relies are not meticulous in reporting the results of such model diagnostics, as good statistical and epidemiological practice requires'' (Document ID 2307, Attachment 4, p. 21). In his post-hearing brief, Dr. Cox further described these diagnostic tests to include plots of residuals, quantification of the effects of removing outliers and influential observations, and comparisons of alternative model forms using model cross-validation (Document ID 4027, p. 2). He also suggested using Bayesian Model Averaging (BMA) or other model ensemble methods to quantify the effects of model uncertainty (Document ID 4027, p. 3).

OSHA believes that guidelines for which diagnostic procedures should be performed, and whether and how they are reported in published papers, are best determined by the scientific community through the pre-publication peer review process. Many studies in

the silica literature did not report the results of diagnostic tests. For example, the Vacek et al. (2009) study of lung cancer and silicosis mortality, which was submitted to the rulemaking record by the ACC to support its position, made no mention of the results of model diagnostic tests; rather, the authors simply stated that models were fitted by maximum likelihood, with the deviance used to examine model fitting (Document ID 2307, Attachment 6, pp. 11–12). As illustrated by this example, authors of epidemiological studies do not normally report the results of diagnostic tests; nor do such authors publish their raw data. Therefore, there is no data readily available to OSHA with which it could perform the diagnostic analysis that Dr. Cox states is necessary. If the suggestion is that no well-conducted epidemiological study that failed to report a battery of diagnostic tests or disclose what they showed should be relied upon for regulatory purposes, there would be virtually no body of scientific study left for OSHA to consider, raising the legal standard for issuing toxic substance standards far above what the *Benzene* decision requires. Despite this, OSHA maintains that, given the large number of peer-reviewed studies in the published scientific literature on crystalline silica, subjecting each model in each study to diagnostic testing along the lines advocated by Dr. Cox would not fundamentally change the collective conclusions when examining the literature base as a whole. Despite Dr. Cox's criticisms, the scientific literature that OSHA reviewed to draw its conclusions regarding material impairment of health and used in its quantitative risk assessment, constitutes the best available evidence upon which to base this toxic substance standard, in accordance with 29 U.S.C. 655(b) and the *Benzene* decision and subsequent case law.

Dr. Cox's other suggested approach to addressing model uncertainty, BMA, can be used to construct a risk estimate based on multiple exposure-response models. Unlike BMA, standard statistical practice in the epidemiological literature is to evaluate multiple possible models, identify the model that best represents the observations in the data set, and use this model to estimate risk. In some cases, analysts may report the results of two or more models, along with their respective fit statistics and other information to aid model selection for risk assessment and show the sensitivity of the results to modeling choices (*e.g.,* Rice *et al.,* 2001, Document ID 1118). These standard approaches were used in each of the studies relied on by OSHA in its Preliminary QRA.

In contrast, BMA is a probabilistic approach designed to account for uncertainty inherent in the model selection process. The analyst begins with a set of possible models (M_i) and assigns each a prior probability ($Pr[M_i]$) that reflects the analyst's initial belief that model M_i represents the true exposure-response relationship. Next, a data set is used to update the probabilities assigned to the models, generating the posterior probability for each model. Finally, the models are used in combination to derive a risk estimate that is a composite of the risk estimates from each model, weighted by each model's posterior probability (*see* Viallefont *et al.,* 2001, Document ID 3600, Attachment 34, pp. 3216–3217). Thus, BMA combines multiple models, and uses quantitative weights accounting for the analyst's belief about the plausibility of each model, to generate a single weighted-average risk estimate. These aspects of BMA are regarded by some analysts as improvements to the standard approaches to exposure-response modeling.

However, Kyle Steenland, Ph.D., Professor, Department of Environmental Health, Rollins School of Public Health, Emory University, the principal author of a pooled study that OSHA heavily relied upon, noted that BMA is not a standard method for risk assessment. ''[Bayesian] model averaging, to my knowledge, has not been used in risk assessment ever. And so, sure, you could try that. You could try a million things. But I think OSHA has correctly used standard methods to do their risk assessment and [BMA] is not one of those standard methods'' (Document ID 3580, Tr. 1259).

Indeed, BMA is a relatively new method in risk analysis. Because of its novelty, best practices for important steps in BMA, such as defining the class of models to include in the analysis, and choosing prior probabilities, have not been developed. Until best practices for BMA are established, it would be difficult for OSHA to conduct and properly evaluate the quality of BMA analyses. Evaluation of the quality of available analyses is a key step in the Agency's identification of the best available evidence on which to base its significant risk determination and benefits analysis.

OSHA also emphasizes that, as noted by Dr. Steenland, scientifically accepted and standard practices were used to estimate risk from occupational exposure to crystalline silica (Document ID 3580, Tr. 1259). Thus OSHA has decided that it is not necessary to use BMA in its QRA, and that the standard statistical methods used in the studies it relies upon to estimate risk are appropriate as a basis for risk estimation. OSHA notes that it is possible to incorporate risk estimates based on more than one model in its risk assessment by presenting ranges of risk, a strategy often used by OSHA when the best available evidence includes more than one model, analytical approach, or data set. In its Preliminary QRA, OSHA presented ranges of risks for silica-related lung cancer and silicosis based on different data sets and models, thus further lessening the utility of using more complex techniques such as BMA. OSHA continued this practice in its final risk assessment, presented in Section VI, Final Quantitative Risk Assessment and Significance of Risk.

2. Study Selection Bias

Another bias described by Dr. Cox is study selection bias, which he stated occurs when only studies that support a positive exposure-response relationship are included in the risk assessment, and when criteria for the inclusion and exclusion of studies are not clearly specified in advance (Document ID 2307, Attachment 4, pp. 22–23). Dr. Cox noted the criteria used by OSHA to select studies, as described in the Supplemental Literature Review of Epidemiological Studies on Lung Cancer Associated with Exposure to Respirable Crystalline Silica (Supplemental Literature Review) (Document ID 1711, Attachment 1, p. 29). Dr. Cox, however, claimed that OSHA did not apply these criteria consistently, in that there may still be exposure misclassification or confounding present in the studies OSHA relied upon to estimate the risk of the health effects evaluated by the Agency (Document ID 2307, Attachment 4, pp. 24–25). Similarly, the American Foundry Society (AFS), in its post-hearing brief, asserted that, ''No formal process is described for search criteria or study selection'' and that OSHA's approach of identifying studies based upon the IARC (1997) and NIOSH (2002) evaluations of the literature ''is a haphazard approach that is not reproducible and is subject to bias. Moreover it appears to rely primarily on information that is more than 10 years old'' (Document ID 4229, p. 4).

OSHA disagrees with the arguments presented by Dr. Cox and the AFS, as did some commenters. The American Public Health Association (APHA), in its post-hearing brief, expressed strong

support for OSHA's study selection methods. Dr. Georges Benjamin, Executive Director, wrote, ''APHA recognizes that OSHA has thoroughly reviewed and evaluated the peer-reviewed literature on the health effects associated with exposure to respirable crystalline silica. OSHA's quantitative risk assessment is sound. The agency has relied on the best available evidence and acted appropriately in giving greater weight to those studies with the most robust designs and statistical analyses'' (Document ID 2178, Attachment 1, p. 1). Similarly, Dr. Steenland testified that ''OSHA has done a very capable job in conducting the summary of the literature'' (Document ID 3580, Tr. 1235).

In response to the criticisms by Dr. Cox and the AFS, OSHA notes that the silica literature was exhaustively reviewed by IARC in 1997 and NIOSH in 2002 (Document ID 1062; 1110). As a result, there was no need for OSHA to initiate a new review of the historical literature. Instead, OSHA used the IARC and NIOSH reviews as a starting point for its own review. As recognized by the APHA, OSHA evaluated and summarized many of the studies referenced in the IARC and NIOSH reviews, and then performed literature searches to identify new studies published since the time of the IARC and NIOSH reviews. OSHA clearly described this process in its Review of Health Effects Literature: ''OSHA has included in its review all published studies that the Agency deems relevant to assessing the hazards associated with exposure to respirable crystalline silica. These studies were identified from numerous scientific reviews that have been published previously such as the IARC (1997) and NIOSH (2002) evaluations of the scientific literature as well as from literature searches and contact with experts and stakeholders'' (Document ID 1711, p. 8). For its Preliminary QRA, OSHA relied heavily on the IARC pooled exposure-response analyses and risk assessment for lung cancer in 10 cohorts of silica-exposed workers (Steenland *et al.,* 2001a, Document ID 0452) and multi-center study of silicosis mortality (Mannetje *et al.,* 2002b, Document ID 1089). As stated in the Review of Health Effects Literature, these two studies ''relied on all available cohort data from previously published epidemiological studies for which there were adequate quantitative data on worker exposures to crystalline silica to derive pooled estimates of disease risk'' (Document ID 1711, p. 267).

In addition to relying on these two pooled IARC multi-center studies, OSHA also identified single cohort studies with sufficient quantitative information on exposures and disease incidence and mortality rates. As pointed out by Dr. Cox, OSHA described the criteria used for selection of the single cohort studies of lung cancer mortality:

> OSHA gave studies greater weight and consideration if they (1) included a robust number of workers; (2) had adequate length of follow-up; (3) had sufficient power to detect modest increases in lung cancer incidence and mortality; (4) used quantitative exposure data of sufficient quality to avoid exposure misclassification; (5) evaluated exposure-response relationships between exposure to silica and lung cancer; and (6) considered confounding factors including smoking and exposure to other carcinogens (Document ID 1711, Attachment 1, p. 29).

Using these criteria, OSHA identified four single-cohort studies of lung cancer mortality that were suitable for quantitative risk assessment; two of these cohorts (Attfield and Costello, 2004, Document ID 0285; Rice *et al.,* 2001, 1118) were included among the 10 used in the IARC multi-center study and two appeared later (Hughes *et al.,* 2001, Document ID 1060; Miller and MacCalman, 2009, 1306) (Document ID 1711, p. 267). For NMRD mortality, in addition to the IARC multi-center study (Mannetje *et al.*, 2002b, Document ID 1089), OSHA relied on Park *et al.* (2002) (Document ID 0405), who presented an exposure-response analysis of NMRD mortality (including silicosis and other chronic obstructive pulmonary diseases) among diatomaceous earth workers (Document ID 1711, p. 267). For silicosis morbidity, several single-cohort studies with exposure-response analyses were selected (Chen *et al.,* 2005, Document ID 0985; Hnizdo and Sluis-Cremer, 1993, 1052; Steenland and Brown, 1995b, 0451; Miller *et al.,* 1998, 0374; Buchanan *et al.,* 2003, 0306) (Document ID 1711, p. 267).

With respect to Dr. Cox's claim that OSHA did not apply its criteria consistently, on the basis that there may still be exposure misclassification or confounding present, OSHA notes that it selected studies that best addressed the criteria; OSHA did not state that it only selected studies that addressed all of the criteria. Given the fact that some of the epidemiological studies concern exposures of worker populations dating back to the 1930's, there is always some potential for exposure misclassification or the absence of information on smoking. When this was the case, OSHA discussed these limitations in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711). For example, OSHA discussed the lack of smoking information for cases and controls in the Steenland *et al.* (2001a, Document ID 0452) pooled lung cancer analysis (Document ID 1711, pp. 150–151).

With respect to the AFS's claim that OSHA relied on studies that were more than 10 years old, OSHA again notes that it reviewed, in its Review of Health Effects Literature and its Supplemental Literature Review, the studies in the silica literature and selected the ones that best met the criteria described above (Document ID 1711; 1711, Attachment 1). It would be improper to only select the most recent studies, particularly if the older studies are of higher quality based on the criteria. Furthermore, the studies OSHA relied upon in its Preliminary QRA were published between 1993 and 2009; the claim that OSHA primarily relied on older studies is thus misleading, when the studies were of relatively recent vintage and determined to be of high quality based on the criteria described above. The AFS also suggested that OSHA examine several additional foundry studies of lung cancer (Document ID 2379, Attachment 2, p. 24); OSHA retrieved all of these suggested studies, added them to the rulemaking docket following the informal public hearings, and discusses them in Section V.F, Comments and Responses Concerning Lung Cancer Mortality.

3. Data Selection Bias

A related bias presented by Dr. Cox is data selection bias, which he stated occurs when only a subset of the data is used in the analysis ''to guarantee a finding of a positive'' exposure-response relationship (Document ID 2307, Attachment 4, p. 26). He provided an example, the Attfield and Costello (2004, Document ID 0285) study of lung cancer mortality, which excluded data as a result of attenuation observed in the highest exposure group (Document ID 2307, Attachment 4, pp. 26–27). Attenuation of response means the exposure-response relationship leveled off or decreased in the highest exposure group. Referring to another study of the same cohort, Vacek *et al.* (2009, Document ID 2307, Attachment 6; 2011, 1486), Dr. Cox stated, ''OSHA endorses the Attfield and Costello findings, based on dropping cases that do not support the hypothesis of an ER [exposure-response] relation for lung cancer, while rejecting the Vacek *et al.* study that included more complete data (that was not subjected to post hoc subset selection) but that did not find a significant ER [exposure-response]

relation'' (Document ID 2307, Attachment 4, pp. 26–27).

OSHA believes there are very valid reasons for the observance of attenuation of response in the highest exposure group that would justify the exclusion of data in Attfield and Costello (2004, Document ID 0285) and other studies. This issue was discussed by Gary Ginsberg, Ph.D., an OSHA peer reviewer from the Connecticut Department of Public Health, in his post-hearing comments. Dr. Ginsberg noted that several epidemiological studies have found an attenuation of response at higher doses, with possible explanations including: (1) Measurement error, which arises from the fact that the highest doses are associated with the oldest datasets, which are most prone to measurement error; (2) ''intercurrent causes of mortality'' from high dose exposures that result in death to the subject prior to the completion of the long latency period for cancer; and (3) the healthy worker survivor effect, which occurs when workers with ill health leave the workforce early (Document ID 3574, p. 24). As discussed in Section V.F, Comments and Responses Concerning Lung Cancer Mortality, OSHA disagrees strongly with Dr. Cox's assertion that data were excluded to ensure a positive exposure-response relationship (Document ID 2307, Attachment 4, p. 26). In addition, as detailed in Section VI, Final Quantitative Risk Assessment and Significance of Risk, OSHA calculated quantitative risk estimates for lung cancer mortality from several other studies that did not rely on a subset of the data (Rice *et al.,* 2001, Document ID 1118; Hughes *et al.,* 2001, 1060; Miller and MacCalman, 2009, 1306; ToxaChemica, 2004, 0469; 1711, p. 351). These studies also demonstrated positive exposure-response relationships.

4. Model Selection Bias

Another selection bias presented by Dr. Cox is model selection bias, which he said occurs when many different combinations of models, including alternative exposure metrics, different lags, alternative model forms, and different subsets of data, are tried with respect to their ''ability to produce 'significant'-looking regression coefficients'' (Document ID 2307, Attachment 4, p. 27). This is another aspect of model specification error, as discussed above under model averaging. Dr. Cox wrote:

> This type of multiple testing of hypotheses and multiple comparisons of alternative approaches, followed by selection of a final choice based [on] the outcomes of these multiple attempts, completely invalidates the claimed significance levels and confidence intervals reported for the final ER [exposure-response] associations. Trying in multiple ways to find a positive association, and then selecting a combination that succeeds in doing so and reporting it as 'significant,' while leaving the nominal (reported) statistical significance level of the final selection unchanged (typically at p=0.05), is a well-known recipe for producing false-positive associations (Document ID 2307, Attachment 4, p. 28).

Dr. Cox further stated that unless methods of significance level reduction (*i.e.,* reducing the nominal statistical significance level of the final selection) are used, the study is biased towards false-positive results (Document ID 2307, Attachment 4, p. 28).

During the informal public hearings, counsel for the ACC asked Mr. Park of NIOSH's Risk Evaluation Branch about this issue, *i.e.,* trying a number of modeling choices, including exposure metrics, log-transformations, lag periods, and model subsets (Document ID 3579, Tr. 149–150). Mr. Park's reply supports the use of multiple modeling choices in the risk assessment as a form of sensitivity analysis:

> Investigations like this look at a number of options. They come into the study not totally naïve. They, in fact, have some very strong preference even before looking at the data based on prior knowledge. So cumulative exposure, for example, is a generally very high confidence choice in a metric. Trying different lags is interesting. It helps validate the study because you know what it ought to look like sort of. And in many cases, the choice does not make a lot of difference. So it's kind of a robust test, and similarly, the choice of the final model is not just coming in naïve. A linear exposure response has a lot of biological support in many different contexts, but it could be not the best choice (Document ID 3579, Tr. 150–151).

ACC counsel further asked, ''And does one at the end of this process, though, make any adjustment in what you consider to be the statistically significant relationship in light of the fact that you've looked at so many different models and arrangements?'' (Document ID 3579, Tr. 151–152). Mr. Park replied, ''No, I don't think that's a legitimate application of a multiple comparison question'' (Document ID 3579, Tr. 152). OSHA agrees with Mr. Park that significance level reduction is not appropriate in the context of testing model forms for risk estimation, and notes that, in the Agency's experience, significance level reduction is not typically performed in the occupational epidemiology literature. In addition, OSHA notes that, in many of the key studies relied upon by the Agency to estimate quantitative risks, the authors presented the results of multiple models that showed statistically significant exposure-response relationships. For example, Rice *et al.* (2001) presented the results of six model forms, with all except one being significant (Table 1, Document ID 1118, p. 41). Attfield and Costello (2004) presented the results of their model with and without a 15-year lag and log transformation, with many results being significant (Table VII, Document ID 0285, p. 135). Thus, OSHA concludes that model selection bias is not a problem in its quantitative risk assessment.

Furthermore, OSHA disagrees with Dr. Cox's assertion that modeling choices are used to ''produce 'significant'-looking regression coefficients'' (Document ID 2307, Attachment 4, p. 27). OSHA believes that the investigators of the studies it relied upon in its Preliminary, and now final, QRA made knowledgeable modeling choices based upon the exposure distribution and health outcome being examined. For example, in long-term cohort studies, such as those of lung cancer mortality relied upon by OSHA, most authors relied upon cumulative exposure (mg/m^3-yrs or mg/m^3-days), *i.e.,* the concentration of crystalline silica exposure (mg/m^3) multiplied by the duration of exposure (years or days), as an exposure metric. Consistent with standard statistical techniques used in epidemiology, the cumulative exposure metric may then be log-transformed to account for an asymmetric distribution with a long right tail, or attenuation, and the metric may be lagged by several years to account for the long latency period between the exposure and the development of lung cancer. When investigators use subsets of the data, they typically explain the rationale and the effect of using the subset in the analysis. These choices all have important justifications and are not used purely to produce the authors' desired results, as Dr. Cox suggested (Document ID 2307, Attachment 4, p. 27).

5. Model Uncertainty Bias

Related to model selection bias is Dr. Cox's assertion of model uncertainty bias, which he said occurs when many different models are examined and then one is selected on which to base risk calculations; this approach ''treats the finally selected model as if it were known to be correct, for purposes of calculating confidence intervals and significance levels. But, in reality, there remains great uncertainty about what the true causal relation between exposure and response looks like (if there is one)'' (Document ID 2307,

Attachment 4, pp. 28–29). He further stated that ignoring this bias leads to artificially narrow confidence intervals, which bias conclusions towards false-positive findings. He then cited a paper (Piegorsch, 2013, included in Document ID 3600) describing statistical methods for overcoming this bias by ''including multiple possible models in the calculation of results'' (Document ID 2307, Attachment 4, p. 29). OSHA concludes this bias is really an extension of model specification error and model selection bias, previously discussed, and maintains that best practices for model averaging have not yet been established, making it difficult for the Agency to conduct and properly evaluate the quality of BMA analyses.

6. Model Over-Fitting Bias

Next, Dr. Cox discussed model over-fitting bias, which he said occurs when the same data set is used both to fit a model and to assess the fit; this ''leads to biased results: Estimated confidence intervals are too narrow (and hence lower confidence limits on estimated ER [exposure-response] slopes are too high); estimated significance levels are too small (*i.e.,* significance is exaggerated); and estimated measures of goodness-of-fit overstate how well the model fits the data'' (Document ID 2307, Attachment 4, p. 39). He suggested using appropriate statistical methods, such as ''k-fold cross-validation,'' to overcome the bias (Document ID 2307, Attachment 4, p. 39).

OSHA does not agree that using the same data set to fit and assess a model necessarily results in an over-fitting bias. The Agency understands over-fitting to occur when a model is excessively complex relative to the amount of data available such that there are a large number of predictors relative to the total number of observations available. For survival models, it is the number of events, *i.e.,* deaths, that is relevant, rather than the size of the entire sample (Babyak, 2004, included in Document ID 3600, p. 415). If the number of predictors (*e.g.*, exposure, age, gender) is small relative to the number of events, then there should be no bias from over-fitting. In an article cited and submitted to the rulemaking docket by Dr. Cox, Babyak (2004) discussed a simulation study that found, for survival models, an unacceptable bias when there were fewer than 10 to 15 events per independent predictor (included in Document ID 3600, p. 415). In the studies that OSHA relied on in its Preliminary QRA, there were generally a large number of events relative to the small number of predictors. For example, in the Miller and MacCalman (2009) study of British coal miners, in the lung cancer model using both quartz and coal dust exposures, there was a large number of events (973 lung cancer deaths) relative to the few predictors in the model (quartz exposure, coal dust exposure, cohort entry date, smoking habits at entry, cohort effects, and differences in regional background cause-specific rates) (Document ID 1306, pp. 6, 9). Thus, OSHA does not agree the studies it relied upon were substantially influenced by over-fitting bias. OSHA also notes that k-fold cross-validation, as recommended by Dr. Cox, is not typically reported in published occupational epidemiology studies, and that the studies the Agency relied upon in the Preliminary QRA were published in peer-reviewed journals and used statistical techniques typically used in the field of occupational epidemiology and epidemiology generally.

7. Residual Confounding Bias

Dr. Cox also asserted a bias due to residual confounding by age. Bias due to confounding occurs in an epidemiological study, in very general terms, when the effect of an exposure is mixed together with the effect of another variable (*e.g.*, age) not accounted for in the analysis. Residual confounding occurs when additional confounding factors are not considered, control of confounding is not precise enough (*e.g.*, controlling for age by using groups with age spans that are too wide), or subjects are misclassified with respect to confounders (Document ID 3607, p. 1). Dr. Cox stated in his comments that:

> key studies relied on by OSHA, such as Park *et al.* (2002), do not correct for biases in reported ER [exposure-response] relations due to residual confounding by age (within age categories), *i.e.,* the fact that older workers may tend to have both higher lung cancer risks and higher values of occupational exposure metrics, even if one does not cause the other. This can induce a non-causal association between the occupational exposure metrics and the risk of cancer (Document ID 2307, Attachment 4, p. 29).

The Park *et al.* (2002) study of non-malignant respiratory disease mortality, which Dr. Cox cited as not considering residual confounding by age, used 13 five-year age groups (<25, 25–29, 30–34, etc.) in the models (Document ID 0405, p. 37). Regarding this issue in the Park *et al.* (2002) study, in its post-hearing comments, NIOSH stated:

> This is a non-issue. The five-year categorization was used only for deriving the expected numbers of cases as an offset in the Poisson analysis using national rates which typically are classified in five-year intervals (on age and chronological time). The cumulative exposures were calculated with a 10-day resolution over follow-up and then averaged across observation time within 50 cumulative exposure levels cross-classified with the five-year age-chronological time cells of the classification table. There would be virtually no confounding between age and exposure [using this approach] (Document ID 4233, p. 33).

OSHA agrees with this assessment, noting that it appears that age groups were adequately constructed to prevent residual confounding. OSHA thus rejects this assertion of residual confounding by age in the Park *et al.* (2002) study.

8. Summary of Biases

In summary, OSHA received comments and heard testimony on potential biases in the studies upon which it relied for its QRA. The ACC's Dr. Cox, in particular, posited a long list of biases, including model form specification bias, study selection bias, data selection bias, model selection bias, model over-fitting bias, model uncertainty bias, residual confounding bias, and bias as a result of exposure measurement error. OSHA, in this section, has specifically addressed each of these types of bias (except for bias due to exposure estimation error, which is addressed in Section V.K, Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis).

In addition, OSHA heard testimony that countered the claims of biases and their potential to cause false positive results. When asked about the biases alleged by Dr. Cox and Dr. Long, Dr. Goldsmith testified, ''All of these other things, it seems to me, are smoke screens for an inability to want to try and see what the body of evidence really shows'' (Document ID 3577, Tr. 895–896). Later in his testimony, when asked about exposure misclassification, Dr. Goldsmith similarly noted, ''[a]nd for a lot of the arguments that are being put forward by industry, they are speculating that there is the potential for these biases, but they haven't gotten, [from] my perspective, the actual evidence that this is the case'' (Document ID 3577, Tr. 901). Similarly, OSHA has reviewed the record evidence extensively and is not aware of any specific, non-speculative evidence of biases in the studies that it relied upon.

There also is a question of the extent to which Dr. Cox actually reviewed all of the studies that he asserted to be biased. Upon questioning from Anne Ryder, Attorney in the Office of the Solicitor, Department of Labor, Dr. Cox admitted that he had not examined the

issue of silica and silicosis, and that his statements about false positives were based on his review of the Preliminary QRA with relation to lung cancer only:

MS. RYDER: . . . You talked a little bit earlier about the false positives that are . . . present with a lot of the studies on lung cancer. And, but I believe, in your comment you didn't say that there are any of those same false positives with studies dealing with silicosis and silica exposure. Is that correct?

DR. COX: I don't think I opined on that. So—and I really haven't looked carefully at the question. I do take it as given that silica at sufficiently high and prolonged exposures causes silicosis. I've not really examined that literature.

MS. RYDER: So you don't think that those studies have the same issues that some of the lung cancer studies have?

DR. COX: I don't really know (Document ID 3576, Tr. 426).

Dr. Cox further testified, regarding the likelihood that the conclusions of the Preliminary QRA for silicosis are correct, ''I expect that the evidence is much stronger for silica and silicosis. But I haven't reviewed it, so I can't testify to it'' (Document ID 3576, Tr. 427).

OSHA believes this testimony to be inconsistent with some of the broad conclusions in Dr. Cox's pre-hearing written submission to the rulemaking record, in which he claimed that all adverse outcomes in the Preliminary QRA may have been affected by false positives. Dr. Cox concluded in this submission that:

These multiple uncontrolled sources of false-positive bias can generate findings of statistically ''significant'' positive ER [exposure-response] associations even in random data, or in data for which there is no true causal relation between exposure and risk of adverse health responses. Because OSHA's Preliminary QRA and the studies on which it relies did not apply appropriate technical methods (which are readily available, as discussed in the references) to diagnose, avoid, or correct for these sources of false-positive conclusions, the reported findings of ''significantly'' positive ER [exposure-response] associations between crystalline silica exposures at and below the current PEL and adverse outcomes (lung cancer, non-malignant lung disease, renal disease) are not different from what might be expected in the absence of any true ER [exposure-response] relations. They therefore provide no evidence for (or against) the hypothesis that a true ER [exposure-response] relation exists. Thus, OSHA has not established that a non-random association exists between crystalline silica exposures at or below the current PEL and the adverse health effects on which it bases its determination of significant risk and calculates supposed health effect benefits (Document ID 2307, Attachment 4, pp. 29–30).

OSHA notes that ''non-malignant lung disease'' includes silicosis, studies of which Dr. Cox subsequently testified that he did not examine.

In conclusion, the studies relied upon by OSHA for its risk assessment were peer-reviewed and used methods for epidemiology and risk assessment that are commonly used. Dr. Cox provided no study-specific evidence (*e.g.*, data re-analysis) to support his comments that the studies OSHA relied upon were adversely affected by numerous different types of bias. As described above, OSHA recognizes that there are uncertainties associated with the results of the studies relied on for its risk assessment, as is typically the case for epidemiological studies such as these. Nevertheless, as previously stated, OSHA maintains that it has used a body of peer-reviewed scientific literature that, as a whole, constitutes the best available evidence of the relationship between respirable crystalline silica exposure and silicosis, lung cancer, and the other health effects studied by the Agency in promulgating this final rule.

K. Comments and Responses Concerning Exposure Estimation Error and ToxaChemica's Uncertainty Analysis

Exposure estimation error, a typical feature of epidemiological studies, occurs when the authors of an exposure-response study construct estimates of the study subjects' exposures using uncertain or incomplete exposure data. Prior to the publication of its Preliminary Quantitative Risk Assessment (Preliminary QRA), the Agency commissioned an uncertainty analysis conducted by Drs. Kyle Steenland and Scott Bartell, through its contractor, ToxaChemica, Inc., to address exposure estimation error in OSHA's risk assessment, and incorporated the results into the Preliminary QRA. After reviewing comments submitted to the record on the topic of exposure estimation error, OSHA maintains that it has relied upon the best available evidence by: (1) Using high-quality exposure-response studies and modeling approaches; (2) performing an uncertainty analysis of the effect of exposure estimation error on the risk assessment results; and (3) further submitting that analysis to peer review. OSHA concludes from its uncertainty analysis that exposure estimation error did not substantially affect the results in the majority of studies examined (Document ID 1711, pp. 299–314).

Furthermore, having carefully considered the public comments criticizing ToxaChemica's uncertainty analysis, OSHA has concluded that it was not necessary to conduct additional analyses to modify the approach adopted by Drs. Steenland and Bartell in the uncertainty analysis. Nor was it necessary to incorporate additional sources of uncertainty in the analysis. Also, given the evidence in the rulemaking record that these estimation errors bias results towards underestimating rather than overestimating the risks from exposure in many circumstances, it is very unlikely that regression coefficients and risk estimates from all of the different studies relied on in the Preliminary QRA were biased upward. Accordingly, OSHA remains convinced that the conclusions of the Agency's risk assessment are correct and largely unaffected by potential error in exposure measurement.

OSHA received significant comments on the topic of exposure estimation error in the studies it relied on in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711). A number of commenters discussed the importance of accounting for exposure estimation error. Dr. Cox, representing the ACC, described exposure estimation error as perhaps the ''most quantitatively important'' issue in the studies OSHA relied upon (Document ID 2307, Attachment 4, p. 40). Similarly, Christopher M. Long, Sc.D., Principal Scientist at Gradient, representing the U.S. Chamber of Commerce (Chamber), testified that exposure measurement error is a ''common source of uncertainty in most occupational and environmental epidemiologic studies'' (Document ID 3576, Tr. 298). According to Dr. Long, this type of error can lead to inaccurate risk estimates by creating error in the exposure-response curve derived from a data set and obscuring the presence of a threshold (Document ID 3576, Tr. 300; *see* Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases, for further discussion on thresholds). Dr. Long further stated that exposure measurement error can lead to over- or under-estimation of risk: ''the impact of exposure measurement error . . . can bias either high or low. It can bias towards the null. It can be a source of positive bias.'' (Document ID 3576, Tr. 358–359). A bias to the null in an exposure-response model used in a quantitative risk assessment is an underestimation of the relationship between exposure level and the rate of the disease or health effect of interest, and results in underestimation of risk.

OSHA agrees with the assessments of the ACC and the Chamber with respect to the importance of exposure

measurement error. Indeed, OSHA peer reviewer, Dr. Gary Ginsberg, in his peer review comments (Document ID 3574, p. 21), and OSHA's risk assessment contractor, Dr. Steenland, in his hearing testimony (Document ID 3580, Tr. 1266–1267), noted the potential for exposure measurement error to bias exposure-response coefficients towards the null. Dr. Steenland explained: ''misclassification I would say in general tends to bias things to the null. It's harder to see positive exposure-response trends in the face of misclassification. It depends partly on the type of error. . . . But, on the whole, I would say that exposure measurement tends to bias things down rather than up'' (Document ID 3580, Tr. 1266–1267). Fewell *et al.*, the authors of a paper on residual confounding submitted by the ACC, wrote, ''It is well recognized that under certain conditions, nondifferential measurement error in the exposure variable produces bias towards the null'' (2007, Document ID 3606, p. 646).

Several commenters representing the ACC challenged the methods used in ToxaChemica's uncertainty analysis on the grounds that the analysis failed to adequately address exposure estimation error. In spite of their criticisms, critics were unable to supply better studies than those OSHA used. Indeed, when asked during the hearing, Dr. Long was unable to identify any studies that the Agency could use that acceptably account for the impact of exposure measurement error on exposure-response associations for crystalline silica (Document ID 3576, Tr. 356–357), and none was supplied following the hearings.

Taking into account the record evidence discussed above, OSHA concludes that it is possible for exposure measurement error to lead to either over- or under-estimation of risk and that this issue of exposure measurement error is not specific to the silica literature. It further concludes that industry representatives could not identify, and failed to submit, any published epidemiological studies of occupational disease that corrected for such bias to their satisfaction (Document ID 3576, Tr. 356–357).

Nevertheless, because OSHA agreed that an analysis of exposure estimation error as a source of uncertainty is important, it commissioned the uncertainty analysis discussed above to explore the potential effects of exposure measurement error on the conclusions of OSHA's risk assessment (Document ID 0469). The analysis examined the potential effects of exposure measurement error on the mortality risk estimates derived from the pooled studies of lung cancer (Steenland *et al.* 2001a, Document ID 0452) and silicosis (Mannetje 2002b, Document ID 1089). This included the effects of estimation error on the detection and location of a possible threshold effect in exposure-response models.

The uncertainty analysis OSHA commissioned from Drs. Steenland and Bartell (2004, Document ID 0469) addressed possible error in silica exposure estimates from: (1) Random error in individual workers' exposure estimates and (2) error in the conversion of dust measurements (typically particle count concentrations) to gravimetric respirable silica concentrations, which could have affected estimates of average exposure for job categories in the job-exposure matrices used to estimate workers' silica exposure. To address possible error in individual workers' exposure estimates, the analysts performed a Monte Carlo analysis, a type of simulation analysis which varies the values of an uncertain input to an analysis (in this case, exposure estimates) to explore the effects of different values on the outcome of the analysis. The Monte Carlo analysis sampled new values for workers' job-specific exposure levels from distributions they believed characterized the exposures of individual workers in each job. In each run of the Monte Carlo analysis, the sampled exposure values were used to calculate new estimates of each worker's cumulative exposures, and the resulting set was used to fit a new exposure-response model.

Similarly, the analysts performed a Monte Carlo analysis to address the issue of uncertainty in conversion from dust to respirable silica exposure, sampling new conversion factors from a normal distribution with means equal to the original conversion factor, calculating new estimates of workers' cumulative exposures, and re-fitting the exposure-response model for each Monte Carlo run. To examine the sensitivity of the model to the joint effects of both error types, the analysts ran 50 Monte Carlo simulations using the sampling procedure for both individual exposures and job-specific conversion factors. They also examined the effects of systematic bias in conversion factors, considering that these may have been consistently under-estimated or over-estimated for any given cohort. They addressed possible biases in either direction, conducting 20 simulations where the true silica content was assumed to be either half or double the estimated silica content of measured exposures.

The results of their analysis indicated that the conclusions of the pooled lung cancer study conducted previously by Steenland *et al.* (Document ID 0452) and included in OSHA's Preliminary QRA were unlikely to be affected by the types of exposure estimation error examined by Drs. Steenland and Bartell, whose analysis of the underlying data was itself reviewed by OSHA's peer review panel. As explained below, after reviewing comments critical of the uncertainty analysis, OSHA reaffirms its conclusion that workers exposed to silica at the previous PELs are at significant risk of disease from their exposure.

Drs. Long and Valberg, representing the Chamber, commented that Drs. Steenland and Bartell's uncertainty analysis did not address all potential sources of error and variability in exposure measurement, such as possible instrument error; possible sampling error; random variability in exposure levels; variability in exposure levels resulting from changes in worker job functions during work shifts, production process changes, or control system changes; variability in sampler type used; variability in laboratory methods for determining sampling results and laboratory errors; variability in duration of exposure sampling; variability in sampling locations; variability in reasons for sample data collection (*e.g.*, compliance sampling, periodic sampling, random survey sampling); variability in type of samples collected (*e.g.*, bulk samples, respirable dust samples); variation among workers and over time in the size distribution, surface area, recency of fracture, and other characteristics of the particles inhaled; and extrapolation of exposure sampling data to time periods for which sampling data are not available (Document ID 2330, pp. 4–5). OSHA notes that these sources of potential error and variability are common in occupational exposure estimation, and are sources of uncertainty in most epidemiological studies, a point with which Drs. Valberg and Long agree (Document ID 2330, p. 14).

OSHA has determined that its reliance on the best available evidence provided it with a solid, scientifically sound foundation from which to conclude that exposure to crystalline silica poses a significant risk of harm, notwithstanding the various uncertainties inherent in epidemiology generally or potentially affecting any given study and that no studies exist entirely free from the types of data limitations or error and variability Drs. Valberg and Long identified. During the public hearing Dr. Long acknowledged

that OSHA had not overlooked studies that he believed adequately addressed the sources of error cited in his comments. He was also unable to provide examples of such analyses in the silica literature, or in any other area of occupational epidemiology (Document ID 3576, Tr. 355–358; *see also* Document ID 3577, Tr. 641, 648 (testimony of Dr. Kenneth Mundt)). Additionally, Drs. Valberg and Long's critique of Drs. Steenland and Bartell's uncertainty analysis ignores constraints on the available data and reasonable limits on the analysts' ability to investigate the full variety of possible errors and their potential effects on OSHA's risk assessment.

OSHA additionally notes that Dr. Kenneth Crump, an OSHA peer reviewer, in his examination of ToxaChemica's (Document ID 0469) study of exposure uncertainty in the Steenland *et al.* pooled study, opined that it was sound. He further observed that the ''analysis of error conducted by [ToxaChemica] is a very strong effort. The assumptions are clearly described and the data upon [which] they are based appear to be appropriate and appropriately applied.'' Dr. Crump was careful to note, however, that ''there are questions, as there will always be with such an analysis . . . A major source of error that apparently was not accounted for is in assuming that the average measure of exposure assigned to a job is the true average'' (Document ID 3574, pp. 161–162). Dr. Cox referenced Dr. Crump's comment in his own pre-hearing comments, in the context of a discussion on the importance of exposure uncertainty in OSHA's risk analysis (Document ID 2307, p. 40). OSHA addressed this particular criticism in the Review of Health Effects Literature and Preliminary QRA. There, it stated that it is possible that some job exposure estimates were above or below the true average for a job; however, there was no ''gold standard'' measurement available to appropriately test or adjust for this potential source of error (Document ID 1711, p. xv). The Agency further stated that the uncertainty, or sensitivity, analysis included potential error in job averages, and found that most cohorts in the lung cancer and silicosis mortality pooled studies were not highly sensitive to random or systematic error in job-average exposure estimates (Document ID 1711, pp. 303–314). In his final evaluation of OSHA's response to his comments of 2009, Dr. Crump stated, ''I believe that my comments have been fairly taken into account in the current draft and I have no further comments to make'' (Document ID 3574, p. 17).

Similarly, Dr. Morfeld, representing the ACC, criticized Drs. Steenland and Bartell for performing only 50 simulations of workplace exposures as part of the uncertainty analysis (Document ID 2307, Attachment 2, p. 10). Peer reviewer Mr. Bruce Allen also remarked that this type of uncertainty analysis typically requires more than 50 simulations (Document ID 3574, p. 114). However, as stated by OSHA in the response to peer review section of the Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 379–400), the results did not appear to change much with an increased number of simulations. Thus, OSHA has concluded that the sensitivity findings would not have changed substantially by running more simulations. Indeed, in the final peer review report conveying his evaluation of OSHA's response to his comments of 2009, Mr. Allen stated that OSHA adequately addressed his comments in the updated risk assessment (Document ID 3574, p. 5).

The overall salient conclusion that OSHA draws from this peer-reviewed analysis is that even in those cohorts where exposure error had some impact on exposure-response models for lung cancer or silicosis, the resulting risk estimates at the previous and new PELs remain clearly significant. Therefore, OSHA continues to rely on, and have confidence in, the risk analysis it had performed. In particular, OSHA concludes that Drs. Steenland and Bartell's modeling choices were based on the best available data from a variety of industrial sources and, through their uncertainty analysis, reached conclusions that survive the ACC and Chamber criticisms of the study methodology. OSHA further concludes that it is not necessary to conduct additional analysis to modify the approach adopted by Drs. Steenland and Bartell or to incorporate additional sources of exposure estimation uncertainty in the analysis.

OSHA also disagrees with other specific criticisms that Drs. Long and Valberg made concerning the uncertainty analysis. Dr. Long testified that ''there are no formal analyses conducted to determine the error structures of the three sources of exposure measurement error included in the sensitivity analyses; for example, without any formal analysis, the OSHA assessment simply assumed a purely Berkson type error structure from the assignment of job-specific average exposure levels for individual exposures'' (Document ID 3576, 304–305).[9] Dr. Cox expressed a similar concern that

> OSHA has not developed an appropriate error model specifically for the exposure estimates in the crystalline silica studies and has not validated (*e.g.*, using a validation subset) that any of the ad hoc error models that they discuss describes the real exposure estimate errors of concern. They have also provided no justification for ToxaChemica's assumption of a log-normal distribution without outliers or mixtures of different distributions . . . and have provided no rationale for the assumption that a=0.8*p (Document ID 2307, Attachment 4, p. 45).

OSHA disagrees with Dr. Long's and Dr. Cox's characterizations, which implies that Drs. Steenland and Bartell did not adequately investigate the patterns of error in the data available to them. As noted in their 2004 report and by Dr. Steenland during the public hearings, ToxaChemica did not have the internal validation data (true exposures for a subset of the data set) that would be required to conduct formal analyses or validation of the error structure within each cohort of the pooled analysis (Document ID 0469, p. 16; 3580, pp. 1229–1231). Such data are not often available to analysts. However, Drs. Steenland and Bartell researched and reviewed worker exposure and dust composition data from several worksites to inform the error structures used in their analyses. For example, their analysis of individual workers' exposure data from the pooled analyses' industrial sand cohort formed the basis of the equation used for the exposure error simulation, which Dr. Cox represented as an assumption lacking any rationale. Drs. Steenland and Bartell also reviewed a number of studies characterizing the distribution of conversion factors across and within jobs at different worksites. OSHA concludes that Drs. Steenland and Bartell made a strong effort to collect data to inform their modeling choices, and that their choices were based on the

[9] The first component of ToxaChemica's analysis takes the exposure level for each job in the job-exposure matrix as the mean exposure level for workers in that job, with error (that results from using the mean to estimate each individual worker's exposure) varying randomly around the mean (Document ID 0469, P. 10). The second type of error examined by ToxaChemica, resulting from the assignment of a single conversion factor to represent quartz percentage in dust samples for multiple jobs, similarly might be expected to vary randomly around a mean equal to the recorded conversion factor. Errors resulting from the assignment of job-specific mean exposures (or conversion factors) to individual workers or jobs results in a type of error known as Berkson error, in which the true exposure level is assumed to vary randomly around the assigned or ''observed'' exposure level for the job (Snedecor and Cochran, 1989).

best available information on error structure.

Dr. Long stated that ''another limitation of the [ToxaChemica uncertainty] assessment was its assumption of log-linear . . . types of models, including log linear models with log-transformed exposure variables, and it focused on cumulative measures of silica exposure that obscure both within-person and between-person variability in exposure rates'' (Document ID 3576 pp. 305–306). Dr. Long's assertion regarding the choice of exposure models is incorrect, as the sensitivity analysis was not limited to log-linear models. It included models with flexibility to capture nonlinearities in exposure-response, including spline analyses and categorical analyses, and log-transformation of the exposure variable was used only in the lung cancer analysis where it was shown in the original pooled analysis to better fit the data and address issues of heterogeneity between cohorts (Document ID 0469). Drs. Steenland and Bartell found only slight differences between the adjusted exposure-response estimates for each type of model.

Drs. Long and Valberg also contended that the cumulative exposure metric used in the Steenland and Bartell pooled study did not sufficiently allow for examination of the effects of exposure measurement uncertainty on the results of OSHA's risk assessment, because other exposure metrics could be more relevant. OSHA disagrees. As discussed in Section V.M, Comments and Responses Concerning Working Life, Life Tables, and Dose Metric, cumulative exposure is widely acknowledged by health experts as a driver of chronic diseases such as silicosis and lung cancer, has been found to fit the exposure-response data well in many studies of silicosis and lung cancer in the silica literature, and best fit the exposure-response data in the underlying pooled data sets to which Drs. Steenland and Bartell applied their subsequent uncertainty analyses. Thus, OSHA believes it was appropriate for this investigation of exposure estimation error to focus on the cumulative exposure metric, for reasons including data fit and general scientific understanding of this disease.

Furthermore, Dr. Long's concern that the choice of cumulative silica exposure might ''obscure within-person variability in exposure rates'' is not well supported in the context of lung cancer and silicosis mortality. Because death from these diseases typically occurs many years after the exposure that caused it, and complete records of past exposures do not typically exist, it is very difficult, using any metric, to trace within-person exposure variability (that is, changes in a person's exposure over time); these factors, not the choice of cumulative exposure metric, make it difficult to address variability in individuals' exposures over time and their effects on risk. OSHA notes that some analysts have explored the use of other exposure metrics in threshold analyses, submitting studies to the record which the Agency has reviewed and discussed in Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases.

Dr. Long also testified that ''[t]here's very little discussion in the OSHA report regarding the potential impacts of exposure measurement error on identification of thresholds . . . [ToxaChemica's 2004 report] noted that exposure-response threshold estimates are imprecise and appear to be highly sensitive to measurement errors'' (Document ID 3576 p. 306). Dr. Cox further noted that exposure misclassification can ''create the appearance of a smooth, monotonically increasing estimated ER [exposure-response] relation'' and shift thresholds to the left (Document ID 2307, Attachment 4, pp. 41–42); that is, create the appearance that a threshold effect occurs at a lower exposure level than would be seen in a data set without exposure misclassification.

In their uncertainty analysis, Drs. Steenland and Bartell estimated an exposure-response threshold for the pooled cohorts in each of the 50 runs conducted for their lung cancer analysis. They defined the ''threshold'' as the highest cumulative exposure for which the estimated odds ratio was less than or equal to 1.0, reporting a mean value of 3.04 mg/m^3-days and median of 33.5 mg/m^3-days across the 50 runs (Document ID 0469, p. 15). The authors observed that ''[t]hese estimates are somewhat lower than the original estimate (Steenland and Deddens 2002) of a threshold at 121 mg/m^3-days (4.8 on the log scale), which translates to about 0.01 mg/m^3 [10 μg/m^3] over a working 30-year lifetime (considering a 15-year lag), or 0.007 [7μg/m^3] over a 45-year lifetime without considering a 15-year lag'' (Document ID 0469, p. 15). These exposure levels are about one-fifth the PEL of 50 μg/m^3 included in the final standard.

As noted by Dr. Long, the threshold estimates were highly variable across the 50 iterations (SD of 1.64 on the log scale), in keeping with other comments received by OSHA that estimates of exposure-response thresholds based on epidemiological data tend to be highly sensitive to sources of measurement error and other issues common to epidemiological investigations (see Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases). However, the Agency notes that the results of the uncertainty analysis, suggesting a possible cumulative exposure threshold at approximately one-fifth the final 50 μg/m^3 PEL, provide no cause to doubt OSHA's determination that significant risk exists at both the previous and the revised PEL.

An additional concern raised by Dr. Cox was based on his misunderstanding that the equation used to characterize the relationship between true and observed exposure in Drs. Steenland and Bartell's simulation, ''Exposuretrue = Exposureobserved + E'', concerned cumulative exposure. Dr. Cox stated that the equation is ''inappropriate for cumulative exposures [because] both the mean and the variance of actual cumulative exposure received typically increase in direct proportion to duration'' (Document ID 2307, Attachment 4, p. 45). That is, the longer period of time over which a cumulative exposure is acquired, the higher variance is likely to be, because cumulative exposure is the sum of the randomly varying exposures received on different days. However, the exposures referred to in the equation are the mean job-specific concentrations recorded in the job-exposure matrix (Exposureobserved) and individuals' actual exposure concentrations from each job worked (Exposuretrue), not their cumulative exposures (Document ID 0469, p. 11). Therefore, Dr. Cox's criticism is unfounded.

Dr. Cox additionally criticized the simulation analysis on the basis that ''[t]he usual starting point for inhalation exposures [is] with the random number of particles inhaled per breath modeled as a time-varying (non-homogenous) Poisson process . . . It is unclear why ToxaChemica decided to assume (and why OSHA accepted the assumption) of an underdispersed distribution . . . rather than assuming a Poisson distribution'' (Document ID 2307, Attachment 4, pp. 45–46). OSHA believes this criticism also reflects a misunderstanding of Drs. Steenland and Bartell's analysis. While it could be pertinent to an analysis of workers' silica dose (the amount of silica that enters the body), the analysis addresses the concentration of silica in the air near a worker's breathing zone, not internal dose. The worker's airborne concentration is the regulated exposure endpoint and the exposure of interest for OSHA's risk assessment. Thus, the uncertainty analysis does not need to

account for the number of particles inhaled per breath.

More broadly, Dr. Cox asserted that the Monte Carlo analysis ''is an inappropriate tool for analyzing the effects of exposure measurement error on estimated exposure-response data,'' citing a paper by Gryparis *et al.* (2009) (Document ID 2307, Attachment 4, p. 44). This paper indicates that by randomly simulating exposure measurement error, the Monte Carlo approach can introduce classical error (Document ID 3870, p. 262). Peer reviewer Dr. Noah Seixas similarly commented that ''[t]he typical Monte Carlo simulation, which is what appears to have been done, would introduce classical error,'' that is, error which is independent of the unobserved variable (in this case, the true exposure value). He explained that, as a result, ''the estimated risks [from the simulation analyses] are most likely to be underestimates, or conservatively estimating risk. This is an important aspect of measurement error with significant implications for risk assessment and should not be overlooked.'' (Document ID 3574, pp. 116–117). Addressing Dr. Cox's broader point, Dr. Seixas in his peer review stated that the ''simulation of exposure measurement error in assessing the degree of bias that may have been present is a reasonable approach to assessing this source of uncertainty'' (Document ID 3574, pp. 116). Dr. Crump similarly characterized the uncertainty analysis used in the Steenland and Bartell study as ''a strong effort'' that ''appropriately applied'' this method (Document ID 3574, pp. 161–162). In this regard, OSHA generally notes that the advantages and limitations of various methods to address exposure measurement error in exposure-response models is an area of ongoing investigation in risk assessment. As shown by the comments of OSHA's peer reviewers above, there is no scientific consensus to support Dr. Cox's opinion that the Monte Carlo analysis is an inappropriate approach to analyze the effects of exposure measurement error.

In conclusion, through use of high quality studies and modeling, performance of an uncertainty analysis, and submission of the results of that analysis to peer review, OSHA maintains that it has relied upon the best available evidence. In addition, OSHA has carefully considered the public comments criticizing ToxaChemica's uncertainty analysis and has concluded that exposure estimation error did not substantially affect the results in the majority of studies examined (Document ID 1711, pp. 299–314). As a result, it was not necessary to conduct additional analyses modifying the approach adopted by Drs. Steenland and Bartell. Accordingly, OSHA reaffirms its determination that the conclusions of the Agency's risk assessment are correct and largely unaffected by potential error in exposure measurement.

L. Comments and Responses Concerning Causation

As discussed in Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA, OSHA finds, based upon the best available evidence in the published, peer-reviewed scientific literature, that exposure to respirable crystalline silica increases the risk of silicosis, lung cancer, other non-malignant respiratory disease (NMRD), and renal and autoimmune effects. Exposure to respirable crystalline silica causes silicosis and is the only known cause of silicosis. For other health endpoints like lung cancer that have both occupational and non-occupational sources of exposure, OSHA used a comprehensive weight-of-evidence approach to evaluate the published, peer-reviewed scientific studies in the literature to determine their overall quality and whether there is substantial evidence that exposure to respirable crystalline silica increases the risk of a particular health effect. For example, with respect to lung cancer, OSHA reviewed 60 epidemiological studies covering more than 30 occupational groups in over a dozen industrial sectors and concluded that exposure to respirable crystalline silica increases the risk of lung cancer (Document ID 1711, pp. 77–170). This conclusion is consistent with that of the World Health Organization's International Agency for Research on Cancer (IARC), HHS' National Toxicology Program (NTP), the National Institute for Occupational Safety and Health (NIOSH), and many other organizations and individuals, as evidenced in the rulemaking record and discussed throughout this section.

In spite of this, and in addition to asserting that OSHA's Preliminary QRA was affected by many biases, Dr. Cox, on behalf of the ACC, argued that OSHA failed to conduct statistical analyses of causation, which led to inaccurate conclusions about causation. He specifically challenged OSHA's reliance upon the IARC determination of carcinogenicity, as discussed in Section V.F, Comments and Responses Concerning Lung Cancer Mortality, and its use of the criteria for evaluating causality developed by the noted epidemiologist Bradford Hill (Document ID 2307, Attachment 4, pp. 13–14; 4027, p. 28). The Hill criteria are nine aspects of an association that should be considered when examining causation: (1) The strength of the association; (2) the consistency of the association; (3) the specificity of the association; (4) the temporal relationship of the association; (5) the biological gradient (*i.e.*, dose-response curve); (6) the biological plausibility of the association; (7) coherency; (8) experimentation; and (9) analogy (Document ID 3948, pp. 295–299).

Instead, Dr. Cox suggested that OSHA use the methods listed in Table 1 of his 2013 paper, ''Improving causal inferences in risk analysis,'' which he described as ''the most useful study designs and methods for valid causal analysis and modeling of causal exposure-response (CER) relations'' (Document ID 2307, Attachment 4, p. 11). Because OSHA did not use these methods, Dr. Cox maintained that the Agency's Preliminary QRA ''asserts causal conclusions based on non-causal studies, data, and analyses'' (Document ID 2307, Attachment 4, p. 3). He also contended that OSHA ''ha[d] conflated *association* and *causation*, ignoring the fact that modeling choices can create findings of statistical associations that do not predict correctly the changes in health effects (if any) that would be caused by changes in exposures'' (Document ID 2307, Attachment 4, p. 3). He claimed that ''[t]his lapse all by itself invalidates the Preliminary QRA's predictions and conclusions'' (Document ID 2307, Attachment 4, p. 3). As discussed below, since OSHA's methodology and conclusions regarding causation are based on the best available evidence, they are sound. Consequently, Dr. Cox's contrary position is unpersuasive.

1. IARC Determination

Dr. Cox asserted that OSHA erred in its reliance on the IARC determination of carcinogenicity for crystalline silica inhaled in the forms of quartz or cristobalite. He believed OSHA only relied on the IARC findings because they aligned with the Agency's opinion, noting that the ''IARC analysis involved some of the same researchers, same methodological flaws, and same gaps in explicit, well-documented derivations of benefits and conclusions as OSHA's own preliminary QRA'' (Document ID 2307, Attachment 4, pp. 13–14). OSHA, however, relied on IARC's determination to include lung cancer in its quantitative risk assessment because it constitutes the best available evidence. For this reason, Dr. Cox's position is without merit and OSHA's

findings are supported by substantial evidence in the record and reasonable.

As discussed in Section V.F, Comments and Responses Concerning Lung Cancer Mortality, the IARC classifications and accompanying monographs are well recognized in the scientific community, and have been described by scientists as ''the most comprehensive and respected collection of systematically evaluated agents in the field of cancer epidemiology'' (Demetriou *et al.*, 2012, Document ID 4131, p. 1273). IARC's conclusions resulted from a thorough expert committee review of the peer-reviewed scientific literature, in which crystalline silica dust, in the form of quartz or cristobalite, was classified as Group 1, ''carcinogenic to humans,'' in 1997 (Document ID 2258, Attachment 8, p. 210). Since the publication of these conclusions, the scientific community has reaffirmed their soundness. In March of 2009, 27 scientists from eight countries participated in an additional IARC review of the scientific literature and reaffirmed that crystalline silica dust is a Group 1 carcinogen, *i.e.*, ''carcinogenic to humans'' (Document ID 1473, p. 396). Additionally, the HHS' U.S. National Toxicology Program also concluded that respirable crystalline silica is a known human carcinogen (Document ID 1164, p. 1).

Further supporting OSHA's reliance on IARC's determination of carcinogenicity for its quantitative risk assessment is testimony offered by scientists during the informal public hearings. This testimony highlighted IARC's carcinogenicity determinations as very thorough examinations of the scientific literature that demonstrate that exposure to respirable crystalline silica causes lung cancer. For example, when asked about Dr. Cox's causation claims during the informal public hearings, David Goldsmith, Ph.D., noted that causation was very carefully examined by IARC. He believed that IARC, in its 1997 evaluation of evidence for cancer and silica, ''. . . chose . . . the best six studies that were the least confounded for inability to control for smoking or other kinds of hazardous exposures like radiation and asbestos and arsenic . . .'' (Document ID 3577, Tr. 894–896). He also believed it ''. . . crucial . . . that we pay attention to those kinds of studies, that we pay attention to the kinds of studies that were looked at by the IARC cohort that Steenland did from 2001. That's where they had the best evidence'' (Document ID 3577, Tr. 894–896).

Regarding IARC's evaluation of possible biases and confounders in epidemiological studies, as well as its overall determination, Frank Mirer, Ph.D., of CUNY School of Public Health, representing the AFL–CIO, testified:

> IARC has active practicing scientists review—I've been on two IARC monographs, but not these monographs, monograph working groups. It's been dealt with. It's been dealt with over a week of intense discussion between the scientists who are on these committees, as to whether there's chance bias in confounding which might have led to these results, and by 1987 for foundries and 1997 for silica, and it's been decided and reaffirmed.
>
> So people who don't believe it are deniers, pure and simple. This is the scientific consensus. I was on the NTP Board of Scientific Counselors when we reviewed the same data. Known to be a human carcinogen. Once you know it's a human carcinogen from studies in humans, you can calculate risk rates (Document ID 3578, Tr. 937).

That OSHA relied on the best available evidence to draw its conclusions was also affirmed by Dr. Cox's inability to provide additional studies that would have cast doubt on the Agency's causal analysis. Indeed, during the informal public hearings, Kenneth Crump, Ph.D., an OSHA peer reviewer from the Louisiana Tech University Foundation, asked Dr. Cox if he could identify ''any causal studies of silica that they [OSHA] should have used but did not use?'' Dr. Cox responded: ''I think OSHA could look at a paper from around 2007 of Brown's, on some of the issues and causal analysis, but I think the crystalline silica area has been behind other particulate matter areas . . . in not using causal analysis methods. So no, I can't point to a good study that they should have included but didn't'' (Document ID 3576, Tr. 401–402). In light of the above, OSHA maintains that in relying on IARC's determination of carcinogenicity, its conclusions on causation are rooted in the best available evidence.

2. Bradford Hill Criteria and Causality

Dr. Cox also challenged OSHA's use of Hill's criteria for causation. He claimed that the Bradford Hill considerations were neither necessary nor sufficient for establishing causation, which was his reason for failing to include them in the statistical methods listed in Table 1 of his written comments for objectively establishing evidence about causation (Document ID 4027, p. 28). As explained below, based on its review of the record, OSHA finds this position meritless, as it is unsupported by the best available evidence.

As a preliminary matter, Hill's criteria for causation (Document ID 3948) are generally accepted as a gold standard for causation in the scientific community. Indeed, OSHA heard testimony during the informal public hearings and received post-hearing comments indicating that Dr. Cox's assertion that statistical methods should be used to establish causality is not consistent with common scientific practice. For example, Andrew Salmon, Ph.D., an OSHA peer reviewer, wrote:

> The identification of causality as opposed to statistical association is, as described by Bradford Hill in his well-known criteria, based mainly on non-statistical considerations such as consistence, temporality and mechanistic plausibility: the role of statistics is mostly limited to establishing that there is in fact a quantitatively credible association to which causality may (or may not) be ascribed. OSHA correctly cites the substantial body of evidence supporting the association and causality for silicosis and lung cancer following silica exposure, and also quotes previous expert reviews (such as IARC). The causal nature of these associations has already been established beyond any reasonable doubt, and OSHA's analysis sufficiently reflects this (Document ID 3574, p. 38).

Similarly, Kyle Steenland, Ph.D., Professor, Department of Environmental Health, Rollins School of Public Health, Emory University, in response to a question about Dr. Cox's testimony on causation from Darius Sivin, Ph.D., of the UAW Health and Safety Department, stated that the Bradford Hill criteria are met for lung cancer and silicosis:

> [M]ost of the Bradford Hill criteria apply here. You know you can never prove causality. But when the evidence builds up to such an extent and you have 100 studies and they tend to be fairly consistent, that's when we draw a causal conclusion. And that was the case for cigarette smoke in lung cancer. That was the case for asbestos in lung cancer. And when the evidence builds up to a certain point, you say, yeah, it's a reasonable assumption that this thing causes, X causes Y (Document ID 3580, pp. 1243–1244).

As a follow-up, OSHA asked if Dr. Steenland felt that the Bradford Hill criteria were met for silica health endpoints. Dr. Steenland replied, ''For silicosis or for lung cancer. I had said they're met for both'' (Document ID 3580, p. 1262).

Gary Ginsberg, Ph.D., an OSHA peer reviewer, agreed with Dr. Steenland, remarking to Dr. Cox during questioning, ''I'm a little dumbfounded about the concern over causality, given all the animal evidence'' (Document ID 3576, Tr. 406). Mr. Park from NIOSH's Risk Evaluation Branch, in his question to Dr. Cox, echoed the sentiments of Dr. Ginsberg, stating:

It's ludicrous to hear someone question causality. There's 100 years of research in occupational medicine, in exposure assessment. People here even in industry would agree that silica they say causes silicosis, which causes lung cancer. There's some debate about whether the middle step is required. There's no question that there's excess lung cancer in silica-exposed populations. We look at literature, and we identify what we call good studies. Good studies are ones that look at confounding, asbestos, whatever. We make judgments. If there's data that allows one to control for confounding, that's part of the analysis. If there is confounding that we can't control for, we evaluate it. We ask how bad could it be? There's a lot of empirical judgment from people who know these populations, know these exposures, know these industries, who can make very good judgments about that. We aren't stupid. So I don't know where you're coming from (Document ID 3576, Tr. 410–411).

Indeed, Kenneth Mundt, Ph.D., testifying on behalf of the International Diatomite Producers Association (part of the ACC Crystalline Silica Panel, which included Dr. Cox), and whose research study was the basis for the Morfeld *et al.* (2013, Document ID 3843) paper that reportedly identified a high exposure threshold for silicosis, also appeared to disagree with Dr. Cox's view of causation. Dr. Mundt testified that while he thought he could appreciate Dr. Cox's testimony, at some point there is sufficiently accumulated evidence of a causal association; he concluded, ''I think here, over time, we've had the advantage with the reduction of exposure to see reduction in disease, which I think just makes it a home run that the diseases are caused by, therefore can be prevented by appropriate intervention'' (Document ID 3577, Tr. 639–640).

OSHA notes that Dr. Cox, upon further questioning by Mr. Park, appeared to concede that exposure to respirable crystalline silica causes silicosis; Dr. Cox stated, ''I do not question that at sufficiently high exposures, there are real effects'' (Document ID 3576, Tr. 412). Later, when questioned by Anne Ryder, an attorney in the Solicitor of Labor's office, he made a similar statement: ''I do take it as given that silica at sufficiently high and prolonged exposures causes silicosis'' (Document ID 3576, Tr. 426). Based upon this testimony of Dr. Cox acknowledging that silica exposure causes silicosis, OSHA interprets his concern with respect to silicosis to be not one of causation, but rather a concern with whether there is a silicosis threshold (*i.e.*, that exposure to crystalline silica must generally be above some level in order for silicosis to occur). Indeed, OSHA peer reviewer Brian Miller, Ph.D., noted in his post-hearing comments that Dr. Cox, when challenged, accepted that silica was causal for silicosis, ''but questioned whether there was evidence for increased risks at low concentrations; *i.e.* whether there was a threshold'' (Document ID 3574, p. 31). Thresholds for silicosis are addressed in great detail in Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases.

Based on the testimony and written comments of numerous scientists representing both public health and industry—all of whom agree that causation is established by applying the Bradford Hill criteria and examining the totality of the evidence—OSHA strongly disagrees with Dr. Cox's claims that the Bradford Hill criteria are inadequate to evaluate causation in epidemiology and that additional statistical techniques are needed to establish causation. OSHA defends its reliance on the IARC determination of 1997 and re-determination of 2012 that crystalline silica is a causal agent for lung cancer. OSHA's own Review of Health Effects Literature further demonstrates the totality of the evidence supporting the causality determination (Document ID 1711). Indeed, other than Dr. Cox representing the ACC, no other individual or entity questioned causation with respect to silicosis. Even Dr. Cox's questioning of causation for silicosis appears to be more of a question about thresholds, which is discussed in Section V.I, Comments and Responses Concerning Thresholds for Silica-Related Diseases.

3. Dr. Cox's Proposed Statistical Methods

OSHA reviewed the statistical methods provided by Dr. Cox in Table 1 of his 2013 paper, ''Improving causal inferences in risk analysis,'' (Document ID 2307, Attachment 4, p. 11), and explains below why the Agency did not adopt them. For example, Intervention Time Series Analysis (ITSA), as proposed by Dr. Cox in his Table 1, is a method for assessing the impact of an intervention or shock on the trend of outcomes of interest (Gilmour *et al.*, 2006, cited in Document ID 2307, Attachment 4, p. 11). Implementing ITSA requires time series data before and after the intervention for both the dependent variable (*e.g.*, disease outcome) and independent variables (*e.g.*, silica exposure and other predictors), as well as the point of occurrence of the intervention. Although time-series data are frequently available in epidemiological studies, for silica we do not have a specific ''intervention point'' comparable to the implementation of a new OSHA standard that can be identified and analyzed. Rather, changes in exposure controls tend to be iterative and piecemeal, gradually bringing workers' exposures down over the course of a facility's history and affecting job-specific exposures differently at different points in time. Furthermore, individual workers' exposures change continually with new job assignments and employment. In addition, in a situation where the intervention really reduces the adverse outcome to a low level, such as 1/1000 lifetime excess risk, ITSA would require an enormous observational database in order to be able to estimate the actual post-intervention level of risk. OSHA believes the standard risk analysis approach of estimating an exposure-response relationship based on workers' exposures over time and using this model to predict the effects of a new standard on risk appropriately reflects the typical pattern of multiple and gradual changes in the workers' exposures over time found in most industrial facilities.

Another method listed in Dr. Cox's Table 1, marginal structural models (MSM), was introduced in the late 1990s (Robins, 1998, cited in Document ID 2307, Attachment 4, p. 11) to address issues that can arise in standard modeling approaches when time-varying exposure and/or time-dependent confounders are present.[10] These methods are actively being explored in the epidemiological literature, but have not yet become a standard method in occupational epidemiology. As such, OSHA faces some of the same issues with MSM as were previously noted with BMA: Published, peer-reviewed studies using this approach are not available for the silica literature, and best practices are not yet well established. Thus, the incorporation of MSM in the silica risk assessment is not possible using the currently available literature and would be premature for OSHA's risk assessment generally.

In addition, in his post-hearing brief, Dr. Cox contended that ''[a] well-done QRA should explicitly address the causal fraction (and explain the value used), rather than tacitly assuming that it is 1'' (Document ID 4027, p. 4). However, this claim is without grounds. OSHA understands Dr. Cox's reference to the ''causal fraction'' to mean that,

[10] A time-dependent confounder is a covariate whose post-baseline value is a risk factor for both the subsequent exposure and the outcome.

when estimating risk from an exposure-response model, only a fraction of the total estimated risk should be attributed to disease caused by the occupational exposure of interest. The Agency notes that the ''causal fraction'' of risk is typically addressed through the use of life table analyses, which incorporate background rates for the disease in question. Such analyses, which OSHA used in its Preliminary QRA, calculate the excess risk, over and above background risk, that is solely attributable to the exposure in question. Thus, there is no need to estimate a causal fraction due to exposure. These approaches are further discussed in Section V.M, Comments and Responses Concerning Working Life, Life Tables, and Dose Metric. Furthermore, nowhere in the silica epidemiological literature has the use of an alternative ''causal fraction'' approach to ascribing the causal relationship between silica exposure and silicosis and lung cancer been deemed necessary to reliably estimate risk.

4. The Assertion That the Silica Scientific Literature May Be False

Dr. Cox also asserted that the same biases and issues with causation in OSHA's Quantitative Risk Assessment (QRA) were likewise present in the silica literature. He wrote, ''In general, the statistical methods and causal inferences described in this literature are no more credible or sound than those in OSHA's Preliminary QRA, and for the same reasons'' (Document ID 2307, Attachment 4, p. 30).

The rulemaking record contains evidence that contradicts Dr. Cox's claims with respect to the scientific foundation of the QRA. Such evidence includes scientific testimony and the findings of many expert bodies, including IARC, the HHS National Toxicology Program, and NIOSH, concluding that exposure to respirable crystalline silica causes lung cancer. At the public hearing, Dr. Steenland, Professor at Emory University, testified that the body of evidence pertaining to silica was of equal quality to that of other occupational health hazards (Document ID 3580, pp. 1245–1246). Dr. Goldsmith similarly testified:

> Silica dust . . . is like asbestos and cigarette smoking in that exposure clearly increases the risk of many diseases. There have been literally thousands of research studies on exposure to crystalline silica in the past 30 years. Almost every study tells the occupational research community that workers need better protection to prevent severe chronic respiratory diseases, including lung cancer and other diseases in the future. What OSHA is proposing to do in revising the workplace standard for silica seems to be a rational response to the accumulation of published evidence (Document ID 3577, Tr. 865–866).

OSHA agrees with these experts, whose positive view of the science supporting the need for better protection from silica exposures stands in contrast to Dr. Cox's claim regarding what he believes to be the problematic nature of the silica literature. Dr. Cox asserted in his written statement:

> Scientists with subject matter expertise in areas such as crystalline silica health effects epidemiology are not necessarily or usually also experts in causal analysis and valid causal interpretation of data, and their causal conclusions are often mistaken, with a pronounced bias toward declaring and publishing findings of 'significant' effects where none actually exists (false positives). This has led some commentators to worry that 'science is failing us,' due largely to widely publicized but false beliefs about causation (Lehrer, 2012); and that, in recent times, 'Most published research findings are wrong' (Ioannadis, 2005), with the most sensational and publicized claims being most likely to be wrong. (Document ID 2307, Attachment 4, pp. 15–16).

Moreover, during the public hearing, Dr. Cox stated that, with respect to lung cancer in the context of crystalline silica, the literature base may be false:

> MR. PERRY [OSHA Director of the Directorate of Standards and Guidance]: So as I understand it, you basically think there's a good possibility that the entire literature base, with respect to lung cancer now, I'm talking about, is wrong?
>
> DR. COX: You mean with respect to lung cancer in the context of crystalline silica?
>
> MR. PERRY: Yes, sir.
>
> DR. COX: I think that consistent with the findings of Lauer [Lehrer] and Ioannidis and others, I think that it's very possible and plausible that there is a consistent pattern of false positives in the literature base, yes. And that implies, yes, they are wrong. False positives are false (Document ID 3576, Tr. 423).

The Ioannidis paper (Document ID 3851) used mathematical constructs to purportedly demonstrate that most claimed research findings are false, and then provided suggestions for improvement (Document ID 3851, p. 0696). Two of his suggestions appear particularly relevant to the silica literature: ''Better powered evidence, *e.g.*, large studies or low-bias meta-analyses, may help, as it comes closer to the unknown 'gold' standard. However, large studies may still have biases and these should be acknowledged and avoided''; and ''second, most research questions are addressed by many teams, and it is misleading to emphasize the statistically significant findings of any single team. What matters is the totality of the evidence'' (Document ID 3851, pp. 0700–0701). OSHA finds no merit in the claim that most claimed research findings are false. Instead, it finds that the silica literature for lung cancer is overall trustworthy, particularly because the ''totality of the evidence'' characterized by large studies demonstrates a causal relationship between crystalline silica exposure and lung cancer, as IARC determined in 1997 and 2012 (Document ID 2258, Attachment 8, p. 210; 1473, p. 396).

OSHA likewise notes that there was disagreement on Ioannidis' methods and conclusions. Jonathan D. Wren of the University of Oklahoma, in a correspondence to the journal that published the paper, noted that Ioannidis, ''after all, relies heavily on other studies to support his premise, so if most (*i.e.*, greater than 50%) of his cited studies are themselves false (including the eight of 37 that pertain to his own work), then his argument is automatically on shaky ground'' (Document ID 4087, p. 1193). In addition, Steven Goodman of Johns Hopkins School of Medicine and Sander Greenland of the University of California, Los Angeles, performed a substantive mathematical review (Document ID 4081) of the Ioannidis models and concluded in their correspondence to the same journal that ''the claims that the model employed in this paper constitutes 'proof' that most published medical research claims are false, and that research in 'hot' areas is most likely to be false, are unfounded'' (Document ID 4095, p. 0773).

Christiana A. Demetriou, Imperial College London, *et al.* (2012), analyzed this issue of potential false positive associations in the field of cancer epidemiology (Document ID 4131). They examined the scientific literature for 509 agents classified by IARC as Group 3, ''not classifiable as to its carcinogenicity to humans'' (Document ID 4131). Of the 509 agents, 37 had potential false positive associations in the studies reviewed by IARC; this represented an overall frequency of potential false positive associations between 0.03 and 0.10 (Document ID 4131). Regarding this overall false positive frequency of about 10 percent, the authors concluded, ''In terms of public health care decisions, given that the production of evidence is historical, public health care professionals are not expected to react immediately to a single positive association. Instead, they are likely to wait for further support or enough evidence to reach a consensus, and if a hypothesis is repeatedly tested, then any initial false-positive results will be quickly undermined'' (Document ID 4131, p. 1277). The

authors also cautioned that ''Reasons for criticisms that are most common in studies with false-positive findings can also underestimate an association and in terms of public health care, false-negative results may be a more important problem than false-positives'' (Document ID 4131, pp. 1278–1279). Thus, this study suggested that the false positive frequency in published literature is actually rather low, and stressed the importance of considering the totality of the literature, rather than a single study.

Given these responses to Ioannidis, OSHA fundamentally rejects the claim that most published research findings are false. The Agency concludes that, most likely, where, as here, there are multiple, statistically significant positive findings of an association between silica and lung cancer made by different researchers in independent studies looking at distinct cohorts, the chances that there is a consistent pattern of false positives are small; OSHA's mandate is met when the weight of the evidence in the body of science constituting the best available evidence supports such a conclusion.

M. Comments and Responses Concerning Working Life, Life Tables, and Dose Metric

As discussed in Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA, OSHA presented risk estimates associated with exposure over a working lifetime to 25, 50, 100, 250, and 500 μg/m^3 respirable crystalline silica (corresponding to cumulative exposures over 45 years to 1.125, 2.25, 4.5, 11.25, and 22.5 mg/m^3-yrs). For mortality from silica-related disease (*i.e.*, lung cancer, silicosis and non-malignant respiratory disease (NMRD), and renal disease), OSHA estimated lifetime risks using a life table analysis that accounted for background and competing causes of death. The mortality risk estimates were presented as excess risk per 1,000 workers for exposures over an 8-hour working day, 250 days per year, and a 45-year working lifetime. This is a legal standard that OSHA typically uses in health standards to satisfy the statutory mandate to ''set the standard which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' 29 U.S.C. 655(b)(5). For silicosis morbidity, OSHA based its risk estimates on cumulative risk models used by various investigators to develop quantitative exposure-response relationships. These models characterized the risk of developing silicosis (as detected by chest radiography) up to the time that cohort members (including both active and retired workers) were last examined. Thus, risk estimates derived from these studies represent less-than-lifetime risks of developing radiographic silicosis. OSHA did not attempt to estimate lifetime risk (*i.e.*, up to age 85) for silicosis morbidity because the relationships between age, time, and disease onset post-exposure have not been well characterized.

OSHA received critical comments from representatives of the ACC and the Chamber. These commenters expressed concern that (1) the working lifetime exposure of 45 years was not realistic for workers, (2) the use of life tables was improper and alternative methods should be used, and (3) the cumulative exposure metric does not consider the exposure intensity and possible resulting dose-rate effects. OSHA examines these comments in detail in this section, and shows why they do not alter its conclusion that the best available evidence in the rulemaking record fully supports the Agency's use of a 45-year working life in a life table analysis with cumulative exposure as the exposure metric of concern.

1. Working Life

The Chamber commented that 45-year career silica exposures do not exist in today's working world, particularly in ''short term work-site industries'' such as construction and energy production (Document ID 4194, p. 11; 2288, p. 11). The Chamber stated that careers in these jobs are closer to 6 years, pointing out that OSHA's contractor, ERG, estimated a 64 percent annual turnover rate in the construction industry. Referring to Section 6(b)(5) of the Occupational Safety and Health (OSH) Act of 1970, the Chamber concluded, ''OSHA improperly inflates risk estimates with its false 45-year policy, contradicting the Act, which requires standards based on actual, 'working life' exposures—not dated hypotheticals'' (Document ID 4194, pp. 11–12; 2288, pp. 11–12).

As stated previously, OSHA believes that the 45-year exposure estimate satisfies its statutory obligation to evaluate risks from exposure over a working life, and notes that the Agency has historically based its significance-of-risk determinations on a 45-year working life from age 20 to age 65 in each of its substance-specific rulemakings conducted since 1980. The Agency's use of a 45-year working life in risk assessment has also been upheld by the DC Circuit (*Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1264–65 (D.C. Cir. 1988)) (*also see* Section II, Pertinent Legal Authority). Even if most workers are not exposed for such a long period, some will be, and OSHA is legally obligated to set a standard that protects those workers to the extent such standard is feasible. For reasons explained throughout this preamble, OSHA has set the PEL for this standard at 50 μg/m^3 TWA. In setting the PEL, the Agency reasoned that while this level does not eliminate all risk from 45 years of exposures for each employee, it is the lowest level feasible for most operations.

In addition, OSHA heard testimony and received several comments with accompanying data that support a 45-year working life in affected industries. For example, six worker representatives of the International Union of Bricklayers and Allied Craftworkers (BAC), which represents a portion of the unionized masonry construction industry (Document ID 4053, p. 2), raised their hands in the affirmative when asked if they had colleagues who worked for longer than 40 years in their trade (Document ID 3585, Tr. 3053). Following the hearings, BAC reviewed its International Pension Fund and counted 116 members who had worked in the industry for 40 years or longer. It noted that this figure was likely an understatement, as many workers had previous experience in the industry prior to being represented by BAC, and many BAC affiliates did not begin participation in the Fund until approximately a decade after its establishment in 1972 (Document ID 4053, p. 2).

OSHA heard similar testimony from representatives of other labor groups and unions. Appearing with the Laborers' Health and Safety Fund of North America (LHSFNA), Eddie Mallon, a long-time member of the New York City tunnel workers' local union, testified that he had worked in the tunnel business for 50 years, mainly on underground construction projects (Document ID 3589, Tr. 4209). Appearing with the United Steelworkers, Allen Harville, of the Newport News Shipbuilding Facility and Drydock, testified that there are workers at his shipyard with more than 50 years of experience. He also believed that 15 to 20 percent of workers had 20 to 40 years of experience (Document ID 3584, Tr. 2571).

In addition, several union representatives appearing with the Building and Construction Trades Department (BCTD) of the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) also

commented on the working life exposure estimate. Deven Johnson, of the Operative Plasterers' and Cement Masons' International Association, testified that he thought 45 years was relevant, as many members of his union had received gold cards for 50 and 60 years of membership; he also noted that there was a 75-year member in his own local union (Document ID 3581, Tr. 1625–1626). Similarly, Sarah Coyne, representing the International Union of Painters and Allied Trades, testified that 45 years was adequate, as ''we have many, many members who continue to work out in the field with the 45 years'' (Document ID 3581, Tr. 1626). Charles Austin, of the International Association of Sheet Metal, Air, Rail and Transportation Workers, added that thousands of workers in the union's dust screening program have been in the field for 20 to 30 years (Document ID 3581, Tr. 1628–1629).

In its post-hearing comment, the BCTD submitted evidence on behalf of the United Association of Plumbers, Fitters, Welders and HVAC Service Techs, which represents a portion of the workers in the construction industry. A review of membership records for this association revealed 35,649 active members with 45 years or more of service as a member of the union. Laurie Shadrick, Safety and Health National Coordinator for the United Association, indicated that this membership figure is considered an underestimate, as many members had previous work experience in the construction industry prior to joining the union, or were not tracked by the union after transitioning to other construction trades (Document ID 4073, Attachment 1b). The post-hearing comment of the BCTD also indicated a trend of an aging workforce in the construction industry, with workers 65 years of age and older predicted to increase from 5 percent in 2012 to 8.3 percent in 2022 (Document ID 4073, Attachment 1a, p. 1). This age increase is likely due to the fact that few construction workers have a defined benefit pension plan, and the age for collecting Social Security retirement benefits has been increasing; as a result, many construction workers are staying employed for longer in the industry (Document ID 4073, Attachment 1a, p. 1). Thus, the BCTD expressed its support for using a 45-year working life in the construction industry for risk assessment purposes (Document ID 4073, Attachment 1a, p. 1).

In addition to BAC and BCTD, OSHA received post-hearing comments on the 45-year working life from the International Union of Operating Engineers (IUOE) and the American Federation of State, County and Municipal Employees (AFSCME). The IUOE reviewed records of the Central Pension Fund, in which IUOE construction and stationary local unions participate, and determined that the average years of service amongst all retirees (75,877 participants) was 21.34 years, with a maximum of 49.93 years of active service. Of these retirees, 15,836 participants recorded over 30 years of service, and 1,957 participants recorded over 40 years of service (Document ID 4025, pp. 6–7). The IUOE also pointed to the testimony of Anthony Bodway, Special Projects Manager at Payne & Dolan, Inc. and appearing with the National Asphalt Pavement Association (NAPA), who indicated that some workers in his company's milling division had been with the company anywhere from 35 to 40 years (Document ID 3583, Tr. 2227, 2228). Similarly, the AFSCME reported that, according to its 2011 poll, 49 percent of its membership had over 10 years of experience, and 21 percent had over 20 years (Document ID 3760, p. 2).

The rulemaking record on this topic of the working life thus factually refutes the Chamber's assertion that ''no such 45-year career silica exposures exist in today's working world, particularly in construction, energy production, and other short term work-site industries'' (Document ID 4194, p. 11; 2288, p. 11). Instead, OSHA concludes that the rulemaking record demonstrates that the Agency's use of a 45-year working life as a basis for estimating risk is legally justified and factually appropriate.

2. Life Tables

Dr. Cox, on behalf of the ACC, commented that OSHA should use ''modern methods,'' such as Bayesian competing-risks analyses, expectation-maximization (EM) methods, and copula-based approaches that account for subdistributions and interdependencies among competing risks (Document ID 2307, Attachment 4, p. 61). Such methods, according to Dr. Cox, are needed ''[t]o obtain risk estimates . . . that have some resemblance to reality, and that overcome known biases in the naïve life table method used by OSHA'' (Document ID 2307, Attachment 4, p. 61). Dr. Cox then asserted that the life table method used in the following studies to estimate mortality risks is also incorrect: Steenland *et al.* (2001a, Document ID 0452), Rice *et al.* (2001, Document ID 1118), and Attfield and Costello (2004, Document ID 0285) (Document ID 2307, Attachment 4, pp. 61–63).

OSHA does not agree that the life table method it used to estimate mortality risks is incorrect or inappropriate. Indeed, the Agency's life table approach is a standard method commonly used to estimate the quantitative risks of mortality. As pointed out by Rice et al. (2001), the life table method was developed by the National Research Council's BEIR IV Committee on the Biological Effects of Ionizing Radiations (BEIR), Board of Radiation Effects Research, in its 1988 publication on radon (Document ID 1118, p. 40). OSHA notes that the National Research Council is the operating arm of the National Academy of Sciences and the National Academy of Engineering, and is highly respected in the scientific community. As further described by Rice *et al.,* an ''advantage of this [actuarial] method is that it accounts for competing causes of death which act to remove a fraction of the population each year from the risk of death from lung cancer so that it is not necessary to assume that all workers would survive these competing causes to a given age'' (Document ID 1118, p. 40). Because this life table method is generally accepted in the scientific community and has been used in a variety of peer-reviewed, published journal articles, including some of the key studies relied upon by the Agency in its Preliminary QRA (*e.g.,* Rice *et al.,* 2001, Document ID 1118, p. 40; Park *et al.,* 2002, 0405, p. 38), OSHA believes it is appropriate here.

Regarding the alternative methods proposed by Dr. Cox, OSHA believes that these methods are not widely used in the occupational epidemiology community. In addition, OSHA notes that Dr. Cox did not provide any alternate risk estimates to support the use of his proposed alternative methods, despite the fact that the Agency made its life table data available in the Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 360–378). Thus, for these reasons, OSHA disagrees with Dr. Cox's claim that the life table method used by the Agency to estimate quantitative risks was inappropriate.

3. Exposure Metric

In its risk assessment, OSHA uses cumulative exposure, i.e., average exposure concentration multiplied by duration of exposure, as the exposure metric to quantify exposure-response relationships. It uses this metric because each of the key epidemiological studies on which the Agency relied to estimate risks used cumulative exposure as the exposure metric to quantify exposure-response relationships, although some

also reported significant relationships based on exposure intensity (Document ID 1711, p. 342). As noted in the Review of Health Effects Literature, the majority of studies for lung cancer and silicosis morbidity and mortality have consistently found significant positive relationships between risk and cumulative exposure (Document ID 1711, p. 343). For example, nine of the ten epidemiological studies included in the pooled analysis by Steenland et al. (2001a, Document ID 0452) showed positive exposure coefficients when exposure was expressed as cumulative exposure (Document ID 1711, p. 343).

Commenting on this exposure metric, the ACC argued that cumulative exposure undervalues the role of exposure intensity, as some studies of silicosis have indicated a dose-rate effect, *i.e.,* short-term exposure to high concentrations results in greater risk than longer-term exposure to lower concentrations at an equivalent cumulative exposure level (Document ID 4209, p. 58; 2307, Attachment A, pp. 93–94). The ACC added that, given that silica-related lung cancer and silicosis may both involve an inflammation-mediated mechanism, a dose-rate effect would also be expected for lung cancer (Document ID 4209, p. 58). It concluded that ''assessments of risk based solely on cumulative exposure do not account adequately for the role played by intensity of exposure and, accordingly, do not yield reliable estimates of risk'' (Document ID 4209, p. 68). Patrick Hessel, Ph.D., representing the Chamber, pointed to the initial comments of OSHA peer reviewer Kenneth Crump, Ph.D., who stated that ''[n]ot accounting for a dose-rate effect, if one exists, could overestimate risk at lower concentrations'' (Document ID 4016, p. 2, citing 1716, pp. 165–167).

OSHA acknowledges these concerns regarding the exposure metric and finds them to have some merit. However, it notes that the best available studies use cumulative exposure as the exposure metric, as in common in occupational epidemiological studies. As discussed below, there is also substantial good evidence in the record supporting the use of cumulative exposure as the exposure metric for crystalline silica risk assessment.

Paul Schulte, Ph.D., of NIOSH testified that ''cumulative exposure is a standard and appropriate metric for irreversible effects that occur soon after actual exposure is experienced. For lung cancer and nonmalignant respiratory disease, NMRD mortality, cumulative exposure lagged for cancer is fully justified . . . For silicosis risk assessment purposes, cumulative exposure is a reasonable and practical choice'' (Document ID 3579, Tr. 127). NIOSH also conducted a simulated dose rate analysis for silicosis incidence with data from a Chinese tin miners cohort and, in comparing exposure metrics, concluded that the best fit to the data was cumulative exposure with no dose-rate effect (Document ID 4233, pp. 36–39). This finding is consistent with the testimony of Dr. Steenland, who stated, ''Cumulative exposure, I might say, is often the best predictor of chronic disease in general, in epidemiology'' (Document ID 3580, Tr. 1227). OSHA also notes that using a cumulative exposure metric (*e.g.,* mg/m^3-yrs) factors in both exposure intensity and duration, while using only an exposure intensity metric (*e.g.,* µg/m^3) ignores the influence of exposure duration. Dr. Crump's comment that ''[e]stimating risk based on an 'incomplete' exposure metric like average exposure is not recommended . . . . [E]xposure to a particular air concentration for one week is unlikely to carry the same risk as exposure to that concentration for 20 years, although the average exposures are the same'' also supports the use of a cumulative exposure metric (Document ID 1716, p. 166).

With regard to a possible dose-rate effect, OSHA agrees with Dr. Crump that if one exists and is unaccounted for, the result could be an overestimation of risks at lower concentrations (Document ID 1716, pp. 165–167). OSHA is aware of two studies discussed in its Review of Health Effects Literature and Preliminary QRA that examined dose-rate effects on silicosis exposure-response (Document ID 1711, pp. 342–344). Neither study found a dose-rate effect relative to cumulative exposure at silica concentrations near the previous OSHA PEL (Document ID 1711, pp. 342–344). However, they did observe a dose-rate effect in instances where workers were exposed to crystalline silica concentrations far above the previous PEL (*i.e.*, several-fold to orders of magnitude above 100 µg/m^3) (Buchanan *et al.*, 2003, Document ID 0306; Hughes *et al.,* 1998, 1059). For example, the Hughes *et al.* (1998) study of diatomaceous earth workers found that the relationship between cumulative silica exposure and risk of silicosis was steeper for workers hired prior to 1950 and exposed to average concentrations above 500 µg/m^3 compared to workers hired after 1950 and exposed to lower average concentrations (Document ID 1059). Similarly, the Buchanan *et al.* (2003) study of Scottish coal miners adjusted the cumulative exposure metric in the risk model to account for the effects of exposures to high concentrations where the investigators found that, at concentrations above 2000 µg/m^3, the risk of silicosis was about three times higher than the risk associated with exposure to lower concentrations but at the same cumulative exposure (Document ID 0306, p. 162). OSHA concluded that there is little evidence that a dose-rate effect exists at concentrations in the range of the previous PEL (100 µg/m^3) (Document ID 1711, p. 344). However, at the suggestion of Dr. Crump, OSHA used the model from the Buchanan *et al.* study in its silicosis morbidity risk assessment to account for possible dose-rate effects at high average concentrations (Document ID 1711, pp. 335–342). OSHA notes that the risk estimates in the exposure range of interest (25–500 µg/m^3) derived from the Buchanan *et al.* (2003) study were not appreciably different from those derived from the other studies of silicosis morbidity (see Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1.).

In its post-hearing brief, NIOSH also added that a ''detailed examination of dose rate would require extensive and real time exposure history which does not exist for silica (or almost any other agent)'' (Document ID 4233, p. 36). Similarly, Dr. Crump wrote, ''Having noted that there is evidence for a dose-rate effect for silicosis, it may be difficult to account for it quantitatively. The data are likely to be limited by uncertainty in exposures at earlier times, which were likely to be higher'' (Document ID 1716, p. 167). OSHA agrees with Dr. Crump, and believes that it has used the best available evidence to estimate risks of silicosis morbidity and sufficiently accounted for any dose-rate effect at high silica average concentrations by using the Buchanan *et al.* (2003) study.

For silicosis/NMRD mortality, the ACC noted that Vacek *et al.* (2009, Document ID 2307, Attachment 6) reported that, in their categorical analysis of the years worked at various levels of exposure intensity, only years worked at >200 µg/m^3 for silicosis and >300 µg/m^3 for NMRD were associated with increased mortality (Document ID 2307, Attachment A, p. 93, citing 2307, Attachment 6, pp. 21, 23). However, OSHA believes it to be inappropriate to consider these results in isolation from the other study findings, and notes that Vacek *et al.* (2009) also reported statistically significant associations of silicosis mortality with cumulative exposure, exposure duration, and average exposure intensity in their

continuous analyses with univariate models; for NMRD mortality, there were statistically significant associations with cumulative exposure and average exposure intensity (Document ID 2307, Attachment 6, pp. 21, 23).

In addition, OSHA notes that Vacek *et al.* (2009) did not include both an exposure intensity term and a cumulative exposure term in the multivariate model, after testing for correlation between cumulative exposure and years at particular exposure intensity; such a model would indicate how exposure intensity affects any relationship with cumulative exposure. As Dr. Crump stated in his comments:

> To demonstrate evidence for a dose-rate effect that is not captured by cumulative exposure, it would be most convincing to show some effect of dose rate that is in addition to the effect of cumulative exposure. To demonstrate such an effect one would need to model both cumulative exposure and some effect of dose rate, and show that adding the effect of dose rate makes a statistically significant improvement to the model over that predicted by cumulative exposure alone (Document ID 1716, p. 166).

Indeed, both Buchanan *et al.* (2003, Document ID 0306) and Hughes *et al.* (1998, Document ID 1059), when examining possible dose-rate effects for silicosis morbidity, specifically included both cumulative exposure and exposure intensity in their multivariate models. Additionally, as described in the lung cancer section of this preamble, the Vacek *et al.* study may be affected by both exposure misclassification and the healthy worker survivor effect. Both of these biases may flatten an exposure-response relationship, obscuring the relationship at lower exposure levels, which could be the reason why a significant effect was not found at the lower exposure levels in the Vacek *et al.* (2009, Document ID 2307, Attachment 6) multivariate analysis.

Regarding lung cancer mortality, the ACC pointed out that Steenland *et al.* (2001a, Document ID 0452) acknowledged that duration of exposure did not fit the data well in their pooled lung cancer study. The ACC indicated that exposure intensity should be considered (Document ID 2307, Attachment A, p. 93; 4209, p. 58, citing 0452, p. 779). OSHA interpreted the results of the Steenland *et al.* (2001, Document ID 0452) study to simply mean that duration of exposure alone was not a good predictor for lung cancer mortality, where a lag period may be important between the exposure and the development of disease. Indeed, Steenland *et al.* found the model with logged cumulative exposure, with a 15-year lag, to be a strong predictor of lung cancer (Document ID 0452, p. 779). Additionally, no new evidence of a dose-rate effect in lung cancer studies was submitted to the record.

For these reasons, OSHA does not believe there to be any persuasive data in the record that supports a dose-rate effect at exposure concentrations near the revised or previous PELs. OSHA concludes that cumulative exposure is a reasonable exposure metric on which to base estimates of risk to workers exposed to crystalline silica in the exposure range of interest (25 to 500 μg/m^3).

N. Comments and Responses Concerning Physico-Chemical and Toxicological Properties of Respirable Crystalline Silica

As discussed in the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment (Document ID 1711, pp. 344–350), the toxicological potency of crystalline silica is influenced by a number of physical and chemical factors that affect the biological activity of the silica particles inhaled in the lung. The toxicological potency of crystalline silica is largely influenced by the presence of oxygen free radicals on the surfaces of respirable particles; these chemically-reactive oxygen species interact with cellular components in the lung to promote and sustain the inflammatory reaction responsible for the lung damage associated with exposure to crystalline silica. The reactivity of particle surfaces is greatest when crystalline silica has been freshly fractured by high-energy work processes such as abrasive blasting, rock drilling, or sawing concrete materials. As particles age in the air, the surface reactivity decreases and exhibits lower toxicologic potency (Porter *et al.,* 2002, Document ID 1114; Shoemaker *et al.,* 1995, 0437; Vallyathan *et al.,* 1995, 1128). In addition, surface impurities have been shown to alter silica toxicity. For example, aluminum and aluminosilicate clay on silica particles has been shown to decrease toxicity (Castranova *et al.,* 1997, Document ID 0978; Donaldson and Borm, 1998, 1004; Fubini, 1998, 1016; Donaldson and Borm, 1998, Document ID 1004; Fubini, 1998, 1016).

In the preamble to the proposed standard, OSHA preliminarily concluded that although there is evidence that several environmental influences can modify surface activity to either enhance or diminish the toxicity of silica, the available information was insufficient to determine to what extent these influences may affect risk to workers in any particular workplace setting (Document 1711, p. 350). NIOSH affirmed OSHA's preliminary conclusion regarding the silica-related risks of exposure to clay-occluded quartz particles, which was based on what OSHA believed to be the best available evidence. NIOSH stated:

> NIOSH concurs with this assessment by OSHA. Currently available information is not adequate to inform differential quantitative risk management approaches for crystalline silica that are based on surface property measurements. Thus, NIOSH recommends a single PEL for respirable crystalline silica without consideration of surface properties (Document ID 4233, p. 44).

Two rulemaking participants, the Brick Industry Association (BIA), which represents distributors and manufacturers of clay brick, and the Sorptive Minerals Institute (SMI), which represents many industries that process and mine sorptive clays for consumer products and commercial and industrial applications, provided comment and supporting evidence that the crystalline silica encountered in their workplace environments presents a substantially lower risk of silica-related disease than that reflected in the Agency's Preliminary QRA.

BIA argued that the quartz particles found in clays and shales used in clay brick are occluded in aluminum-rich clay coatings. BIA submitted to the record several studies indicating reduced toxicity and fibrogenicity from exposure to quartz in aluminum-rich clays (Document ID 2343, Attachment 2, p. 2). It purported that ''OSHA lacks the statutory authority to impose the proposed rule upon the brick and structural clay manufacturing industry because employees in that industry do not face a significant risk of material impairment of health or functional capacity'' (Document ID 2242, pp. 2–3). BIA concluded that its industry should be exempted from the rule, stating: ''OSHA should exercise its discretion to exempt the brickmaking industry from compliance with the proposed rule unless and until it determines how best to take into account the industry's low incidence of adverse health effects from silica toxicity'' (Document ID 2242, p. 11).

SMI argued that silica in sorptive clays exists as either amorphous silica or as geologically ancient, occluded quartz, ''neither of which pose the health risk identified and studied in OSHA's risk assessment'' (Document ID 4230, p. 2). SMI further contended that OSHA's discussion of aged silica ''does not accurately reflect the risk of geologically ancient, (occluded) silica formed millions of years ago found in

sorptive clays'' (Document ID 4230, p. 2). Additionally, SMI noted that clay products produced by the sorptive minerals industry are not heated to high temperatures or fractured, making them different from brick and pottery clays (Document ID 2377, p. 7). In support of its position, SMI submitted to the record several toxicity studies of silica in sorptive clays. It stated that the evidence does not provide the basis for a finding of a significant risk of material impairment of health from exposure to silica in sorptive clays (Document ID 4230, p. 2). Consequently, SMI concluded that the application of a reduced PEL and comprehensive standard is not warranted.

Having considered the evidence SMI submitted to the record, OSHA finds that although quartz originating from bentonite deposits exhibits some biological activity, it is clear that it is considerably less toxic than unoccluded quartz. Moreover, evidence does not exist that would permit the Agency to evaluate the magnitude of the lifetime risk resulting from exposure to quartz in bentonite-containing materials and similar sorptive clays. This finding does not extend to the brick industry, where workers are exposed to silica through occluded quartz in aluminum rich clays. The Love et al. study (1999, Document ID 0369), which BIA claimed would be of useful quality for OSHA's risk assessment, shows sufficient cases of silicosis to demonstrate significant risk within the meaning used by OSHA for regulatory purposes. In addition, OSHA found a reduced, although still significant, risk of silicosis morbidity in the study of pottery workers (Chen *et al.,* 2005, Document ID 0985) that BIA put forth as being representative of mortality in the brick industry (Document ID 3577, Tr. 674). These findings are discussed in detail below.

1. The Clay Brick Industry

BIA did not support a reduction in the PEL because although brick industry employees are exposed to crystalline silica-bearing materials, BIA believes silicosis is virtually non-existent in that industry. It contended that silica exposure in the brick industry does not cause similar rates of disease as in other industries because brick industry workers are exposed to quartz occluded in aluminum-rich layers, reducing the silica's toxicity. BIA concluded that ''no significant workplace risk for brick workers from crystalline silica exposure exists at the current exposure limit'' (Document ID 3577, Tr. 654) and that reducing the PEL would have no benefit to workers in the brick industry (Document ID 2300, p. 2). These concerns were also echoed by individual companies in the brick industry, such as Acme Brick (Document ID 2085, Attachment 1), Belden Brick Company (Document ID 2378), and Riverside Brick & Supply Company, Inc. (Document ID 2346, Attachment 1). In addition, OSHA received over 50 letters as part of a letter campaign from brick industry representatives referring to BIA's comments on the lack of silicosis in the brick industry (*e.g.,* Document ID 2004).

The Tile Council of North America, Inc., also noted that ''[c]lay raw materials used in tile manufacturing are similar to those used in brick and sanitary ware manufacturing'' and also suggested that aluminosilicates decrease toxicity (Document ID 3528, p. 1). OSHA agrees with the Tile Council of North America, Inc., that their concerns mirror those of the BIA and, therefore, the Agency's consideration and response to BIA also applies to the tile industry.

a. Evidence on the Toxicity of Silica in Clay Brick.

On behalf of BIA, Mr. Robert Glenn presented a series of published and unpublished studies (Document ID 3418), also summarized by BIA (Document ID 2300, Attachment 1) as evidence that ''no significant workplace risk for brick workers from crystalline silica exposure exists at the current exposure limit'' (Document ID 3577, Tr. 654). Most of these studies, including an unpublished report on West Virginia brick workers (West Virginia State Health Department, 1939), a study of North Carolina brick workers (Trice, 1941), a study of brick workers in England (Keatinge and Potter, 1949), a study of Canadian brick workers (Ontario Health Department, 1972), two studies of North Carolina brick workers (NIOSH, 1978 and NIOSH, 1980), a study of English and Scottish brick workers (Love *et al.,* 1999, Document ID 0369), and an unpublished study commissioned by BIA of workers at 13 of its member companies (BIA, 2006), reported little or no silicosis among the workers examined (Document ID 3418; 3577, Tr. 655–669).

Based on its review of the record evidence, OSHA finds that there are many silica-containing materials (*e.g.,* other clays, sand, etc.) in brick and concludes that BIA's position is not supported by the best available evidence. The analysis contained in the studies Mr. Glenn presents does not meet the rigorous standards used in the studies on which OSHA's risk assessment relies. Indeed the studies cited by Mr. Glenn and BIA do not adequately support their contention that silicosis is ''essentially non-existent.'' Several studies were poorly designed and applied inappropriate procedures for evaluating chest X-rays (Document ID 3577, Tr. 682–685). Dr. David Weissman of NIOSH underscored the significance of such issues, stating: ''It's very important, for example, to use multiple [B] readers [to evaluate chest X-rays] and medians of readings, and it is very important for people to be blinded to how readings are done'' (Document ID 3577, Tr. 682). Also problematic was Mr. Glenn's failure to provide key information on the length of exposure or time since the first exposure in any of the studies he presented, which examined only currently employed workers. Information on duration of exposure or time since first exposure is essential to evaluating risk of silicosis because silicosis typically develops slowly and becomes detectable between 10 years and several decades following a worker's first exposure. In the hearing, Dr. Ken Rosenman also noted inadequacies related to silicosis latency, testifying that ''we know that silicosis occurs 20, 30 years after . . . first exposure . . . if people have high exposure but short duration, short latency, you are not going to see positive x-rays [even if silicosis is developing] and so it's not going to be useful'' (Document ID 3577, Tr. 688–689).

Mr. Glenn acknowledged shortcomings in the studies he submitted for OSHA's consideration, agreeing with Dr. Weissman's points about quality assurance for X-ray interpretation and study design (*e.g.,* Document ID 3577, Tr. 683). In response to Dr. Rosenman's concerns about silicosis latency, he reported that no information on worker tenure or time since first exposure was presented in Trice (1941), Keatings and Potter (1949), Rajhans and Buldovsky (1972), the NIOSH studies (1978, 1980), or Love *et al.* (1999), and that more than half of the West Virginia brick workers studied by NIOSH (1939) had a tenure of less than 10 years (Document ID 4021, pp. 5–6), a time period that OSHA believes is too short to see development of most forms of silicosis. He suggested that high exposures in two areas of the West Virginia facilities could trigger accelerated or acute silicosis, which could be observed in less than 10 years, if the toxicity of the silica in clay brick was comparable to silica found in other industries (post-hearing comments, p. 5). However, OSHA notes that a cross-sectional report on actively employed workers would not necessarily capture cases of accelerated or acute silicosis,

which are associated with severe symptoms that compromise individuals' ability to continue work, and therefore would result in a survivor effect where only unaffected workers remain at the time of study.

Mr. Glenn further argued that the Agency should assess risk to brick workers based on studies from that industry because the incidence of silicosis among brick workers appears to be lower than among workers in other industries (Document ID 3577, Tr. 670). For the reasons discussed above, OSHA does not believe the studies submitted by Mr. Glenn provide an adequate basis for risk assessment. In addition, studies presented did not: (1) Include retired workers; (2) report the duration of workers' exposure to silica; (3) employ, in most cases, quality-assurance practices for interpreting workers' medical exams; or (4) include estimates of workers' silica exposures. Furthermore, Mr. Glenn acknowledged in the informal public hearing that the Love *et al.* (1999, Document ID 0369) study of 1,925 workers employed at brick plants in England and Scotland in 1990–1991 is the only available study of brick workers that presented exposure-response information (Document ID 3577, Tr. 692). He characterized the results of that study as contradictory to OSHA's risk assessment for silicosis morbidity because the authors concluded that frequency of pneumoconiosis is low in comparison to other quartz-exposed workers (Document ID 4021, p. 2). He also cited an analysis by Miller and Soutar (Document ID 1098) (Dr. Soutar is a co-author of the Love *et al.* study) that compared silicosis risk estimates derived from Love *et al.* and those from Buchanan *et al.*'s study of Scottish coal workers exposed to silica, and concluded that silicosis risk among the coal workers far exceeded that among brick workers (Document ID 3577, Tr. 671). He furthermore concluded that the Love *et al.* study is ''the only sensible study to be used for setting an exposure limit for quartz in brick manufacturing.'' (Document ID 3577, Tr. 679).

Based on review of the Love *et al.* study (Document ID 0369), OSHA agrees with Mr. Glenn's claim that the silicosis risk among workers in clay brick industries appears to be somewhat lower than might be expected in other industries. However, OSHA is unconvinced by Mr. Glenn's argument that risk to workers exposed at the previous PEL is not significant because the cases of silicosis reported in this study are sufficient to show significant risk within the meaning used by OSHA for regulatory purposes (1 in 1,000 workers exposed for a working lifetime).

Love *et al.* reported that 3.7 percent of workers with radiographs were classified as ILO Category 0/1 (any signs of small opacities) and 1.4 percent of workers were classified as ILO Category 1/0 (small radiographic opacities) or greater. Furthermore, among workers aged 55 and older, the age category most likely to have had sufficient time since first exposure to develop detectable lung abnormalities from silicosis exposure, Love et al. reported prevalences of abnormal radiographs ranging from 2.9 percent (cumulative exposure below 0.5 mg/yr-m^3) to 16.4 percent (exposure at least 4 mg/yr-m^3) (Love *et al.* 1999, Document ID 0369, Table 4, p. 129). According to the study authors, these abnormalities ''are the most likely dust related pathology—namely, silicosis'' (Document ID 0369, p. 132). Given that OSHA considers a lifetime risk of 0.1 percent (1 in 1,000) to clearly represent a significant risk, OSHA considers the Love *et al.* study to have demonstrated a significant risk to brick workers even if only a tiny fraction of the abnormalities observed in the study population represent developing silicosis (*see Benzene,* 448 U.S. 607, 655 n. 2). According to the study authors, ''the estimated exposure-response relation for quartz suggests considerable risks of radiological abnormality even at concentrations of 0.1 mg/m^3 [100 µg/m^3] of quartz'' (Document ID 0369, p. 132).

OSHA concludes that, despite the possibly lower toxicity of silica in the clay brick industry compared to other forms, and despite the Love *et al.* study's likely underestimation of risk due to exclusion of retired workers, the study demonstrates significant risk among brick workers exposed at the previous general industry PEL. It also suggests that the silicosis risk among brick workers would remain significant even at the new PEL. Furthermore, OSHA is unconvinced by Mr. Glenn's argument that the Agency should develop a quantitative risk assessment based on the Love *et al.* study, because that study excluded retired workers and had inadequate worker follow-up. As explained earlier in this section, adequate follow-up time and inclusion of retired workers is extremely important to allow for latency in the development of silicosis. Therefore, OSHA relied on studies including retired workers in its QRA for silicosis morbidity.

Mr. Glenn additionally argued that the risk of lung cancer from silica exposure among brick workers is likely to be lower than among workers exposed to silica in other work settings. Mr. Glenn acknowledged that ''there are no published mortality studies of brick workers that look at cause of death or lung cancer death'' (Document ID 3577, Tr. 674). However, he stated that ''pottery clays are similar to the structural clays used in brickmaking in that the quartz is occluded in aluminum-rich layers of bentonite, kaolinite, and illite,'' and that OSHA should consider studies of mortality among pottery workers as representative of the brick industry (Tr. 674). Mr. Glenn cited the Chen *et al.* (2005) study of Chinese pottery workers, which reported a weak exposure-response relationship between silica exposure and lung cancer mortality, and which appeared to be affected by PAH-related confounding. He concluded that the Chen *et al.* study ''provides strong evidence for aluminum-rich clays suppressing any potential carcinogenesis from quartz'' (Document ID 3577, Tr. 675).

OSHA acknowledges that occlusion may weaken the carcinogenicity of silica in the brick clay industry, but does not believe that the Chen *et al.* study provides conclusive evidence of such an effect. This is because of the relatively low carcinogenic potential of silica and the difficulty involved in interpreting one cohort with known issues of confounding (see Section V.F, Comments and Responses Concerning Lung Cancer Mortality). OSHA also notes, however, that it estimated risks of silicosis morbidity from the cited Chen *et al.* (2005, Document ID 0985) study, and found the risk among pottery workers to be significant, with 60 deaths per 1,000 workers at the previous PEL of 100 µg/m^3 and 20 deaths per 1,000 workers at the revised PEL of 50 µg/m^3 (as indicated in Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1). Thus, given Mr. Glenn's assertion that pottery clays are similar to the clays used in brickmaking, OSHA believes that while the risk of silicosis morbidity may be lower than that seen in other industry sectors, it is likely to still be significant in the brickmaking industry.

Thus, OSHA concludes that the BIA's position is not supported by the best available evidence. The studies cited by Mr. Glenn to support his contention that brick workers are not at significant risk of silica-related disease do not have the same standards as those studies used by OSHA in its quantitative risk assessment. Furthermore, in the highest-quality study brought forward by Mr. Glenn (Love *et al.* 1999, Document ID 0369), there are sufficient cases of silicosis to demonstrate significant risk within the meaning used by OSHA for

regulatory purposes. Even if the commenters' arguments that silica in clay brick is less toxic were, to some extent, legitimate, this would not significantly affect OSHA's own estimates from the epidemiological evidence of the risks of silicosis.

2. Sorptive Minerals (Bentonite Clay) Processing

SMI asserted that the physico-chemical form of respirable crystalline silica in sorptive clays reduces the toxicologic potency of crystalline silica relative to the forms of silica common to most studies relied on in OSHA's Preliminary QRA. In other words, the risk associated with exposure to silica in sorptive clays is assertedly lower than the risk associated with exposure to silica in other materials. SMI based this view on what it deemed the ''best available scientific literature,'' epidemiological, in vitro, and animal evidence OSHA had not previously considered. It believed the evidence showed reduced risk from exposure to occluded quartz found in the sorptive clays and that occluded quartz does not create a risk similar to that posed by freshly fractured quartz (Document ID 2377, p. 7). Based on this, SMI contended that the results of OSHA's Preliminary QRA were not applicable to the sorptive minerals industry, and a more stringent standard for crystalline silica is ''neither warranted nor legally permissible'' (Document ID 4230, p. 1). As discussed below, OSHA reviewed the evidence submitted by SMI and finds that although the studies provide evidence of some biological activity in quartz originating from bentonite deposits, there is not quantitative evidence that would permit the Agency to evaluate the magnitude of the lifetime risk resulting from exposure to quartz in bentonite-containing materials and similar sorptive clays.

a. Evidence on the Toxicity of Silica in Sorptive Minerals

SMI submitted a number of studies to the rulemaking record. First, it summarized a retrospective study by Waxweiler *et al.* (Document ID 3998, Attachment 18e) of attapulgite clay workers in Georgia in which the authors concluded that there was a significant deficit of non-malignant respiratory disease mortality and no clear excess of lung cancer mortality among these workers. It used the study as the basis for its recommendation to OSHA that the study ''be cited and that exposures in the industry be recognized in the final rule as not posing the same hazard as those in industries with reactive crystalline silica'' (Document ID 2377, p. 10).

Based on its review of the rulemaking record, OSHA concludes that the Waxweiler *et al.* study is of limited value for assessing the hazard potential of quartz in bentonite clay because of the low airborne levels of silica to which the workers were exposed. The Agency's conclusion is supported by NIOSH's summary of the time-weighted average (TWA) exposures calculated for each job category in Waxweiler *et al.* (1988, Document ID 3998, Attachment 18e), which were found to be ''within the acceptable limits as recommended by NIOSH (*i.e.,* <0.05 mg/m^3 [50 µg/m^3]) . . . and most were substantially lower'' (Document ID 4233, p. 41). It cannot be known to what extent the low toxicity of the dust or the low exposures experienced by the workers each contributed to the lack of observed disease.

SMI also presented a World Health Organization (WHO) document (2005, Document ID 3929), which recognized that ''studies of workers exposed to sorptive clays have not identified significant silicosis risk'' (Document ID 2377, p. 10). However, although WHO did find that there were no reported cases of fibrotic reaction in humans exposed to montmorillonite minerals in the absence of crystalline silica (Document ID 3929, p. 130), the WHO report does discuss the long-term effects from exposure to crystalline silica, including silicosis and lung cancer. In fact, with respect to evaluating the hazards associated with exposure to bentonite clay, WHO regarded silica as a potential confounder (Document ID 3929, p. 136). Thus, WHO did not specifically make any findings with respect to the hazard potential of quartz in the bentonite clay mineral matrix but instead recognized the hazard presented by exposure to crystalline silica generally.

Additionally, the WHO (Document ID 3929, pp. 114, 118) cited two case/case series reports of bentonite-exposed workers, one demonstrating increasing prevalence of silicosis with increasing exposure to bentonite dust (Rombola and Guardascione, 1955, Document ID 3998, Attachment 18) and another describing cases of silicosis among workers exposed to bentonite dust (Phibbs *et al.* 1971, Document ID 3998, Attachment 18b). Rombola and Guardascione (1955) found silicosis prevalences of 35.5 and 12.8 percent in two bentonite processing factories, and 6 percent in a bentonite mine. In the factory where the highest exposures occurred, 10 of the 26 cases found were severe and all cases developed with seven or fewer years of exposure, indicating that exposure levels were extremely high (Document ID 4233, p. 42, citing 3998, Attachment 18). Phibbs *et al.* (1971) reviewed chest x-rays of 32 workers in two bentonite plants, of which x-ray films for 14 indicated silicosis ranging from minimal to advanced. Although the exposure of affected workers to respirable dust or quartz is not known, industrial hygiene surveys conducted in four bentonite plants showed some areas having particle counts in excess of 3 to 11 times the ACGIH particle count limit (Document ID 3998, Attachment 18b, p. 4). This is roughly equivalent to exposure levels between 8 and 28 times OSHA's former general industry PEL of 100 µg/m^3 (given that the particle count limit is about 2.5 or more times higher than the gravimetric limit for respirable quartz (*see* Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA). Exposures of this magnitude are considerably higher than those experienced by worker cohorts of the studies relied on by OSHA in its Final Risk Assessment and discussed in Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA. For example, the median of average exposures reported in the ten cohort studies used by Steenland *et al.* (2001, Document ID 0684, p. 775) ranged from about one-half to six times the former general industry PEL.

The lack of specific exposure information on bentonite workers found with silicosis, combined with the extraordinary exposures experienced by workers in the bentonite plants studied by Phibbs *et al.* (1971), make this study, while concerning, unsuitable for evaluating risks in the range of the former and final rule PELs. OSHA notes that the WHO report also concluded that available data were inadequate to conclusively establish a dose-response relationship or even a cause-and-effect relationship for bentonite dust, and that its role in inducing pneumoconiosis remains uncertain.

SMI also presented evidence from animal and in vitro studies that it believes shows that respirable crystalline quartz present in sorptive clays exists in a distinct occluded form, which significantly mitigates adverse health effects due to the physico-chemical characteristics of the occluded quartz. As discussed below, based on careful review of the studies SMI cited, OSHA believes these studies indicate that silica in bentonite clay is of lower toxicologic potency than that found in other industry sectors.

SMI submitted two studies: an animal study (Creutzenberg *et al.* 2008,

Document ID 3891) and a study of the characteristics of quartz samples isolated from bentonite (Miles *et al.* 2008, Document ID 4173). SMI contended that these studies demonstrate the low toxicity potential of geologically ancient occluded quartz found in sorptive clays (Document ID 2377, pp. 8–9).

Creutzenberg *et al.* (2008) summarized the findings from a rat study aimed at ''characterizing the differences in biological activity between crystalline ground reference quartz (DQ12) and a quartz with occluded surfaces (quartz isolate) obtained from a clay deposit formed 110–112 million years ago'' (Document ID 3891, p. 995). Based on histopathological assessment of the lungs in each treatment group, Creutzenberg *et al.* (2008, Document ID 3891) found that the DQ12 reference quartz group exhibited a significantly stronger inflammatory reaction than the quartz isolate, which showed a slight but still statistically significant inflammatory response compared to the control group. The increased inflammatory response was observed at day 3 but not at 28 or 90 days. Thus, reaction elicited by the quartz isolate, thought to have similar properties to bentonite, was considered by the investigators to represent a moderate effect that did not progress. In light of this, the implications of this study for development of silicosis are unclear.

SMI also cited Miles *et al.* (2008, Document ID 4173), who studied the mineralogical and chemical characteristics of quartz samples isolated from bentonite, including the quartz isolate used by Creutzenberg *et al.* (2008) in their animal study. Their evaluation identified several differences in the chemical and physical properties of the quartz isolates and unoccluded quartz that could help explain the observed differences in toxicity (Document ID 4173); these included differences in crystal structure, electrical potential of particle surfaces, and, possibly, differences in the reactivity of surface-free radicals owing to the presence of iron ions in the residual clay material associated with the quartz isolates.

With respect to the two studies just discussed, animal evidence cited by SMI demonstrates that quartz in bentonite induces a modest inflammatory reaction in the lung that does not persist (Creutzenberg *et al.*, 2008, Document ID 3891). Such a reaction is notably different from the persistent and stronger response seen with standard experimental quartz material without surface occlusion (Creutzenberg *et al.*, 2008, Document ID 3891). Physical and chemical characteristics of quartz from bentonite deposits have been shown to differ from standard experimental quartz in ways that can explain its reduced toxicity (Miles *et al.*, 2008, Document ID 4173). However, the animal studies cited by SMI are not suitable for risk assessment since they were short-term (90 days), single-dose experiments.

In sum, human evidence on the toxicity of quartz in bentonite clay includes one study cited by SMI that did not find an excess risk of respiratory disease (Waxweiller *et al.*, Document ID 3998, Attachment 18e). However, because exposures experienced by the workers were low with most less than that of the final rule PEL, the lack of an observed effect cannot be solely attributed to the nature of the quartz particles. Two studies of bentonite workers found a high prevalence of silicosis based on x-ray findings (Rombola and Guardascione, 1955, Document ID 3998, Attachment 18; Phibbs *et al.*, 1971, Document ID 3998, Attachment 18b). Limited exposure data provided in the studies as well as the relatively short latencies seen among cases of severe silicosis make it clear that the bentonite workers were exposed to extremely high dust levels. Neither of these studies can be relied on to evaluate disease risk in the exposure range of the former and revised respirable crystalline silica PELs.

OSHA finds that the evidence for quartz originating from bentonite deposits indicates some biological activity, but also indicates lower toxicity than standard experimental quartz (which has similar characteristics to quartz encountered in most workplaces where exposures occur). For regulatory purposes, however, OSHA finds that the evidence does not exist that would permit the Agency to evaluate the magnitude of the lifetime risk resulting from exposure to quartz in sorptive clays at the 100 $\mu g/m^3$ PEL. Instead, OSHA finds that the record provides no sound basis for determining the significance of risk for exposure to sorptive clays containing respirable quartz. Thus, OSHA is excluding sorptive clays (as described specifically in the Scope part of Section XV, Summary and Explanation) from the scope of the rule, until such time that sufficient science has been developed to permit evaluation of the significance of the risk. However, in excluding sorptive clays from the rule, the general industry PEL, as described in 29 CFR 1910.1000 Table Z–3, will continue to apply.

VI. Final Quantitative Risk Assessment and Significance of Risk

A. Introduction

To promulgate a standard that regulates workplace exposure to toxic materials or harmful physical agents, OSHA must first determine that the standard reduces a ''significant risk'' of ''material impairment.'' Section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b). The first part of this requirement, ''significant risk,'' refers to the likelihood of harm, whereas the second part, ''material impairment,'' refers to the severity of the consequences of exposure. Section II, Pertinent Legal Authority, of this preamble addresses the statutory bases for these requirements and how they have been construed by the Supreme Court and federal courts of appeals.

It is the Agency's practice to estimate risk to workers by using quantitative risk assessment and determining the significance of that risk based on the best available evidence. Using that evidence, OSHA identifies material health impairments associated with potentially hazardous occupational exposures, and, when possible, provides a quantitative assessment of exposed workers' risk of these impairments. The Agency then evaluates whether these risks are severe enough to warrant regulatory action and determines whether a new or revised rule will substantially reduce these risks. For single-substance standards governed by section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b)(5), OSHA sets a permissible exposure limit (PEL) based on that risk assessment as well as feasibility considerations. These health and risk determinations are made in the context of a rulemaking record in which the body of evidence used to establish material impairment, assess risks, and identify affected worker population, as well as the Agency's preliminary risk assessment, are placed in a public rulemaking record and subject to public comment. Final determinations regarding the standard, including final determinations of material impairment and risk, are thus based on consideration of the entire rulemaking record.

In this case, OSHA reviewed extensive toxicological, epidemiological, and experimental research pertaining to the adverse health effects of occupational exposure to respirable crystalline silica, including silicosis, other non-malignant respiratory disease (NMRD), lung cancer, and autoimmune and renal diseases. Using the information collected during this review, the Agency

developed quantitative estimates of the excess risk of mortality and morbidity attributable to the previously allowed and revised respirable crystalline silica PELs; these estimates were published with the proposed rule. The Agency subsequently reexamined these estimates in light of the rulemaking record as a whole, including comments, testimony, data, and other information, and has determined that long-term exposure at and above the previous PELs would pose a significant risk to workers' health, and that adoption of the new PEL and other provisions of the final rule will substantially reduce this risk. Based on these findings, the Agency is adopting a new PEL of 50 μg/m³.

Even though OSHA's risk assessment indicates that a significant risk also exists at the revised action level of 25 μg/m³, the Agency is not adopting a PEL below the revised 50 μg/m³ limit because OSHA must also consider the technological and economic feasibility of the standard in determining exposure limits. As explained in the Summary and Explanation for paragraph (c), Permissible Exposure Limit (PEL), of the general industry/maritime standard (paragraph (d) for construction), OSHA has determined that, with the adoption of additional engineering and work practice controls, the revised PEL of 50 μg/m³ is technologically and economically feasible in most operations in the affected general industrial and maritime sectors and in the construction industry, but that a lower PEL of 25 μg/m³ is not technologically feasible for most of these operations (*see* Section VII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA) and Chapter IV, Technological Feasibility, of the FEA). Therefore, OSHA concludes that by establishing the 50 μg/m³ PEL, the Agency has reduced significant risk to the extent feasible.

B. OSHA's Findings of Material Impairments of Health

As discussed below and in OSHA's Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 7–229), there is convincing evidence that inhalation exposure to respirable crystalline silica increases the risk of a variety of adverse health effects, including silicosis, NMRD (such as chronic bronchitis and emphysema), lung cancer, kidney disease, immunological effects, and infectious tuberculosis (TB). OSHA considers each of these conditions to be a material impairment of health. These diseases make it difficult or impossible to work and result in significant and permanent functional limitations, reduced quality of life, and sometimes death. When these diseases coexist, as is common, the effects are particularly debilitating (Rice and Stayner, 1995, Document ID 0418; Rosenman *et al.*, 1999, 0421). Based on these findings and on the scientific evidence that respirable crystalline silica substantially increases the risk of each of these conditions, OSHA has determined that exposure to respirable crystalline silica increases the risk of ''material impairment of health or functional capacity'' within the meaning of the Occupational Safety and Health Act.

1. Silicosis

OSHA considers silicosis, an irreversible and potentially fatal disease, to be a clear material impairment of health. The term ''silicosis'' refers to a spectrum of lung diseases attributable to the inhalation of respirable crystalline silica. As described more fully in the Review of Health Effects Literature (Document ID 1711, pp. 16–71), the three types of silicosis are acute, accelerated, and chronic. Acute silicosis can occur within a few weeks to months after inhalation exposure to extremely high levels of respirable crystalline silica. Death from acute silicosis can occur within months to a few years of disease onset, with the affected person drowning in his or her own lung fluid (NIOSH, 1996, Document ID 0840). Accelerated silicosis results from exposure to high levels of airborne respirable crystalline silica, and disease usually occurs within 5 to 10 years of initial exposure (NIOSH, 1996, Document ID 0840). Both acute and accelerated silicosis are associated with exposures that are substantially above the previous general industry PEL, although no precise information on the relationships between exposure and occurrence of disease exists.

Chronic silicosis is the most common form of silicosis seen today, and is a progressive and irreversible condition characterized as a diffuse nodular pulmonary fibrosis (NIOSH, 1996, Document ID 0840). Chronic silicosis generally occurs after 10 years or more of inhalation exposure to respirable crystalline silica at levels below those associated with acute and accelerated silicosis. Affected workers may have a dry chronic cough, sputum production, shortness of breath, and reduced pulmonary function. These symptoms result from airway restriction caused by the development of fibrotic scarring in the lower regions of the lungs. The scarring can be detected in chest x-ray films when the lesions become large enough to appear as visible opacities. The result is a restriction of lung volumes and decreased pulmonary compliance with concomitant reduced gas transfer. Chronic silicosis is characterized by small, rounded opacities that are symmetrically distributed in the upper lung zones on chest radiograph (Balaan and Banks, 1992, Document ID 0289, pp. 347, 350–351).

The diagnosis of silicosis is based on a history of exposure to respirable crystalline silica, chest radiograph findings, and the exclusion of other conditions that appear similar. Because workers affected by early stages of chronic silicosis are often asymptomatic, the finding of opacities in the lung is key to detecting silicosis and characterizing its severity. The International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses (ILO, 1980, Document ID 1063; 2002, 1064) is the currently accepted standard against which chest radiographs are evaluated for use in epidemiological studies, medical surveillance, and clinical evaluation. The ILO system standardizes the description of chest x-rays, and is based on a 12-step scale of severity and extent of silicosis as evidenced by the size, shape, and density of opacities seen on the x-ray film. Profusion (frequency) of small opacities is classified on a 4-point major category scale (0–3), with each major category divided into three, giving a 12-point scale between 0/− and 3/+. Large opacities are defined as any opacity greater than 1 cm that is present in a film (ILO, 1980, Document ID 1063; 2002, 1064, p. 6).

The small rounded opacities seen in early stage chronic silicosis (ILO major category 1 profusion) may progress (through ILO major categories 2 and/or 3) and develop into large fibrotic masses that destroy the lung architecture, resulting in progressive massive fibrosis (PMF). This stage of advanced silicosis is usually characterized by impaired pulmonary function, permanent disability, and premature death. In cases involving PMF, death is commonly attributable to progressive respiratory insufficiency (Balaan and Banks, 1992, Document ID 0289).

Patients with ILO category 2 or 3 background profusion of small opacities are at increased risk, compared to those with category 1 profusion, of developing the large opacities characteristic of PMF. In one study of silicosis patients in Hong Kong, Ng and Chan (1991, Document ID 1106, p. 231) found the risk of PMF increased by 42 and 64 percent among patients whose chest x-

ray films were classified as ILO major category 2 or 3, respectively. Research has shown that people with silicosis advanced beyond ILO major category 1 have reduced life expectancy compared to the general population (Infante-Rivard *et al.*, 1991, Document ID 1065; Ng *et al.*, 1992a, 0383; Westerholm, 1980, 0484).

Silicosis is the oldest known occupational lung disease and is still today the cause of significant premature mortality. As discussed further in Section V.E, Comments and Responses Concerning Surveillance Data on Silicosis Morbidity and Mortality, in 2013, there were 111 deaths in the U.S. where silicosis was recorded as an underlying or contributing cause of death on a death certificate (NCHS data). Between 1996 and 2005, deaths attributed to silicosis resulted in an average of 11.6 years of life lost by affected workers (NIOSH, 2007, Document ID 1362). In addition, exposure to respirable crystalline silica remains an important cause of morbidity and hospitalizations. National inpatient hospitalization data show that in the year 2011, 2,082 silicosis-related hospitalizations occurred, indicating that silicosis continues to be a significant health issue in the U.S. (Document ID 3577, Tr. 854–855). Although there is no national silicosis disease surveillance system in the U.S., a published analysis of state-based surveillance data from the time period 1987–1996 estimated that between 3,600–7,000 new cases of silicosis occurred in the U.S. each year (Rosenman *et al.*, 2003, Document ID 1166).

It has been widely reported that available statistics on silicosis-related mortality and morbidity are likely to be understated due to misclassification of causes of death (for example, as tuberculosis, chronic bronchitis, emphysema, or cor pulmonale), lack of occupational information on death certificates, or misdiagnosis of disease by health care providers (Goodwin *et al.*, 2003, Document ID 1030; Windau *et al.*, 1991, 0487; Rosenman *et al.*, 2003, 1166). Furthermore, reliance on chest x-ray findings may miss cases of silicosis because fibrotic changes in the lung may not be visible on chest radiograph; thus, silicosis may be present absent x-ray signs or may be more severe than indicated by x-ray (Hnizdo *et al.*, 1993, Document ID 1050; Craighhead and Vallyahan, 1980, 0995; Rosenman *et al.*, 1997, 4181).

Although most workers with early-stage silicosis (ILO categories 0/1 or 1/0) typically do not experience respiratory symptoms, the primary risk to the affected worker is progression of disease with progressive decline of lung function. Several studies of workers exposed to crystalline silica have shown that, once silicosis is detected by x-ray, a substantial proportion of affected workers can progress beyond ILO category 1 silicosis, even after exposure has ceased (*e.g.*, Hughes, 1982, Document ID 0362; Hessel *et al.*, 1988, 1042; Miller *et al.*, 1998, 0374; Ng *et al.*, 1987a, 1108; Yang *et al.*, 2006, 1134). In a population of coal miners whose last chest x-ray while employed was classified as major category 0, and who were examined again 10 years after the mine had closed, 20 percent had developed opacities consistent with a classification of at least 1/0, and 4 percent progressed further to at least 2/1 (Miller *et al.*, 1998, Document ID 0374). Although there were periods of extremely high exposure to respirable quartz in the mine (greater than 2,000 $\mu g/m^3$ in some jobs between 1972 and 1976, and more than 10 percent of exposures between 1969 and 1977 were greater than 1,000 $\mu g/m^3$), the mean cumulative exposure for the cohort over the period 1964–1978 was 1.8 mg/m^3-yrs, corresponding to an average silica concentration of 120 $\mu g/m^3$. In a population of granite quarry workers exposed to an average respirable silica concentration of 480 $\mu g/m^3$ (mean length of employment was 23.4 years), 45 percent of those diagnosed with simple silicosis (*i.e.*, presence of small opacities only on chest x-ray films) showed radiological progression of disease after 2 to 10 years of follow up (Ng *et al.*, 1987a, Document ID 1108). Among a population of gold miners, 92 percent progressed in 14 years; exposures of high-, medium-, and low-exposure groups were 970, 450, and 240 $\mu g/m^3$, respectively (Hessel *et al.*, 1988, Document ID 1042). Chinese mine and factory workers categorized under the Chinese system of x-ray classification as ''suspected'' silicosis cases (analogous to ILO 0/1) had a progression rate to stage I (analogous to ILO major category 1) of 48.7 percent, and the average interval was about 5.1 years (Yang *et al.*, 2006, Document ID 1134).

The risk of silicosis carries with it an increased risk of reduced lung function as the disease irreversibly progresses. There is strong evidence in the literature for the finding that lung function deteriorates more rapidly in workers exposed to silica, especially those with silicosis, than what is expected from a normal aging process (Cowie, 1988, Document ID 0993; Hughes *et al.*, 1982, 0362; Malmberg *et al.*, 1993, 0370; Ng and Chan, 1992, 1107). The rates of decline in lung function are greater in those whose disease showed evidence of radiologic progression (Begin *et al.*, 1987, Document ID 0295; Cowie, 1988, 0993; Ng and Chan, 1992, 1107; Ng *et al.*, 1987a, 1108). Additionally, the average deterioration of lung function exceeds that in smokers (Hughes *et al.*, 1982, Document ID 0362).

Several studies have reported no decrease in pulmonary function with an ILO category 1 level of profusion of small opacities but found declines in pulmonary function with categories 2 and 3 (Ng *et al.*, 1987a, Document ID 1108; Begin *et al.*, 1988, 0296; Moore *et al.*, 1988, 1099). However, one study found a statistically significantly greater annual loss in forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) among those with category 1 profusion compared to category 0 (Cowie, 1988, Document ID 0993). In another study, the degree of profusion of opacities was associated with reductions in several pulmonary function metrics (Cowie and Mabena, 1991, Document ID 0342). Some studies have reported no associations between radiographic silicosis and decreases in pulmonary function (Ng *et al.*, 1987a, Document ID 1108; Wiles *et al.*, 1972, 0485; Hnizdo, 1992, 1046), while other studies (Ng *et al.*, 1987a, Document ID 1108; Wang *et al.*, 1997, 0478) have found that measurable changes in pulmonary function are evident well before the changes seen on chest x-ray. Findings of pulmonary function decrements absent radiologic signs of silicosis may reflect the general insensitivity of chest radiography in detecting lung fibrosis, or may also reflect that exposure to respirable silica has been shown to increase the risk of non-malignant respiratory disease (NMRD) and its attendant pulmonary function losses (*see* Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA).

Moreover, exposure to respirable crystalline silica in and of itself, with or without silicosis, increases the risk that latent tuberculosis infection can convert to active disease. Early descriptions of dust diseases of the lung did not distinguish between TB and silicosis, and most fatal cases described in the first half of this century were a combination of silicosis and TB (Castranova *et al.*, 1996, Document ID 0314). More recent findings demonstrate that exposure to silica, even without silicosis, increases the risk of infectious (*i.e.*, active) pulmonary TB (Sherson and Lander, 1990, Document ID 0434; Cowie, 1994, 0992; Hnizdo and Murray, 1998, 0360; teWaterNaude *et al.*, 2006, 0465). Both conditions together can

hasten the development of respiratory impairment and increase mortality risk even beyond that experienced by persons with active TB who have not been exposed to respirable crystalline silica (Banks, 2005, Document ID 0291).

Based on the information presented above and in its review of the health literature, OSHA concludes that silicosis remains a significant cause of early death and of serious illness, despite the existence of an enforceable exposure limit over the past 40 years. Silicosis in its later stages of progression (*i.e.*, with chest x-ray findings of ILO category 2 or 3 profusion of small opacities, or the presence of large opacities) is characterized by the likely appearance of respiratory symptoms and decreased pulmonary function, as well as increased risk of progression to PMF, disability, and early mortality. Early-stage silicosis, although without symptoms among many who are affected, nevertheless reflects the formation of fibrotic lesions in the lung and increases the risk of progression to later stages, even after exposure to respirable crystalline silica ceases. In addition, the presence of silicosis increases the risk of pulmonary infections, including conversion of latent TB infection to active TB. Silicosis is not a reversible condition, and there is no specific treatment for the disease, other than administration of drugs to alleviate inflammation and maintain open airways, or administration of oxygen therapy in severe cases. Based on these considerations, OSHA finds that silicosis of any form, and at any stage of progression, is a material impairment of health and that fibrotic scarring of the lungs represents loss of functional respiratory capacity.

2. Lung Cancer

OSHA considers lung cancer, an irreversible and frequently fatal disease, to be a clear material impairment of health (*see* Homer *et al.*, 2009, Document ID 1343). According to the National Cancer Institute (SEER Cancer Statistics Review, 2006, Document ID 1343), the five-year survival rate for all forms of lung cancer is only 15.6 percent, a rate that has not improved in nearly two decades. After reviewing the record as a whole, OSHA finds that respirable crystalline silica exposure substantially increases the risk of lung cancer. This finding is based on the best available toxicological and epidemiological data, reflects substantial supportive evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations, including the International Agency for Research on Cancer (1997, Document ID 1062; 2012, Document ID 1473), the HHS National Toxicology Program (2000, Document ID 1417), the CDC's National Institute for Occupational Safety and Health (2002, Document ID 1110), the American Thoracic Society (1997, Document ID 0283), and the American Conference of Governmental Industrial Hygienists (2010, Document ID 0515).

The Agency's primary evidence comes from evaluation of more than 50 studies of occupational cohorts from many different industry sectors in which exposure to respirable crystalline silica occurs, including: Granite and stone quarrying; the refractory brick industry; gold, tin, and tungsten mining; the diatomaceous earth industry; the industrial sand industry; and construction. In addition, the association between exposure to respirable crystalline silica and lung cancer risk was reported in a national mortality surveillance study (Calvert *et al.*, 2003, Document ID 0309) and in two community-based studies (Pukkala *et al.*, 2005, Document ID 0412; Cassidy *et al.*, 2007, 0313), as well as in a pooled analysis of 10 occupational cohort studies (Steenland *et al.*, 2001a, Document ID 0452). Toxicity studies provide supportive evidence of the carcinogenicity of crystalline silica, in that they demonstrate biologically plausible mechanisms by which crystalline silica in the deep lung can give rise to biochemical and cellular events leading to tumor development (*see* Section V.H, Mechanisms of Silica-Induced Adverse Health Effects).

3. Non-Malignant Respiratory Disease (NMRD) (Other Than Silicosis)

Although many of the stakeholders in this rule have focused their attention on the evidence related to silicosis and lung cancer, the available evidence shows that exposure to respirable crystalline silica also increases the risk of developing NMRD, in particular chronic bronchitis and emphysema. OSHA has determined that NMRD, which results in loss of pulmonary function that restricts normal activity in individuals afflicted with these conditions (*see* American Thoracic Society, 2003, Document ID 1332), constitutes a material impairment of health. Both chronic bronchitis and emphysema can occur in conjunction with the development of silicosis. Several studies have documented increased prevalence of chronic bronchitis and emphysema among silica-exposed workers even absent evidence of silicosis (*see* Document ID 1711, pp. 182–192; NIOSH, 2002, 1110; American Thoracic Society, 2003, 1332). There is also evidence that smoking may have an additive or synergistic effect on silica-related NMRD morbidity or mortality (Hnizdo, 1990, Document ID 1045; Hnizdo *et al.*, 1990, 1047; Wyndham *et al.*, 1986, 0490; NIOSH, 2002, 1110). In a study of diatomaceous earth workers, Park *et al.* (2002, Document ID 0405) found a positive exposure-response relationship between exposure to respirable cristobalite (a form of silica) and increased mortality from NMRD.

Decrements in pulmonary function have often been found among workers exposed to respirable crystalline silica absent radiologic evidence of silicosis. Several cross-sectional studies have reported such findings among granite workers (Theriault *et al.,* 1974a, Document ID 0466; Wallsh, 1997, 0477; Ng *et al.,* 1992b, 0387; Montes II *et al.,* 2004b, 0377), gold miners (Irwig and Rocks, 1978, Document ID 1067; Hnizdo *et al.,* 1990, 1047; Cowie and Mabena, 1991, 0342), gemstone cutters (Ng *et al.,* 1987b, Document ID 1113), concrete workers (Meijer *et al.,* 2001, Document ID 1243), refractory brick workers (Wang *et al.,* 1997, Document ID 0478), hard rock miners (Manfreda *et al.,* 1982, Document ID 1094; Kreiss *et al.,* 1989, 1079), pottery workers (Neukirk *et al.,* 1994, Document ID 0381), slate workers (Surh, 2003, Document ID 0462), and potato sorters exposed to silica in diatomaceous earth (Jorna *et al,* 1994, Document ID 1071).

OSHA also evaluated several longitudinal studies where exposed workers were examined over a period of time to track changes in pulmonary function. Among both active and retired granite workers exposed to an average of 60 μg/m ^{3}, Graham *et al.* did not find exposure-related decrements in pulmonary function (1981, Document ID 1280; 1984, 0354). However, Eisen *et al.* (1995, Document ID 1010) did find significant pulmonary decrements among a subset of granite workers (termed ''dropouts'') who left work and consequently did not voluntarily participate in the last of a series of annual pulmonary function tests. This group of workers experienced steeper declines in FEV1 compared to the subset of workers who remained at work and participated in all tests (termed ''survivors''), and these declines were significantly related to dust exposure. Thus, in this study, workers who had left work had exposure-related declines in pulmonary function to a greater extent than did workers who remained on the job, clearly demonstrating a survivor effect among the active

workers. Exposure-related changes in lung function were also reported in a 12-year study of granite workers (Malmberg, 1993, Document ID 0370), in two 5-year studies of South African miners (Hnizdo, 1992, Document ID 1046; Cowie, 1988, 0993), and in a study of foundry workers whose lung function was assessed between 1978 and 1992 (Hertzberg *et al.,* 2002, Document ID 0358).

Each of these studies reported their findings in terms of rates of decline in any of several pulmonary function measures, such as FVC, FEV_1, and FEV_1/FVC. To put these declines in perspective, Eisen *et al.* (1995, Document ID 1010) reported that the rate of decline in FEV_1 seen among the dropout subgroup of Vermont granite workers was 4 ml per mg/m^3-yrs of exposure to respirable granite dust; by comparison, FEV_1 declines at a rate of 10 ml/year from smoking one pack of cigarettes daily. From their study of foundry workers, Hertzberg *et al.,* reported finding a 1.1 ml/year decline in FEV_1 and a 1.6 ml/year decline in FVC for each mg/m^3-yrs of respirable silica exposure after controlling for ethnicity and smoking (2002, Document ID 0358, p. 725). From these rates of decline, they estimated that exposure to the previous OSHA general industry quartz standard of 100 µg/m^3 for 40 years would result in a total loss of FEV_1 and FVC that is less than but still comparable to smoking a pack of cigarettes daily for 40 years. Hertzberg et al. also estimated that exposure to the current standard for 40 years would increase the risk of developing abnormal FEV1 or FVC by factors of 1.68 and 1.42, respectively (2002, Document ID 0358, pp. 725–726). OSHA believes that this magnitude of reduced pulmonary function, as well as the increased morbidity and mortality from non-malignant respiratory disease (NMRD) that has been documented in the studies summarized above, constitute material impairments of health and loss of functional respiratory capacity.

4. Renal and Autoimmune Effects

Finally, OSHA's review of the literature reflects substantial evidence that exposure to crystalline silica increases the risk of renal and autoimmune diseases, both of which OSHA considers to be material impairments of health (*see* Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA). Epidemiological studies have found statistically significant associations between occupational exposure to silica dust and chronic renal disease (*e.g.,* Calvert *et al.,* 1997, Document ID 0976), subclinical renal changes including proteinurea and elevated serum creatinine (*e.g.,* Ng *et al.,* 1992c, Document ID 0386; Rosenman *et al.,* 2000, 1120; Hotz, *et al.,* 1995, 0361), end-stage renal disease morbidity (*e.g.,* Steenland *et al.,* 1990, Document ID 1125), chronic renal disease mortality (Steenland *et al.,* 2001b, Document ID 0456; 2002a, 0448), and granulomatosis with polyangitis (Nuyts *et al.,* 1995, Document ID 0397). Granulomatosis with polyangitis is characterized by inflammation of blood vessels, leading to damaging granulomatous formation in the lung and damage to the glomeruli of the kidneys, a network of capillaries responsible for the first stage of blood filtration. If untreated, this condition often leads to renal failure (Nuyts *et al.,* 1995, Document ID 0397, p. 1162). Possible mechanisms for silica-induced renal disease include a direct toxic effect on the kidney and an autoimmune mechanism (see Section V.H, Mechanisms of Silica-Induced Adverse Health Effects; Calvert *et al.,* 1997, Document ID 0976; Gregorini *et al.,* 1993, 1032). Steenland *et al.* (2002a, Document ID 0448) demonstrated a positive exposure-response relationship between exposure to respirable crystalline silica and end-stage renal disease mortality.

In addition, there are a number of studies that show exposure to be related to increased risks of autoimmune disease, including scleroderma (*e.g.,* Sluis-Cremer *et al.,* 1985, Document ID 0439), rheumatoid arthritis (*e.g.,* Klockars *et al.,* 1987, Document ID 1075; Rosenman and Zhu, 1995, 0424), and systemic lupus erythematosus (*e.g.,* Brown *et al.,* 1997, Document ID 0974). Scleroderma is a degenerative disorder that leads to over-production of collagen in connective tissue that can cause a wide variety of symptoms including skin discoloration and ulceration, joint pain, swelling and discomfort in the extremities, breathing problems, and digestive problems. Rheumatoid arthritis is characterized by joint pain and tenderness, fatigue, fever, and weight loss. Systemic lupus erythematosus is a chronic disease of connective tissue that can present a wide range of symptoms including skin rash, fever, malaise, joint pain, and, in many cases, anemia and iron deficiency. OSHA considers chronic renal disease, end-stage renal disease mortality, granulomatosis with polyangitis, scleroderma, rheumatoid arthritis, and systemic lupus erythematosus clearly to be material impairments of health.

C. OSHA's Final Quantitative Risk Estimates

To evaluate the significance of the health risks that result from exposure to hazardous chemical agents, OSHA relies on epidemiological and experimental data, as well as statistical methods. The Agency uses these data and methods to characterize the risk of disease resulting from workers' exposure to a given hazard over a working lifetime at levels of exposure reflecting both compliance with previous standards and compliance with the new standard. In the case of respirable crystalline silica, the previous general industry, construction, and shipyard PELs were formulas that limit 8-hour TWA exposures to respirable dust; the limit on exposure decreased with increasing crystalline silica content of the dust. OSHA's previous general industry PEL for respirable quartz was expressed both in terms of a particle count and a gravimetric concentration, while the previous construction and shipyard employment PELs for respirable quartz were only expressed in terms of a particle count formula. For general industry, the gravimetric formula PEL for quartz approaches 100 µg/m^3 of respirable crystalline silica when the quartz content of the dust is about 10 percent or greater. The previous PEL's particle count formula for the construction and shipyard industries is equal to a range of about 250 µg/m^3 to 500 µg/m^3 expressed as respirable quartz. In general industry, the previous PELs for cristobalite and tridymite, which are forms (polymorphs) of silica, were one-half the PEL for quartz.

In this final rule, OSHA has established a uniform PEL for respirable crystalline silica by revising the PELs applicable to general industry, construction, and maritime to 50 µg/m^3 TWA of respirable crystalline silica. OSHA has also established an action level of 25 µg/m^3 TWA. In this section of the preamble, OSHA presents its final estimates of health risks associated with a working lifetime (45 years) of exposure to 25, 50, and 100 µg/m^3 respirable crystalline silica. These levels represent the risks associated with exposure over a working lifetime to the new action level, new PEL, and previous general industry PEL, respectively. OSHA also presents estimates associated with exposure to 250 and 500 µg/m^3 to represent a range of risks likely to be associated with exposure to the former construction and shipyard PELs. Risk estimates are presented for mortality due to lung cancer, silicosis and other non-malignant respiratory disease (NMRD),

and end-stage renal disease, as well as silicosis morbidity. These estimates are the product of OSHA's risk assessment, following the Agency's consideration of new data introduced into the rulemaking record and of the numerous comments in the record that raised questions about OSHA's preliminary findings and analysis.

After reviewing the evidence and testimony in the record, OSHA has determined that it is appropriate to base its final risk estimates on the same studies and models as were used in the NPRM (*see* Section V.C, Summary of the Review of Health Effects Literature and Preliminary QRA). For mortality risk estimates, OSHA used the models developed by various investigators and employed a life table analysis to implement the models using the same background all-cause mortality data and consistent assumption for length of lifetime (85 years). The life table is a technique that allows estimation of excess risk of disease mortality factoring in the probability of surviving to a particular age assuming no exposure to the agent in question and given the background probability of dying from any cause at or before that age (*see* Section V.M, Comments and Responses Concerning Working Life, Life Tables, and Dose Metric). Since the time of OSHA's preliminary analysis, the National Center for Health Statistics (NCHS) released updated all-cause mortality background rates from 2011; these rates are available in an internet web-based query by year and 2010 International Classification of Diseases (ICD) code through the Centers of Disease Control and Prevention (CDC) Wonder database (*http://wonder.cdc.gov/udc-icd10.html*). Using these updated statistics, OSHA revised its life table analyses to estimate lifetime risks of mortality that result from 45 years of exposure to respirable crystalline silica. OSHA's final quantitative mortality risk estimates are presented in Table VI–1 below.

For silicosis morbidity risk estimates, OSHA relied on the cumulative risk models developed by investigators of five studies who conducted studies relating cumulative disease risk to cumulative exposure to respirable crystalline silica (*see* footnotes to Table VI–1). Of these, only one, the study by Steenland and Brown (1995) of U.S. gold miners, employed a life-table analysis. Table VI–1 also presents OSHA's final quantitative estimates of silicosis morbidity risks.

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Table VI-1. Summary of Lifetime or Cumulative Risk Estimates for Crystalline Silica*

Health Endpoint (Source)	Risk Associated with 45 Years of Occupational Exposure (per 1,000 Workers)				
	Respirable Crystalline Silica Exposure ($\mu g/m^3$)				
	25	50	100	250	500
Lung Cancer Mortality (Lifetime Risk)					
Pooled Analysis, ToxaChemica, Inc (2004)[a,b]	10-21	16-23	20-26	24-30	32-33
Diatomaceous Earth Worker study (Rice et al., 2001)[a,c]	8	15	30	72	137
U.S. Granite Worker study (Attfield and Costello, 2004)[a,d]	10	22	54	231	657
North American Industrial Sand Worker study (Hughes et al., 2001)[a,e]	7	14	33	120	407
British Coal Miner study (Miller and MacCalman, 2009)[a,f]	3	5	11	33	86
Silicosis and Non-Malignant Lung Disease Mortality (Lifetime Risk)					
Pooled Analysis (ToxaChemica, Inc., 2004) (silicosis)[g]	4	7	11	17	22
Diatomaceous Earth Worker study (Park et al., 2002) (NMRD)[h]	22	44	85	192	329
Renal Disease Mortality (Lifetime Risk)					
Pooled Cohort study (Steenland et al., 2002a)[i]	25	32	39	52	63
Silicosis Morbidity (Cumulative Risk)					
Chest x-ray category of 2/1 or greater (Buchanan et al., 2003)[j]	21	55	301	994	1,000
Silicosis mortality and/or x-ray of 1/1 or greater (Steenland and Brown, 1995b)[k]	31	75	440	601	634
Chest x-ray category of 1/1 or greater (Hnizdo and Sluis-Cremer, 1993)[l]	6	127	773	995	1,000
Chest x-ray category of 1or greater (Chen et al., 2001)[m]	40	170	590	1,000	1,000
Chest x-ray category of 1or greater (Chen et al., 2005)[n]					
Tin miners	40	100	400	950	1,000
Tungsten miners	5	20	120	750	1,000
Pottery workers	5	20	60	300	700

* The numbers in these tables represent central estimates based on the given underlying study. Although they account for data uncertainty, they do not always account for model uncertainty. Furthermore, the strength of the evidence available for each of the health effects listed varies. For instance, we are less certain about the causality determination for renal mortality than for lung cancer mortality and silicosis mortality and morbidity. See accompanying text for a discussion of the uncertainties around these risk estimates, which vary in kind and magnitude.

[a] Lifetime risks through age 85 calculated from a life table that accounts for competing causes of death. Background all-cause and lung cancer mortality rates are 2011 rates for all males (National Center for Health Statistics, accessed at http://wonder.cdc.gov/ucd-icd10.html). Background lung cancer mortality rate is based on ICD-10 categories C-33-C34, malignant neoplasms of trachea, bronchus, lung. Exposure to crystalline

silica is assumed to occur at ages 20 through 65.
[b] Range based on three models (log-linear, linear, and linear spline, see Table II-2 of Document ID 1711, p. 290).
[c] Based on the linear relative risk model with exposures lagged 10 years, RR = 1 + (0.1441*E) where E is cumulative respirable crystalline silica exposure in mg/m^3-yrs.
[d] Based on the log-linear relative risk model with exposures lagged 15 years, RR = exp(0.19*E) where E is cumulative respirable crystalline silica exposure in mg/m^3-yrs.
[e] Based on the log-linear relative risk model with exposures lagged 15 years, RR = exp(0.13*E) where E is cumulative respirable crystalline silica exposure in mg/m^3-yrs.
[f] Based on the log-linear relative risk model with exposures lagged 15 years, RR = exp(0.0524*E) where E is cumulative respirable crystalline silica exposure in mg/m^3-yrs.
[g] Estimates derived from rate ratios based on the categorical model after accounting for exposure measurement uncertainty, from Table 7 of ToxaChemica, Inc. (2004, Document ID 0469). Absolute risk calculated as 1 – exp(-∑time*rate), where rate is the rate ratio for a given cumulative exposure times a base rate of 4.7E-5.
[h] Estimated by OSHA based on the Park et al. (2002, Document ID 0405) linear relative rate model, RR = 1 + (0.5469*E) where E is cumulative respirable crystalline silica exposure in mg/m^3-yrs. Lifetime risks through age 85 calculated from a life table that accounts for competing causes of death. Background all-cause and non-malignant lung disease mortality rates are 2011 rates for all males (National Center for Health Statistics, accessed at http://wonder.cdc.gov/ucd-icd10.html). Non-malignant lung disease mortality rates reflect those for ICD-10 disease codes J40-J47 (chronic lower respiratory diseases) and J60-J66 (pneumoconioses and chemical effects). Exposure to crystalline silica is assumed to begin at age 20 through age 65.
[i] Estimated by OSHA based on the Steenland et al. (2002a, Document ID 0448) log-linear model with log cumulative exposure, RR = exp(0.269(lnE)) where E is cumulative respirable crystalline silica exposure in mg/m^3-days. Lifetime risks through age 85 were calculated from a life table that accounts for competing causes of death. Background all-cause and end-stage renal disease (ESRD) are 1998 rates for all males (National Center for Health Statistics, 2005, Document ID 1105). Background ESRD mortality rates reflect those for ICD-9 disease codes 580-589. Exposure to crystalline silica is assumed to begin at age 20 through age 65 with 250 days per year of exposure.
[j] Estimated by OSHA from the equation Prob(2/1+) = exp-(-4.83 + 0.443*cum. quartz$_{<2.0\ mg/m^3}$)/ (1+exp-(-4.83 + 0.443*cum. quartz$_{<2.0\ mg/m^3}$)), where "cum. quartz" is cumulative respirable silica exposure in g-hm^3, with one year of work = 2000 hours (250 days per year x 8 hours per day). Exposure to crystalline silica is assumed to begin at age 20 through age 65. Age of cohort at follow-up was between 50 and 74 years.
[k] Lifetime risks through age 85 calculated from a life table that accounts for competing causes of death. Background all-cause mortality rates are 2011 rates for all males (National Center for Health Statistics, accessed at http://wonder.cdc.gov/ucd-icd10.html). Silicosis rate is age- and calendar-time-adjusted, from Table 2 of Steenland et al. (1995b, Document ID 0451). Exposure to crystalline silica is assumed to begin at age 20 through age 65, with no exposure lag.
[l] Estimated by OSHA from the equation CR = 1 – {1/[1 + exp(2.439/.2199)*CDE$^{1/.2199}$]}, where CR is cumulative risk and CDE is cumulative respirable dust exposure in mg/m^3-yrs; assumed quartz content of respirable dust is 30 percent. Assumed 45 years of exposure. Mean age of cohort at onset was 55.9 years (range 38-74).
[m] Estimated by OSHA from the equation CR = 1-exp(-(0.0076*E)$^{2.23}$) where E is cumulative exposure to total dust. Respirable crystalline silica reported by Chen et al. (2001, Document ID 0332) to be 3.6 percent of total dust. Assumed 45 years of exposure. Mean age at onset was 48.3 years.
[n] Estimated from Figure 2B in Chen et al. (2005, Document ID 0985) showing cumulative risk vs. cumulative exposure to respirable crystalline silica. Mean age at onset was 47.9, 41.8, and 52.5 years for tin, tungsten, and pottery workers, respectively.

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OSHA notes that the updated risk estimates are not substantially different from those presented in the Preliminary QRA; for example, for exposure at the previous general industry PEL approaching 100 µg/m³, the excess lung cancer mortality risk ranged from 13 to 60 deaths per 1,000 workers using the original 2006 background data, and from 11 to 54 deaths per 1,000 workers using the updated 2011 background data. For exposure at the revised PEL of 50 µg/m³, the risk estimates ranged from 6 to 26 deaths per 1,000 workers using the 2006 background data, and 5 to 23 deaths per 1,000 workers using the 2011 background data. Similarly, the updated risk estimates for NMRD are not substantially different; for example, for exposure for 45 working years at the previous general industry PEL approaching 100 µg/m³, the excess NMRD mortality risk, using the Park *et al.* (2002, Document 0405) model was 83 deaths per 1,000 workers using the original 2006 background data, and 85 deaths per 1,000 workers using the updated 2011 background data. For exposure at the revised PEL of 50 µg/m³, the risk estimate was 43 deaths per 1,000 workers using the 2006 background data, and 44 deaths per 1,000 workers using the 2011 background data.

OSHA also presents in the table the excess lung cancer mortality risk associated with 45 years of exposure to the previous construction/shipyard PEL (in the range of 250 to 500 µg/m³). It should be noted, however, that exposure to 250 or 500 µg/m³ over 45 years represents cumulative exposures of 11.25 and 22.5 mg/m³-yrs, respectively, which are well above the median cumulative exposure for most of the cohorts used in the risk assessment. Estimating excess risks over this higher range of cumulative exposures required some degree of extrapolation, which adds uncertainty. In addition, at cumulative exposures as high as permitted by the previous construction and maritime PELs, silica-related causes of mortality will compete with each other and it is difficult to determine the risk of any single cause of mortality in the face of such competing risks.

OSHA's final risk estimates for renal disease reflect the 1998 background all-cause mortality and renal mortality rates for U.S. males, rather than the 2011 rates used for lung cancer and NMRD, as updated in the previous sections. Background rates were not adjusted for the renal disease risk estimates because the CDC significantly changed the classification of renal diseases after 1998; they are now inconsistent with those used by Steenland *et al.* (2002a, Document ID 0448), the study relied on by OSHA, to ascertain the cause of death of workers in their study. OSHA notes that the change in classification system, from ICD–9 to ICD–10, did not materially affect background rates for diseases grouped as lung cancer or NMRD. The findings from OSHA's final risk assessment are summarized below.

OSHA notes that the key studies in its final risk assessment were composed of

cohorts with cumulative exposures relevant to those permitted by the preceding General Industry PEL (45 years of exposure at 100 µg/m³ equals 4.5 mg/m³-yrs). Table VI–2 provides the reported cumulative exposure information for each of the cohorts of the key studies. Most of these cohorts had mean or median cumulative exposures below 4.5 mg/m³-yrs. Based on this data, OSHA concludes that the cumulative exposures experienced by the cohorts are relevant and reasonable for use in the Agency's final risk assessment.

Table VI-2. Cumulative Exposure Data for the Cohorts in the Key Studies

Cohort	Study	Reported Cumulative Silica Exposure (mg/m³-yrs)		
		Median	Mean	Distribution*
U.S. diatomaceous earth workers	• ToxaChemica (2004) pooled[ab] (Checkoway et al. 1997) • Rice et al. (2001) lung cancer • Park et al. (2002) NMRD mortality	1.05	 2.16 2.16	 max 62.52 max 62.52
U.S. granite workers	• ToxaChemica (2004) pooled[abc] (Costello & Graham 1988) • Attfield and Costello (2004) lung cancer mortality	0.71 0.72	 2.1	 sd 3.8; 10th 0.02; 90th 6.4
U.S. industrial sand workers	• ToxaChemica (2004) pooled[abc] (Steenland et al. 2001b)	0.13		
S. Africa gold miners	• ToxaChemica (2004) pooled[a] (Hnizdo et al. 1997) • Hnizdo and Sluis-Cremer (1993) silicosis morbidity[f]	4.23	 1.98	 sd 0.81; range 0.36-5.61
U.S. gold miners	• ToxaChemica (2004) pooled[abc] (Steenland & Brown 1995a) • Steenland and Brown (1995b) silicosis morbidity	0.23	 2.58 (silicotics) 0.54 (non-silicotics)	 sd 1.31 (silicotics) sd 0.79 (non-silicotics)
Australian gold miners	• ToxaChemica (2004) pooled[ab] (de Klerk & Musk 1998)	11.37		
Finnish granite workers	• ToxaChemica (2004) pooled[ab] (Koskela et al. 1994)	4.63		
Chinese tin miners	• ToxaChemica (2004) pooled[a] (Chen et al. 1992) • Chen et al. (2001) silicosis morbidity[e] • Chen et al. (2005) silicosis morbidity	5.27[d]	 2.43[g]	 range 0.2-6
Chinese tungsten miners	• ToxaChemica (2004) pooled[a] (Chen et al. 1992) • Chen et al. (2005) silicosis morbidity	8.56[d]	 3.24[g]	
Chinese pottery workers	• ToxaChemica (2004) pooled[a] (Chen et al. 1992) • Chen et al. (2005) silicosis morbidity	6.07[d]	 6.37[g]	
Pooled lung cancer mortality	• ToxaChemica (2004) (Steenland et al. 2001a, 10 cohorts)	4.27		
Pooled silicosis mortality	• ToxaChemica (2004) (Mannetje et al. 2002b, 6 cohorts)	0.62		
Pooled renal mortality	• Steenland et al. (2002a, 3 cohorts)		1.2	
North American industrial sand workers	• Hughes et al. (2001) lung cancer mortality	2.487 (controls) 2.732 (cases)		25th 0.982 (controls), 1.114 (cases) 75th 5.394 (controls), 5.195 (cases)
British coal miners	• Miller and MacCalman (2009) lung cancer mortality[h] • Buchanan et al. (2003)	2.63-3.08	3.59-4.03	25th 0.87-1.49; 75th 5.16-5.67; max 21.40-24.53

* max = maximum; sd = standard deviation; X^{th} = X^{th} percentile; range = minimum to maximum observed

[a] Study used in the pooled lung cancer mortality analysis. [b] Study used in the pooled silicosis mortality analysis. [c] Study used in the pooled renal disease mortality analysis.

[d] Steenland et al. (2001a, Document ID 0452, p. 775) reported that 50%, 40%, and 24% of Chinese pottery, tin, and tungsten cohorts were in largely unexposed jobs; reported median values are for exposed workers only.

[e] Authors stated that Chinese total dust contains about 3.6% respirable crystalline silica.

[f] Authors assumed respirable dust contains about 30% silica.

[g] Calculated by multiplying the reported cumulative total dust concentration (Table II in Chen et al., 2005, Document ID 0985) by the conversion factors in Table AII.

[h] Ranges of reported results from five different surveys.

1. Summary of Excess Risk Estimates for Lung Cancer Mortality

For estimates of lung cancer risk from crystalline silica exposure, OSHA has relied upon studies of exposure-response relationships presented in a pooled analysis of 10 cohort studies (Steenland *et al.*, 2001a, Document ID 0452; ToxaChemica, Inc., 2004, 0469) as well as on individual studies of granite (Attfield and Costello, 2004, Document ID 0543), diatomaceous earth (Rice *et al.*, 2001, Document ID 1118), and industrial sand (Hughes *et al.*, 2001, Document ID 1060) worker cohorts, and a study of coal miners exposed to respirable crystalline silica (Miller *et al.*, 2007, Document ID 1305; Miller and MacCalman, 2009, 1306). OSHA found these studies to have been suitable for use to quantitatively characterize health risks to exposed workers because: (1) Study populations were of sufficient size to provide adequate statistical power to detect low levels of risk; (2) sufficient quantitative exposure data were available over a sufficient span of time to characterize cumulative exposures of cohort members to respirable crystalline silica; (3) the studies either adjusted for or otherwise adequately addressed confounding factors such as smoking and exposure to other carcinogens; and (4) investigators developed quantitative assessments of exposure-response relationships using appropriate statistical models or otherwise provided sufficient information that permits OSHA to do so. OSHA implemented all risk models in its own life table analysis so that the use of background lung cancer rates and assumptions regarding length of exposure and lifetime were consistent across each of the models, and so OSHA could estimate lung cancer risks associated with exposure to specific levels of silica of interest to the Agency.

The Steenland *et al.* (2001a, Document ID 0452) study consisted of a pooled exposure-response analysis and risk assessment based on raw data obtained for ten cohorts of silica-exposed workers (65,980 workers, 1,072 lung cancer deaths). The cohorts in this pooled analysis include U.S. gold miners (Steenland and Brown, 1995a, Document ID 0450), U.S. diatomaceous earth workers (Checkoway *et al.*, 1997, Document ID 0326), Australian gold miners (de Klerk and Musk, 1998, Document ID 0345), Finnish granite workers (Koskela *et al.*, 1994, Document ID 1078), South African gold miners (Hnizdo *et al.*, 1997, Document ID 1049), U.S. industrial sand workers (Steenland *et al.*, 2001b, Document ID 0456), Vermont granite workers (Costello and Graham, 1988, Document ID 0991), and Chinese pottery workers, tin miners, and tungsten miners (Chen *et al.*, 1992, Document ID 0329). To determine the exposure-response relationship between silica exposures and lung cancer, the investigators used a nested case-control design with cases and controls matched for race, sex, age (within five years), and study; 100 controls were matched for each case. An extensive exposure assessment for this pooled analysis was developed and published by Mannetje *et al.* (2002a, Document ID 1090).

Using ToxaChemica's study (2004, Document ID 0469) of this pooled data, the estimated excess lifetime lung cancer risk associated with 45 years of exposure to 100 μg/m^3 (about equal to the previous general industry PEL) is between 20 and 26 deaths per 1,000 workers. The estimated excess lifetime risk associated with 45 years of exposure to silica concentrations in the range of 250 and 500 μg/m^3 (about equal to the previous construction and shipyard PELs) is between 24 and 33 deaths per 1,000. At the final PEL of 50 μg/m^3, the estimated excess lifetime risk ranges from 16 to 23 deaths per 1,000, and, at the action level of 25 μg/m^3, from 10 to 21 deaths per 1,000.

In addition to the pooled cohort study, OSHA's Final Quantitative Risk Assessment presents risk estimates in Table VI–1 derived from four individual studies where investigators presented either lung cancer risk estimates or exposure-response coefficients. Two of these studies, one on diatomaceous earth workers (Rice *et al.*, 2001, Document ID 1118) and one on Vermont granite workers (Attfield and Costello, 2004, Document ID 0543), were included in the 10-cohort pooled study (Steenland *et al.*, 2001a, Document ID 0452; ToxaChemica Inc., 2004, 0469). The other two were of British coal miners (Miller *et al.*, 2007, Document ID 1305; Miller and MacCalman, 2009,1306) and North American industrial sand workers (Hughes *et al.*, 2001, Document ID 1060).

Rice *et al.* (2001, Document ID 1118) presented an exposure-response analysis of the diatomaceous worker cohort studied by Checkoway *et al.* (1993, Document ID 0324; 1996, 0325; 1997, 0326), who found a significant relationship between exposure to respirable cristobalite and increased lung cancer mortality. From this cohort the estimates of the excess risk of lung cancer mortality are 30, 15, and 8 deaths per 1,000 workers for 45 years of exposure to 100, 50, and 25 μg/m^3, respectively. For exposures in the range of the current construction and shipyard PELs over 45 years, estimated risks lie in a range between 72 and 137 excess deaths per 1,000 workers.

Somewhat higher risk estimates are derived from the analysis presented by Attfield and Costello (2004, Document ID 0543) of Vermont granite workers. OSHA's use of this analysis yielded a risk estimate of 54 excess deaths per 1,000 workers for 45 years of exposure to the previous general industry PEL of 100 μg/m^3, 22 excess deaths per 1,000 for 45 years of exposure to the final PEL of 50 μg/m^3, and 10 excess deaths per 1,000 for 45 years of exposure at the action level of 25 μg/m^3. Estimated excess risks associated with 45 years of exposure at the current construction PEL range from 231 to 657 deaths per 1,000.

Hughes *et al.* (2001, Document ID 1060) conducted a study of industrial sand workers in the U.S. and Canada. Using this study, OSHA estimated cancer risks of 33, 14, and 7 deaths per 1,000 for 45 years exposure to the previous general industry PEL of 100 μg/m^3, the final PEL of 50 μg/m^3, and the final action level of 25 μg/m^3 respirable crystalline silica, respectively. For 45 years of exposure to the previous construction PEL, estimated risks range from 120 to 407 deaths per 1,000 workers.

Miller and MacCalman (2010, Document ID 1306; also reported in Miller *et al.*, 2007, Document ID 1305) presented a study of miners from 10 coal mines in the U.K. Based on this study, OSHA estimated the lifetime lung cancer mortality risk to be 11 per 1,000 workers for 45 years of exposure to 100 μg/m^3 respirable crystalline silica. For the final PEL of 50 μg/m^3 and action level of 25 μg/m^3, the lifetime risks are estimated to be 5 and 3 deaths per 1,000, respectively. The range of risks estimated to result from 45 years of exposure to the previous construction and shipyard PELs is from 33 to 86 deaths per 1,000 workers.

2. Summary of Risk Estimates for Silicosis and Other Chronic Lung Disease Mortality

OSHA based its quantitative assessment of silicosis mortality risks on a pooled analysis conducted by Mannetje *et al.* (2002b, Document ID 1089) of data from six of the ten epidemiological studies in the Steenland *et al.* (2001a, Document ID 0452) pooled analysis of lung cancer mortality that also included extensive data on silicosis. Cohorts included in the silicosis study were: U.S. diatomaceous earth workers (Checkoway *et al.*, 1997, Document ID 0326); Finnish granite workers (Koskela

et al., 1994, Document ID 1078); U.S. granite workers (Costello and Graham, 1988, Document ID 0991); U.S. industrial sand workers (Silicosis and Silicate Disease Committee, 1988, Document ID 0455); U.S. gold miners (Steenland and Brown, 1995b, Document ID 0451); and Australian gold miners (de Klerk and Musk, 1998, Document ID 0345). These six cohorts contained 18,634 workers and 170 silicosis deaths, where silicosis mortality was defined as death from silicosis (ICD–9 502, n = 150) or from unspecified pneumoconiosis (ICD–9 505, n = 20). Although Mannetje *et al*, (2002b, Document ID 1089) estimated silicosis risks from a Poisson regression, a subsequent analysis was conducted by Steenland and Bartell (ToxaChemica, 2004, Document ID 0469) based on a case control design. Based on the Steenland and Bartell analysis, OSHA estimated that the lifetime risk of silicosis mortality associated with 45 years of exposure to the previous general industry PEL of 100 μg/m^3 is 11 deaths per 1,000 workers. Exposure for 45 years to the final PEL of 50 μg/m^3 results in an estimated 7 silicosis deaths per 1,000, and exposure for 45 years to the final action level of 25 μg/m^3 results in an estimated 4 silicosis deaths per 1,000. Lifetime risks associated with exposure at the previous construction and shipyard PELs range from 17 to 22 deaths per 1,000 workers.

To study non-malignant respiratory diseases (NMRD), of which silicosis is one, Park *et al.* (2002, Document ID 0405) analyzed the California diatomaceous earth cohort data originally studied by Checkoway *et al.* (1997, Document ID 0326). The authors quantified the relationship between exposure to cristobalite and mortality from NMRD. Diseases in this category included pneumoconiosis (which includes silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. Because of the broader range of silica-related diseases examined by Park *et al.*, OSHA's estimates of the lifetime chronic lung disease mortality risk based on this study are substantially higher than those that OSHA derived from the Mannetje *et al.* (2002b, Document ID 1089) silicosis analysis. For the previous general industry PEL of 100 μg/m^3, exposure for 45 years is estimated to result in 85 excess deaths per 1,000 workers. At the final PEL of 50 μg/m^3 and action level of 25 μg/m^3, OSHA estimates the lifetime risk from 45 years of exposure to be 44 and 22 excess deaths per 1,000, respectively. The range of risks associated with exposure at the former construction and shipyard PELs over a working lifetime is from 192 to 329 excess deaths per 1,000 workers.

3. Summary of Risk Estimates for Renal Disease Mortality

OSHA's analysis of the health effects literature included several studies that have demonstrated that exposure to respirable crystalline silica increases the risk of renal and autoimmune disease (*see* Document ID 1711, Review of Health Effects Literature and Preliminary QRA, pp. 208–229). For autoimmune disease, there was insufficient data on which to base a quantitative risk assessment. OSHA's assessment of the renal disease risks that result from exposure to respirable crystalline silica is based on an analysis of pooled data from three cohort studies (Steenland *et al.*, 2002a, Document ID 0448). The combined cohort for the pooled analysis (Steenland *et al.*, 2002a, Document ID 0448) consisted of 13,382 workers and included industrial sand workers (Steenland *et al.*, 2001b, Document ID 0456), U.S. gold miners (Steenland and Brown, 1995a, Document ID 0450), and Vermont granite workers (Costello and Graham, 1988, Document ID 0991). Exposure data were available for 12,783 workers and analyses conducted by the original investigators demonstrated monotonically increasing exposure-response trends for silicosis, indicating that exposure estimates were not likely subject to significant random misclassification. The mean duration of exposure, cumulative exposure, and concentration of respirable silica for the combined cohort were 13.6 years, 1.2 mg/m^3-years, and 70 μg/m^3, respectively. There were highly statistically significant trends for increasing renal disease mortality with increasing cumulative exposure for both multiple cause analysis of mortality ($p < 0.000001$) and underlying cause analysis ($p = 0.0007$). OSHA's estimates of renal disease mortality risk based on this study are 39 deaths per 1,000 for 45 years of exposure at the previous general industry PEL of 100 μg/m^3, 32 deaths per 1,000 for exposure at the final PEL of 50 μg/m^3, and 25 deaths per 1,000 at the action level of 25 μg/m^3. OSHA also estimates that 45 years of exposure at the previous construction and shipyard PELs would result in a renal disease excess mortality risk ranging from 52 to 63 deaths per 1,000 workers. OSHA acknowledges that the risk estimates for end-stage renal disease mortality are less robust than those for silicosis, lung cancer, and NMRD, and are thus more uncertain.

4. Summary of Risk Estimates for Silicosis Morbidity

OSHA's Final Quantitative Risk Assessment is based on several cross-sectional studies designed to characterize relationships between exposure to respirable crystalline silica and development of silicosis as determined by chest radiography. Due to the long latency periods associated with silicosis, OSHA relied on those studies that were able to contact and evaluate many of the workers who had retired. OSHA believes that relying on studies that included retired workers comes closest to characterizing lifetime risk of silicosis morbidity. OSHA identified studies of six cohorts for which the inclusion of retirees was deemed sufficient to adequately characterize silicosis morbidity risks well past employment (Hnizdo and Sluis-Cremer, 1991, Document ID 1051; Steenland and Brown, 1995b, 0451; Miller *et al.*, 1998, 0374; Buchanan *et al.*, 2003, 0306; Chen *et al.*, 2001, 0332; Chen *et al.*, 2005, 0985). Study populations included five mining cohorts and a Chinese pottery worker cohort. With the exception of a coal miner study (Buchanan *et al.*, 2003, Document ID 0306), risk estimates reflected the risk that a worker will acquire an abnormal chest x-ray classified as ILO major category 1 or greater; the coal miner study evaluated the risk of acquiring an abnormal chest x-ray classified as major category 2 or higher.

For miners exposed to freshly cut respirable crystalline silica, OSHA estimates the risk of developing lesions consistent with an ILO classification of category 1 or greater to range from 120 to 773 cases per 1,000 workers exposed at the previous general industry PEL of 100 μg/m^3 for 45 years; from 20 to 170 cases per 1,000 workers exposed at the final PEL of 50 μg/m^3; and from 5 to 40 cases per 1,000 workers exposed at the new action level of 25 μg/m^3. From the coal miner study of Buchanan *et al.*, (2003, Document ID 0306), OSHA estimates the risks of acquiring an abnormal chest x-ray classified as ILO category 2 or higher to be 301, 55, and 21 cases per 1,000 workers exposed for 45 years to 100, 50, and 25 μg/m^3, respectively. These estimates are within the range of risks obtained by OSHA from the other mining studies. At exposures at or above 250 μg/m^3 (equivalent to the previous construction and shipyard PELs) for 45 years, the risk of acquiring an abnormal chest x-ray approaches 100 percent. OSHA's risk estimates based on the pottery cohort are 60, 20, and 5 cases per 1,000

workers exposed for 45 years to 100, 50, and 25 μg/m³, respectively, which is generally below the range of risks estimated from the other studies and may reflect a lower toxicity of quartz particles in that work environment due to the presence of aluminosilicates on the particle surfaces (*see* Section V.N, Comments and Responses Concerning Physico-chemical and Toxicological Properties of Respirable Crystalline Silica); they are still well over OSHA's 1 in a 1,000 workers benchmark for setting standards, however. According to Chen *et al.* (2005, Document ID 0985), adjustment of the exposure metric to reflect the unoccluded surface area of silica particles resulted in an exposure-response of pottery workers that was similar to the mining cohorts, indicating that the occluded surface reduced the toxic potency of the quartz particles. The finding of a reduced silicosis risk among pottery workers is consistent with other studies of clay and brick industries that have reported finding a lower prevalence of silicosis compared to that experienced in other industry sectors (Love *et al.*, 1999, Document ID 0369; Hessel, 2006, 1299; Miller and Soutar, 2007, 1098) as well as a lower silicosis risk per unit of cumulative exposure (Love *et al.*, 1999, Document ID 0369; Miller and Soutar, 2007, 1098).

D. Significance of Risk and Risk Reduction

In this section, OSHA presents its final findings with respect to the significance of the risks summarized above and the potential of the proposed standard to reduce those risks. Findings related to mortality risk will be presented first, followed by silicosis morbidity risks.

1. Mortality Risks

OSHA's Final Quantitative Risk Assessment described above presents risk estimates for four causes of excess mortality: Lung cancer, silicosis, non-malignant respiratory disease (including silicosis), and renal disease. Table VI–1 above presents OSHA's estimated excess lifetime risks (*i.e.*, to age 85, following 45 years of occupational exposure) of these fatal diseases associated with various levels of respirable crystalline silica exposure allowed under the former PELs and the final PEL and action level promulgated herein. OSHA's mortality risk estimates represent ''excess'' risks in the sense that they reflect the risk of dying from disease over and above that of persons who are not occupationally exposed to respirable crystalline silica.

Assuming a 45-year working life, as OSHA has done in significant risk determinations for previous standards, the Agency finds that the excess risk of disease mortality related to exposure to respirable crystalline silica at levels permitted by the previous OSHA standards is clearly significant. The Agency's estimate of such risk falls well above the level of risk the Supreme Court indicated a reasonable person would consider unacceptable (*Benzene*, 448 U.S. 607, 655). For lung cancer, OSHA estimates the range of risk at the previous general industry PEL to be between 11 and 54 deaths per 1,000 workers. The estimated risk for silicosis mortality is 11 deaths per 1,000 workers; however, the estimated lifetime risk for non-malignant respiratory disease (NMRD) mortality, including silicosis, is about 8-fold higher than that for silicosis alone, at 85 deaths per 1,000. This higher estimate for NMRD is better than the estimate for silicosis mortality at capturing the total respiratory disease burden associated with exposure to crystalline silica dust. The former captures deaths related to other non-malignant diseases, including chronic bronchitis and emphysema, for which there is strong evidence of a causal relationship with exposure to silica, and is also more likely to capture those deaths where silicosis was a contributing factor but where the cause of death was misclassified. Finally, there is an estimated lifetime risk of renal disease mortality of 39 deaths per 1,000. Exposure for 45 years at levels of respirable crystalline silica in the range of the previous limits for construction and shipyards results in even higher risk estimates, as presented in Table VI–1. It should be noted that these risk estimates are not additive because some individuals may suffer from multiple diseases caused by exposure to silica.

To further demonstrate significant risk, OSHA compares the risks at the former PELs and the revised PEL for respirable crystalline silica to risks found across a broad variety of occupations. OSHA also compares the lung cancer risk associated with the former PELs and revised PEL to the risks for other carcinogens OSHA regulates. The Agency has used similar occupational risk comparisons in the significant risk determinations for other substance-specific standards.

Fatal injury rates for most U.S. industries and occupations may be obtained from data collected by the Department of Labor's Bureau of Labor Statistics (BLS). Table VI–3 shows annual fatality rates per 1,000 employees for several industries for 2013, as well as projected fatalities per 1,000 employees assuming exposure to workplace hazards for 45 years based on these annual rates. While it is difficult to meaningfully compare aggregate industry fatality rates to the risks estimated in the quantitative risk assessment for respirable crystalline silica, which address one specific hazard (inhalation exposure to respirable crystalline silica) and several health outcomes (lung cancer, silicosis, NMRD, renal disease mortality), these rates provide a useful frame of reference for considering risk from inhalation exposure to crystalline silica. For example, OSHA's estimated range of 5–54 excess lung cancer deaths per 1,000 workers from regular occupational exposure to respirable crystalline silica in the range of 50–100 μg/m³ is roughly comparable to, or higher than, the expected risk of fatal injuries over a working life in high-risk occupations such as mining and construction (*see* Table VI–3). Regular exposures at higher levels, including the previous construction and shipyard PELs for respirable crystalline silica, are expected to cause substantially more deaths per 1,000 workers from lung cancer alone (ranging from 24 to 657 per 1,000) than result from occupational injuries in most private industry. At the final PEL of 50 μg/m³ respirable crystalline silica, the Agency's estimate of excess lung cancer mortality, from 5 to 23 deaths per 1,000 workers, is still 3- to 15-fold higher than private industry's average fatal injury rate, given the same employment time, and substantially exceeds those rates found in lower-risk industries such as finance and educational and health services. Adding in the mortality from silicosis, NMRD, and renal disease would make these comparisons even more stark.

Table VI-3: Fatal Injuries per 1,000 Employees, by Industry or Sector

	Annual Rate	Over 45 years
All Private Industry	0.033	1.5
Mining (General)	0.124	5.6
Construction	0.097	4.4
Manufacturing	0.021	0.094
Wholesale Trade	0.053	2.4
Transportation and Warehousing	0.14	6.3
Financial Activities	0.009	0.41
Educational and Health Services	0.007	0.31

Source: BLS (2013, http://www.bls.gov/iif/oshwc/cfoi/cfch0012.pdf).

Note: OSHA estimated the 45-year fatality risk (R) using the formula $R=[(1-p^{45})*1,000]$, where p is the probability of surviving in one year, i.e., 1 – (Annual Fatality Rate/1,000).

Because there is little available information on the incidence of occupational cancer across all industries, risk from crystalline silica exposure cannot be compared with overall risk from other workplace carcinogens. However, OSHA's previous risk assessments provide estimates of risk from exposure to certain carcinogens. These risk assessments, as with the current assessment for respirable crystalline silica, were based on animal or human data of reasonable or high quality and used the best information then available. Table VI–4 shows the Agency's best estimates of cancer risk from 45 years of occupational exposure to several carcinogens, as published in the preambles to final rules promulgated since the *Benzene* decision in 1980.

Table VI-4: Selected OSHA Risk Estimates for Prior and Current PELs (Excess Cancers per 1,000 Workers)

Standard	Risk at Prior PEL	Risk at Current PEL	Federal Register Date
Ethylene Oxide	63-109 per 1000	1.2-2.3 per 1000	June 22, 1984
Asbestos	64 per 1000	6.7 per 1000	June 20, 1986
Benzene	95 per 1000	10 per 1000	September 11, 1987
Formaldehyde	*0.43-18.9 per 1000	*0.0056-2.64 per 1000	December 4, 1987
Methylenedianiline	**6-30 per 1000	0.8 per 1000	August 10, 1992
Cadmium	58-157 per 1000	3-15 per 1000	September 14, 1992
1,3-Butadiene	11.2-59.4 per 1000	1.3-8.1 per 1000	November 4, 1996
Methylene Chloride	126 per 1000	3.6 per 1000	January 10, 1997
Chromium VI	101-351 per 1000	10-45 per 1000	February 28, 2006
Crystalline Silica			
General Industry PEL	***11-54 per 1000	****5-23 per 1000	N/A
Construction/Shipyard PEL	***24-657 per 1000	****5-23 per 1000	

* range is based on maximum likelihood estimates (0.43, 0.0056) and 95% upper confidence limit estimates (18.9, 2.64).

** no prior standard; reported risk is based on estimated exposures at the time of the rulemaking.

*** estimated excess lung cancer risks at the previous PEL.

**** estimated excess lung cancer risks at the final PEL.

Source: Risk estimates from prior standards taken from 71 FR 10100, 10225 (2/28/06).

The estimated excess lung cancer mortality risks associated with respirable crystalline silica at the previous general industry PEL, 11–54 deaths per 1,000 workers, are comparable to, and in some cases higher than, the estimated excess cancer risks for many other workplace carcinogens for which OSHA made a determination of significant risk (*see* Table VI–4, ''Selected OSHA Risk Estimates for Prior and Current PELs''). The estimated excess lung cancer risks associated with exposure to the previous construction and shipyard PELs are even higher. The estimated risk from lifetime occupational exposure to respirable crystalline silica at the final PEL of 50 μg/m^3 is 5–23 excess lung cancer deaths per 1,000 workers, a range still higher than the risks from exposure to many other carcinogens regulated by OSHA.

OSHA's risk assessment also shows that reduction of the PELs for respirable crystalline silica to the final level of 50 μg/m^3 will result in substantial reduction in risk, although quantitative estimates of that reduction vary depending on the statistical models used. Risk models that reflect attenuation of the risk with increasing exposure, such as those relating risk to a log transformation of cumulative exposure, will result in lower estimates of risk reduction compared to linear risk models. Thus, for lung cancer risks, the assessment based on the 10-cohort pooled analysis by Steenland *et al.* (2001, Document ID 0455; also 0469; 1312) suggests risk will be reduced by about 14 percent from the previous general industry PEL and by 28–41 percent from the previous construction/shipyard PEL (based on the midpoint of the ranges of estimated risk derived from the three models used for the pooled cohort data). These risk reduction estimates, however, are much lower than those derived from the single cohort studies (Rice *et al.,* 2001, Document ID 1118; Attfield and Costello, 2004, 0543; Hughes *et al.,* 2001, 1060; Miller and MacCalman 2009, 1306). These single cohort studies suggest that reducing the previous PELs to the final PEL will reduce lung cancer risk by more than 50 percent in general industry and by more than 80 percent in construction and shipyards.

For silicosis mortality, OSHA's assessment indicates that risk will be reduced by 36 percent and by 58–68 percent as a result of reducing the previous general industry and construction/shipyard PELs, respectively. NMRD mortality risks will be reduced by 48 percent and by 77–87 percent as a result of reducing the general industry and construction/shipyard PELs, respectively, to the new PEL. There is also a substantial reduction in renal disease mortality risks; an 18-percent reduction associated with reducing the previous general industry PEL and a 38–49 percent reduction associated with reducing the previous construction/shipyard PEL.

Thus, OSHA believes that the final PEL of 50 μg/m^3 respirable crystalline silica will substantially reduce the risk of material health impairments associated with exposure to silica. However, even at this final PEL, as well as the action level of 25 μg/m^3, the risk posed to workers with 45 years of

regular exposure to respirable crystalline silica is greater than 1 per 1,000 workers and is still clearly significant.

2. Silicosis Morbidity Risks

OSHA's Final Quantitative Risk Assessment also characterizes the risk of developing silicosis, defined as developing lung fibrosis detected by chest x-ray. For 45 years of exposure at the previous general industry PEL of 100 μg/m^3, OSHA estimates that the risk of developing lung fibrosis consistent with an ILO category 1+ degree of small opacity profusion ranges from 60 to 773 cases per 1,000. For exposure at the previous construction and shipyard PELs, the risk approaches 100 percent. The wide range of risk estimates derived from the underlying studies relied on for the risk assessment may reflect differences in the relative toxicity of quartz particles in different workplaces; nevertheless, OSHA finds that each of these risk estimates clearly represents a significant risk of developing fibrotic lesions in the lung. Exposure to the final PEL of 50 μg/m^3 respirable crystalline silica for 45 years yields an estimated risk of between 20 and 170 cases per 1,000 for developing fibrotic lesions consistent with an ILO category of 1+. These risk estimates indicate that the final PEL will result in a reduction in risk by about two-thirds or more, which the Agency finds is a substantial reduction of the risk of developing abnormal chest x-ray findings consistent with silicosis.

One study of coal miners also permitted the agency to evaluate the risk of developing lung fibrosis consistent with an ILO category 2+ degree of profusion of small opacities (Buchanan *et al.,* 2003, Document ID 0306). This level of profusion has been shown to be associated with a higher prevalence of lung function decrement and an increased rate of early mortality (Ng *et al.,* 1987a, Document ID 1108; Begin *et al.,* 1988, 0296; Moore *et al.,* 1988, 1099; Ng *et al.,* 1992a, 0383; Infante-Rivard, 1991, 1065). From this study, OSHA estimates that the risk associated with 45 years of exposure to the previous general industry 100 μg/m^3 PEL is 301 cases per 1,000 workers, again a clearly significant risk. Exposure to the final PEL of 50 μg/m^3 respirable crystalline silica for 45 years yields an estimated risk of 55 cases per 1,000 for developing lesions consistent with an ILO category 2+ degree of small opacity profusion. This represents a reduction in risk of over 80 percent, again a clearly substantial reduction of the risk of developing radiologic silicosis consistent with ILO category 2+.

3. Sources of Uncertainty and Variability in OSHA's Risk Assessment

Throughout the development of OSHA's risk assessment for silica-related health effects, sources of uncertainty and variability have been identified by the Agency, peer reviewers, interagency reviewers, stakeholders, scientific experts, and the general public. This subsection reviews and summarizes several general areas of uncertainty and variability in OSHA's risk assessment. As used in this section, ''uncertainty'' refers to lack of knowledge about factors affecting exposure or risk, and ''variability'' refers to heterogeneity, for example, across people, places, or time. For more detailed discussion and evaluation of sources of uncertainty in the risk assessment and a comprehensive review of comments received by OSHA on the risk assessment, (*see* discussions provided throughout the previous section, Section V, Health Effects).

As shown in Table VI–1, OSHA's risk estimates for lung cancer are a range derived from a pooled analysis of 10 cohort studies (Steenland *et al.,* 2001a, Document ID 0452; ToxaChemica, Inc., 2004, 0469), a study of granite workers (Attfield and Costello, 2004, Document ID 0543), a study of diatomaceous earth workers (Rice *et al.*, 2001, Document ID 1118), a multi-cohort study of industrial sand workers (Hughes *et al.,* 2001, Document ID 1060), and a study of coal miners exposed to respirable crystalline silica (Miller *et al.,* 2007, Document ID 1305; Miller and MacCalman, 2009, 1306). Similarly, a variety of studies in several different working populations was used to derive risk estimates of silicosis mortality, silicosis morbidity, and renal disease mortality. The ranges of risks presented in Table VI–1 for silica mortality and the other health endpoints thus reflect silica exposure-response across a variety of industries and worker populations, which may differ for reasons such as the processes in which silica exposure occurs and the various kinds of minerals that co-exist with crystalline silica in the dust particles (see discussion on variability in toxicological potency of crystalline silica later in this section). The ranges presented in Table VI–1 do not reflect statistical uncertainty (*e.g.,* 95% confidence intervals) or model uncertainty (*e.g.,* the slope of the exposure-response curve at exposures higher or lower than the exposures of the study population) but do reflect variability in the sources of data for the different studies.

The risks presented in Table VI–1, however, do not reflect variability in the consistency, duration or frequency of workers' exposures. As discussed previously in this section, OSHA's final estimates of health risks represent risk associated with exposure to an 8-hour time weighted average of 25, 50, 100, 250 and 500 μg/m^3 respirable crystalline silica. These levels represent the risks associated with continuous occupational exposure over a working lifetime of 45 years to the new action level, new PEL, previous general industry PEL, and the range in exposure (250–500 μg/m^3) that approximates the previous construction and shipyard PELs, respectively. OSHA estimates risks assuming exposure over a working life so that it can evaluate the significance of the risk associated with exposure at the previous PELs in a manner consistent with Section 6(b)(5) of the Act, which requires OSHA to set standards that substantially reduce these risks to the extent feasible even if workers are exposed over a full working lifetime. However, while the risk assessment is based on the assumed working life of 45 years, OSHA recognizes that risks associated with shorter-term or intermittent exposures at a given airborne concentration of silica will be less than the risk associated with continuous occupational exposure at the same concentration over a working lifetime. OSHA thus also uses alternatives to the 45-year full-time exposure metric in its projections of the benefits of the final rule (Section VII of this preamble and the FEA) that reflect the reduction in silica-related disease that the Agency expects will result from implementation of the revised standard, using the various estimates of workers' typical exposure levels and patterns.

The remainder of this discussion reviews several general areas of uncertainty and variability in OSHA's risk assessment that are not quantitatively reflected in the risk estimates shown in Table VI–1, but that provide important context for understanding these estimates, including differences in the degree of uncertainty among the estimates. These areas include exposure estimation error, dose-rate effects, model form uncertainty, variability in toxicological potency of crystalline silica, and additional sources of uncertainty specific to particular endpoints, (*e.g.*, the small number of cases in the renal disease analysis), differing conclusions in the literature on silica as a causative factor in renal disease and lung cancer, and reporting error in silicosis mortality and morbidity. These different sources of uncertainty have varying effects that can lead either to under- or over-

estimation of risks. OSHA has taken these sources of uncertainty into account in concluding that the body of scientific literature supports the finding that there is significant risk at existing levels of exposure. The Agency is not required to support the finding that a ''significant risk exists with anything approaching scientific certainty'' (*Benzene,* 448 U.S. at 656).

a. Exposure Estimation Error

As discussed in Section V, OSHA identified exposure estimation error as a key source of uncertainty in most of the studies and thus the Agency's risk assessment. OSHA's contractor, ToxaChemica, Inc., commissioned Drs. Kyle Steenland and Scott Bartell to perform an uncertainty analysis to examine the effect of uncertainty due to exposure estimation error in the pooled studies (Steenland *et al.,* 2001a, Document ID 0452; Mannetje 2002b, 1089) on the lung cancer and silicosis mortality risk estimates (ToxaChemica, Inc., 2004, Document ID 0469). Drs. Steenland and Bartell addressed two main sources of error in the silica exposure estimates. The first arises from the assignment of individual workers' exposures based either on exposure measurements for a sample of workers in the same job or estimated exposure levels for specific jobs in the past when no measurements were available, via a job-exposure matrix (JEM) (Mannetje *et al.,* 2002a, Document ID 1090). The second arises from the conversion of historically-available dust measurements, typically particle count concentrations, to gravimetric respirable silica concentrations. ToxaChemica, Inc. conducted an uncertainty analysis using the raw data from the IARC multi-centric study to address these sources of error (2004, Document ID 0469).

To explore the potential effects of both kinds of uncertainty described above, ToxaChemica, Inc. (2004, Document ID 0469) used the distributions representing the error in job-specific exposure assignment and the error in converting exposure metrics to generate 50 exposure simulations for each cohort. A study-specific coefficient and a pooled coefficient were fit for each new simulation. The results indicated that the only lung cancer cohort for which the mean of the exposure coefficients derived from the simulations differed substantially from the previously calculated exposure coefficient was the South African gold cohort (simulation mean of 0.181 vs. original coefficient of 0.582). This suggests that the results of exposure-response analyses conducted using the South African cohort are sensitive to error in exposure estimates; therefore, there is greater uncertainty due to potential exposure estimation error in an exposure-response model based on this cohort than is the case for the other nine cohorts in Steenland *et al*'s analysis (or, put another way, the exposure estimation for the other nine cohorts was less sensitive to the effects of exposure measurement uncertainty).

For the pooled analysis, the mean coefficient estimate from the simulations was 0.057, just slightly lower than the previous estimate of 0.060. Based on these results, OSHA concluded that random error in the underlying exposure estimates in the Steenland *et al.* (2001a, Document ID 0452) pooled cohort study of lung cancer is not likely to have substantially influenced the original findings.

Following the same procedures described above for the lung cancer analysis, ToxaChemica, Inc. (2004, Document ID 0469) combined both sources of random measurement error in a Monte Carlo analysis of the silicosis mortality data from Mannetje *et al.* (2002b, Document ID 1089). The silicosis mortality dataset appeared to be more sensitive to possible error in exposure measurement than the lung cancer dataset, for which the mean of the simulation coefficients was virtually identical to the original. To reflect this exposure measurement uncertainty, OSHA's final risk estimates derived from the pooled analysis (Mannetje *et al.,* 2002b, Document ID 1089), incorporated ToxaChemica, Inc.'s simulated measurement error (2004, Document ID 0469).

b. Uncertainty Related to Dose-Rate Effects

OSHA received comments citing uncertainty in its risk assessment related to possible dose-rate effects in the silica exposure-response relationships, particularly for silicosis. For example, the ACC commented that extrapolating risks from the high mean exposure levels in the Park *et al.* 2002 cohort (Document ID 0405) to the much lower mean exposure levels relevant to OSHA's risk assessment contributes uncertainty to the analysis (Document ID 4209, pp. 84–85), because of the possibility that risk accrues differently at different exposure concentrations. The ACC thus argued that the risk associated with any particular level of cumulative exposure may be higher for exposure to a high concentration of respirable crystalline silica over a short period of time than for an equivalent cumulative exposure resulting from exposure to a low concentration of respirable crystalline silica over a long period of time (Document ID 4209, p. 58; 2307, Attachment A, pp. 93–94). These and similar comments on dose-rate effects questioned OSHA's use of workers' cumulative exposure levels to estimate risk, as the cumulative exposure metric does not capture dose-rate effects. Thus, according to the ACC, if there are significant dose-rate effects in the exposure-response relationship for a disease or other health endpoint, use of the cumulative exposure metric could lead to error in risk estimates.

The rationale for OSHA's reliance on a cumulative exposure metric to assess the risks of respirable crystalline silica is discussed in Section V. With respect to this issue of uncertainty related to dose-response effects, OSHA finds limited evidence in the record to either support or refute the effects hypothesized by the ACC. As such, OSHA acknowledges some uncertainty. Furthermore, use of an alternative metric such as concentration would not provide assurance that uncertainties would be mitigated or reduced.

Two studies discussed in OSHA's Review of Health Effects Literature and Preliminary QRA examined dose-rate effects on silicosis exposure-response (Document ID 1711, pp. 342–344). Neither study found a dose-rate effect relative to cumulative exposure at silica concentrations near the previous OSHA PEL (Document ID 1711, pp. 342–344). However, they did observe a dose-rate effect in instances where workers were exposed to crystalline silica concentrations far above the previous PEL (*i.e.,* several-fold to orders of magnitude above 100 $\mu g/m^3$) (Buchanan *et al.,* 2003, Document ID 0306; Hughes *et al.*, 1998, 1059). The Hughes *et al.* (1998) study of diatomaceous earth workers found that the relationship between cumulative silica exposure and risk of silicosis was steeper for workers hired prior to 1950 and exposed to average concentrations above 500 $\mu g/m^3$ compared to workers hired after 1950 and exposed to lower average concentrations (Document ID 1059). Hughes *et al.* reported that subdivisions for workers with exposure to concentrations below 500 $\mu g/m^3$ were examined, but that no differences were observed across these groups (Document ID 1059, p. 809). It is unclear whether sparse data at the low end of the concentration range contributed to this finding, as the authors did not provide detailed information on the distribution of exposures in the study population.

The Buchanan *et al.* (2003) study of Scottish coal miners adjusted the cumulative exposure metric in the risk model to account for the effects of exposures to high concentrations where

the investigators found that, at concentrations above 2000 μg/m³, the risk of silicosis was about three times higher than the risk associated with exposure to lower concentrations but at the same cumulative exposure (Document ID 0306, p. 162). Buchanan *et al.* noted that only 16 percent of exposure hours among the workers in the study occurred at levels below 10 μg/m³ (Document ID 0306, p. 161), and cautioned that insufficient data are available to predict effects at very low concentrations where data are sparse (Document ID 0306, p. 163). However, 56 percent of hours occurred at levels between 10 and 100 μg/m³. Detailed information on the hours worked at concentrations within this range was not provided.

Based on its review of these studies, OSHA concluded that there is little evidence that a dose-rate effect exists at concentrations in the range of the previous PEL (100 μg/m³) (Document ID 1711, p. 344). However, there remains some uncertainty related to dose-rate effects in the Agency's silicosis risk assessment. Even if a dose-rate effect exists only at concentrations far higher than the previous PEL, it is possible for the dose-rate effect to impact model form if not properly accounted for in study populations with high-concentration exposures. This is one reason that OSHA presents a range of risk estimates based on a variety of study populations exposed under different working conditions. For example, as OSHA noted in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711, pp. 355–356), the Park *et al.* study is complemented by the Mannetje *et al.* multi-cohort silicosis mortality pooled study. Mannetje *et al.*'s study included several cohorts that had exposure concentrations in the range of interest for this rulemaking and also showed clear evidence of significant risk of silicosis mortality at the previous general industry and construction PELs (2002b, Document ID 1089). In addition, OSHA used the model from the Buchanan *et al.* study in its silicosis morbidity risk assessment to account for possible dose-rate effects at high average concentrations (Document ID 1711, pp. 335–342). OSHA notes that the risk estimates in the exposure range of interest (25–500 μg/m³) derived from the Buchanan *et al.* (2003) study were not appreciably different from those derived from the other studies of silicosis morbidity (see Table VI–1).

c. Model Form Uncertainty

Another source of uncertainty in OSHA's risk analysis is uncertainty with respect to the form of the statistical models used to characterize the relationship between exposure level and risk of adverse health outcomes. As discussed in Section V, some commenters expressed concern that studies relied on by OSHA may not have considered all potential exposure-response relationships and might be unable to discern differences between monotonic and non-monotonic characteristics (*e.g.,* Document ID 2307, Attachment A, p. 113–114).

OSHA acknowledges that the possibility of error in selection of exposure-response model forms is a source of uncertainty in the silica risk assessment. To address this uncertainty, the Agency included studies in the risk assessment that explored a variety of model forms. For example, as discussed in Section V, the ToxaChemica reanalyses of the Mannetje *et al.* silicosis mortality dataset and the Steenland *et al.* lung cancer mortality data set examined several model forms including a five-knot restricted spline analysis, which is a highly flexible model form able to capture a variety of exposure-response shapes (Document ID 0469, p. 50). The ToxaChemica reanalysis addresses the issue of model form uncertainty by finding similar exposure-response relationships regardless of the type of model used.

d. Uncertainty Related to Silica Exposure as a Risk Factor for Lung Cancer

As discussed in Section V, OSHA has reviewed the best available evidence on the relationship between silica exposure and lung cancer mortality, and has concluded that the weight of evidence supports the finding that exposure to silica at the preceding and new PELs increases the risk of lung cancer. However, OSHA acknowledges that not every study in the literature on silica-related lung cancer reached the same conclusions. This variability is to be expected in epidemiology, as there are different cohorts, measurements, study designs, and analytical methods, among other factors. OSHA further acknowledges that there is uncertainty with respect to the magnitude of the risk of lung cancer from silica exposure. In the case of silica, the exposure-response relationship with lung cancer may be easily obscured, as crystalline silica is a comparably weaker carcinogen (*i.e.,* the increase in risk per unit exposure is smaller) than other well-studied, more potent carcinogens such as hexavalent chromium (Steenland *et al.*, 2001, Document ID 0452, p. 781) and tobacco smoke, a common co-exposure in silica-exposed populations.

A study by Vacek *et al.* (2011) illustrates the uncertainties involved in evaluating risk of lung cancer from silica exposure. This study found no significant association between respirable silica exposure and lung cancer mortality in a cohort of Vermont granite workers (Document ID 1486, pp. 75–81). Some commenters criticized OSHA's preliminary risk assessment for rejecting the Vacek *et al.* (2011) study and instead relying upon the Attfield and Costello (2004, Document ID 0284) study of Vermont granite workers (Document ID 2307, Attachment A, pp. 36–47; 4209, pp. 34–36). As discussed in detail in Section V, OSHA reviewed the Vacek *et al.* study and all comments received by the Agency on this issue, and has decided not to reject the Attfield and Costello (2004) study in favor of the Vacek *et al.* (2011) study as a basis for risk assessment. OSHA acknowledges that comprehensive studies, such as those of Attfield and Costello (2004) and Vacek *et al.* (2011), in the Vermont granite industry have shown conflicting results with respect to lung cancer mortality (Document ID 0284; 1486). Although OSHA believes that the Attfield and Costello (2004) study is the most appropriate Vermont granite study to use in its QRA, it also relied upon other studies, and that the risk estimates for lung cancer mortality based on those studies (*i.e.,* Document ID 0543, 1060, 1118, 1306) still provide substantial evidence that respirable crystalline silica poses a significant risk of lung cancer to exposed workers.

e. Uncertainty Related to Renal Disease

As discussed in Section V, OSHA acknowledges that there are considerably less data for renal disease mortality than those for silicosis, lung cancer, and non-malignant respiratory disease (NMRD) mortality. Although the Agency believes the renal disease risk findings are based on credible data, the risk findings based on them are less robust than the findings for silicosis, lung cancer, and NMRD.

Based upon its overall analysis of the literature, including the negative studies, OSHA has concluded that there is substantial evidence suggesting an association between exposure to crystalline silica and increased risks of renal disease. This conclusion is supported by a number of case reports and epidemiological studies that found statistically significant associations between occupational exposure to silica dust and chronic renal disease (Calvert *et al.*, 1997, Document ID 0976), subclinical renal changes (Ng *et al.*, 1992c, Document ID 0386), end-stage renal disease morbidity (Steenland *et*

al., 1990, Document ID 1125), end-stage renal disease incidence (Steenland *et al.,* 2001b, Document ID 0456), chronic renal disease mortality (Steenland *et al.,* 2002a, 0448), and granulomatosis with polyangitis (Nuyts *et al.*, 1995, Document ID 0397). However, as discussed in the Review of Health Effects Literature and Preliminary QRA, the studies reviewed by OSHA included a number of studies that did not show an association between crystalline silica and renal disease (Document ID 1711, pp. 211–229). Additional negative studies by Birk *et al.* (2009, Document ID 1468), and Mundt *et al.* (2011, Document ID 1478) were reviewed in the Supplemental Literature Review of the Review of Health Effects Literature and Preliminary QRA, which noted the short follow-up period as a limitation, which reduces the likelihood that an increased incidence of renal mortality would have been detected (Document ID 1711, Supplement, pp. 6–12). Comments submitted to OSHA by the ACC additionally cited several studies that did not show a statistically significant association between exposure to crystalline silica and renal disease mortality, including McDonald *et al.* (2005, Document ID 1092), Vacek *et al.* (2011, Document ID 2340), Davis *et al.* (1983, Document ID 0999), Koskela *et al.* (1987, Document ID 0363), Cherry *et al.* (2012, article included in Document ID 2340), Steenland *et al.* (2002b, Document ID 0454), Rosenman *et al.* (2000, Document ID 1120), and Calvert *et al.* (2003, Document ID 0309) (Document ID 2307, Attachment A, pp. 140–145).

As discussed in detail in Section V, OSHA concludes that the evidence supporting causality regarding renal risk outweighs the evidence casting doubt on that conclusion, but acknowledges this divergence in the renal disease literature as a source of uncertainty.

OSHA estimated quantitative risks for renal disease mortality (Document ID 1711, pp. 314–316) using data from a pooled analysis of renal disease, conducted by Steenland *et al.* (2002a, Document ID 0448). The data set included 51 deaths from renal disease as an underlying cause, which the authors of the pooled study, Drs. Kyle Steenland and Scott Bartell, acknowledged to be insufficient to provide robust estimates of risk (Document ID 2307, Attachment A, p. 139, citing 0469, p. 27). OSHA agrees with Dr. Steenland and acknowledges, as it did in its Review of Health Effects Literature and Preliminary QRA (Document ID 1711, p. 357), that its quantitative risk estimates for renal disease mortality are less robust than those for the other health effects examined (*i.e.,* lung cancer mortality, silicosis and NMRD mortality, and silicosis morbidity).

f. Uncertainty in Reporting and Diagnosis of Silicosis Mortality and Silicosis Morbidity

OSHA's final quantitative risk assessment includes risk estimates for silicosis mortality and morbidity. Silicosis mortality is ascertained by analysis of death certificates for cause of death, and morbidity is ascertained by the presence of chest radiographic abnormalities consistent with silicosis among silica-exposed workers. Each of these kinds of studies are associated with uncertainties in case ascertainment and use of chest roentgenograms to detect lung scarring due to silicosis.

For silicosis mortality, OSHA's analysis includes a pooled analysis of six epidemiological studies first published by Mannetje *et al.* (2002b, Document ID 1089) and re-analyzed by OSHA's contractor ToxaChemica (2004, Document ID 0469). OSHA finds that the estimates from Mannetje *et al.* and ToxaChemica's analyses are likely to understate the actual risk because silicosis is under-reported as a cause of death, as discussed in Sections VC.2.iv and V.E in the context of silicosis disease surveillance systems. To help address this uncertainty, OSHA's risk analysis also included an exposure-response analysis of diatomaceous earth (DE) workers (Park *et al.*, 2002, Document ID 0405), which better captures the totality of silica-related respiratory disease than do the datasets analyzed by Mannetje *et al.* and ToxaChemica. Park *et al.*. quantified the relationship between cristobalite exposure and mortality caused by NMRD, which includes silicosis, pneumoconiosis, emphysema, and chronic bronchitis. Because NMRD captures much of the silicosis misclassification that results in underestimation of the disease and includes risks from other lung diseases associated with crystalline silica exposures, OSHA finds the risk estimates derived from the Park *et al.* study are important to include as part of OSHA's range of estimates of the risk of death from silica-related respiratory diseases, including silicosis. (Document ID 1711, pp. 297–298). OSHA concludes that the range of silicosis and NMRD risks presented in the final risk assessment, based on both the ToxaChemica reanalysis of Mannetje *et al.*'s silicosis mortality data and Park *et al.*'s study of NMRD mortality, provide a credible range of estimates of mortality risk from silicosis and NMRD across a range of industrial workplaces. The upper end of this range, based on the Park *et al.* study, is less likely to underestimate risk as a result of under-reporting of silicosis mortality, but cannot be directly compared to risk estimates from studies that focused on cohorts of workers from different industries.

OSHA's estimates of silicosis morbidity risks are based on studies of active and retired workers for which exposure histories could be constructed and chest x-ray films could be evaluated for signs of silicosis. There is evidence in the record that chest x-ray films are relatively insensitive to detecting lung fibrosis. Hnizdo *et al.* (1993, Document ID 1050) found chest x-ray films to have low sensitivity for detecting lung fibrosis related to silicosis, compared to pathological examination at autopsy. To address the low sensitivity of chest x-rays for detecting silicosis, Hnizdo *et al.* (1993, Document ID 1050) recommended that radiographs consistent with an ILO category of 0/1 or greater be considered indicative of silicosis among workers exposed to a high concentration of silica-containing dust. In like manner, to maintain high specificity, chest x-rays classified as category 1/0 or 1/1 should be considered as a positive diagnosis of silicosis. Studies relied on in OSHA's risk assessment typically used an ILO category of 1/0 or greater to identify cases of silicosis. According to Hnizdo *et al.*, they are unlikely to include many false positives (diagnoses of silicosis where there is none), but may include false negatives (failure to identify cases of silicosis). Thus, the use of chest roentgenograms to ascertain silicosis cases in the morbidity studies relied on by OSHA in its risk assessment could lead to an underestimation of risk given the low sensitivity of chest roentgenograms for detecting silicosis.

g. Variability in Toxicological Potency of Crystalline Silica

As discussed in Section V, the toxicological potency of crystalline silica is influenced by a number of physical and chemical factors that affect the biological activity of inhaled silica particles. The toxicological potency of crystalline silica is largely influenced by the presence of oxygen free radicals on the surfaces of respirable particles. These chemically-reactive oxygen species interact with cellular components in the lung to promote and sustain the inflammatory reaction responsible for the lung damage associated with exposure to crystalline silica. The reactivity of particle surfaces is greatest when crystalline silica has been freshly fractured by high-energy

work processes such as abrasive blasting, rock drilling, or sawing concrete materials. As particles age in the air, the surface reactivity decreases and exhibits lower toxicologic potency (Porter *et al.*, 2002, Document ID 1114; Shoemaker *et al.*, 1995, 0437; Vallyathan *et al.*, 1995, 1128). In addition, surface impurities have been shown to alter silica toxicity. For example, aluminum and aluminosilicate clay on silica particles has been shown to decrease toxicity (Castranova *et al.*, 1997, Document ID 0978; Donaldson and Borm, 1998, 1004; Fubini, 1998, 1016; Donaldson and Borm, 1998, Document ID 1004; Fubini, 1998, 1016).

In the preamble to the proposed standard, OSHA preliminarily concluded that although there is evidence that several environmental influences can modify surface activity to either enhance or diminish the toxicity of silica, the available information was insufficient to determine to what extent these influences may affect risk to workers in any particular workplace setting (Document 1711, p. 350). OSHA acknowledges that health risks are probably in the low end of the range for workers in the brick manufacturing industry, although the evidence still indicates that there is a significant risk at the previous general industry PEL for those workers. OSHA also acknowledges that there was a lack of evidence for a significant risk in the sorbent minerals industry due to the nature of crystalline silica present in those operations; as a result, it decided to exclude sorptive clay processing from this rule. Furthermore, Dudley and Morriss (2015) raise concerns about the whether the exposures reflected in the historical cohorts used in the risk assessment are sufficiently reflective of rapidly changing working conditions over the last 45 years.[11] However, the risk estimates presented in Table VI–1 are based on studies from a variety of industries, such that the risk ranges presented are likely to include estimates appropriate to most working populations. Thus, in OSHA's view, its significant risk finding is well supported by the weight of best available evidence, notwithstanding uncertainties that may be present to varying degrees in the numerous studies relied upon and the even greater number of studies that the Agency considered.

[11] Dudley, S. E. and Morriss, A. P. (2015), Will the Occupational Safety and Health Administration's Proposed Standards for Occupational Exposure to Respirable Crystalline Silica Reduce Workplace Risk?. Rish Analysis, 35: 1191–1196. doi:10.1111/risa.12341

4. OSHA's Response to Comments on Significant Risk of Material Impairment

OSHA received several comments pertaining to the Agency's determination of a significant risk of material impairment of health posed to workers exposed for a working life to the previous PELs. Although many of these comments were supportive of OSHA's conclusions regarding the significance of risk, others were critical or suggested that OSHA has an obligation to further reduce the risk below that estimated to remain at the revised PEL.

Referring to the previous PELs for respirable crystalline silica, the AFL–CIO commented that ''[w]orkers face a significant risk of harm from silica exposure at the current permissible exposure limits,'' and that ''[t]here is overwhelming evidence in the record that exposure to respirable crystalline silica poses a significant health risk to workers'' (Document ID 4204, pp. 10–11). The AFL–CIO noted that OSHA's mortality risk estimates well exceeded the benchmark of 1/1,000 excess risk over a working lifetime of exposure to the previous PELs, and also highlighted the risks of silicosis morbidity (Document ID 4204, p. 13). The AFL–CIO further pointed out that there is no cure for silicosis, and quoted oral testimony from workers at the informal public hearings demonstrating that ''[s]ilica-related diseases are still destroying workers' lives and livelihoods'' (Document ID 4204, p. 19).

Both the UAW and the Building and Construction Trades Department (BCTD) concurred with the AFL–CIO that the previous PEL needs to be lowered to adequately protect workers. Referring to the previous PEL, the BCTD stated that ''[t]he record supports OSHA's determination that exposures at the current PEL present a significant risk'' (Document ID 4223, p. 6). Although supportive of OSHA's proposed standard, the UAW also suggested the adoption of a PEL of 25 μg/m^3 or lower where feasible (Document ID 2282, Attachment 3, p.1), noting that a PEL set at this level ''will significantly reduce workers' exposure to deadly silica dust and prevent thousands of illnesses and deaths every year'' (Document ID 2282, Attachment 3, p. 25). Similarly, Charles Gordon, a retired occupational safety and health attorney, commented that the revised PEL ''leaves a remaining risk of 97 deaths per 1,000 workers from silicosis, lung cancer, and renal disease combined'' (Document ID 4236, p. 2). Again, it should be noted that these risk estimates are not additive because some individuals may suffer from multiple diseases caused by exposure to silica. Instead, OSHA presents risk estimates for each health endpoint.

As discussed above, OSHA acknowledges that there remains a significant risk of material impairment of health at the revised PEL; a further reduction in the PEL, however, is not currently technologically feasible (see Section VII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis, in which OSHA summarizes its assessment of the technological feasibility of the revised PEL). Despite this, the final PEL will provide a very substantial reduction in the risk of material impairment of health to silica-exposed workers, as described in the *Benzene* decision (*Benzene,* 448 U.S. at 642).

In contrast to the foregoing comments from labor groups contending that OSHA would be setting the PEL too high if it made a final determination to lower the preceding PELs to 50 μg/m^3, critical comments came from industry groups including the American Chemistry Council (ACC), which disagreed with OSHA's determination of a significant risk of material impairment of health at the previous PELs. The ACC stated, ''OSHA's assessment of these risks is flawed, and its conclusions that the risks are significant at a PEL of 100 μg/m^3 and would be substantially reduced by lowering the PEL to 50 μg/m^3 are unsupported'' (Document ID 4209, p. 12). The ACC then asserted several ''fundamental shortcomings'' in OSHA's QRA on which OSHA based its significant risk determination (Document ID 4209, pp. 16–17), including a variety of purported biases in the key studies on which OSHA relied. OSHA addresses the ACC's concerns in detail in Section V of this preamble dealing with the key studies relied upon by the Agency for each health endpoint, as well as separate sections addressing the issues of biases, causation, thresholds, the uncertainty analysis, and the life table and exposure assumptions used in the QRA. As more fully discussed in those sections, OSHA finds these concerns to be unpersuasive. As discussed in Section V, the scientific community and regulators in other advanced industrial societies agree on the need for a PEL of at most 50 μg/m^3 based on demonstrated health risks, and OSHA has used the best available evidence in the scientific literature to estimate quantitative risks of silica-related illnesses and thereby reach the same conclusion. OSHA's preliminary review of the health effects literature and OSHA's preliminary QRA were, further, examined by an independent, external peer review panel of

accomplished scientists, which lent credibility to the Agency's methods and findings and led to some adjustments in the analysis that strengthened OSHA's final risk assessment. There is, additionally, widespread support for the Agency's methods and conclusions in the rulemaking record. As such, OSHA is confident in its conclusion that there is a significant risk of material impairment of health to workers exposed to respirable crystalline silica at the levels of exposure permitted under the previous PELs and under this final standard, and finds no merit in broad assertions purporting to debunk this conclusion.

In summary, as discussed throughout Section V and this final rule, OSHA concludes, based on the best available evidence in the scientific literature, that workers' exposure to respirable crystalline silica at the previous PELs results in a clearly significant risk of material impairment of health. The serious, and potentially fatal, health effects suffered by exposed workers include silicosis, lung cancer, NMRD, renal disease, and autoimmune effects. OSHA finds that the risk is substantially decreased, though still significant, at the new PEL of 50 μg/m^3 and below, including at the new action level of 25 μg/m^3. The Agency is constrained, however, from lowering the PEL further by its finding that a lower PEL would be infeasible in many operations across several industries. Given the significant risks faced by workers exposed to respirable crystalline silica under the previously-existing exposure limits, OSHA believes that it is imperative that it issue this final standard pursuant to its statutory mandate under the OSH Act.

VII. Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis

A. Introduction

OSHA's Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA) addresses issues related to the costs, benefits, technological and economic feasibility, and the economic impacts (including impacts on small entities) of this final respirable crystalline silica rule and evaluates regulatory alternatives to the final rule. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The full FEA has been placed in OSHA rulemaking docket OSHA–2010–0034. This rule is an economically significant regulatory action under Sec. 3(f)(1) of Executive Order 12866 and has been reviewed by the Office of Information and Regulatory Affairs in the Office of Management and Budget, as required by executive order.

The purpose of the FEA is to:

- Identify the establishments and industries potentially affected by the final rule;
- Estimate current exposures and the technologically feasible methods of controlling these exposures;
- Estimate the benefits resulting from employers coming into compliance with the final rule in terms of reductions in cases of silicosis, lung cancer, other forms of chronic obstructive pulmonary disease, and renal failure;
- Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the final rule;
- Assess the economic feasibility of the final rule for affected industries; and
- Assess the impact of the final rule on small entities through a Final Regulatory Flexibility Analysis (FRFA), to include an evaluation of significant regulatory alternatives to the final rule that OSHA has considered.

Significant Changes to the FEA Between the Proposed Standards and the Final Standards

OSHA changed the FEA for several reasons:

- Changes to the rule, summarized in Section I of this preamble and discussed in detail in the Summary and Explanation;
- Comments on the Preliminary Economic Analysis (PEA);
- Updates of economic data; and
- Recognition of errors in the PEA.

OSHA revised its technological and economic analysis in response to these changes and to comments received on the NPRM. The FEA contains some costs that were not included in the PEA and updates data to use more recent data sources and, in some cases, revised methodologies. Detailed discussions of these changes are included in the relevant sections throughout the FEA.

The FEA contains the following chapters:

Chapter I. Introduction
Chapter II. Market Failure and the Need for Regulation
Chapter III. Profile of Affected Industries
Chapter IV. Technological Feasibility
Chapter V. Costs of Compliance
Chapter VI. Economic Feasibility Analysis and Regulatory Flexibility Determination
Chapter VII. Benefits and Net Benefits
Chapter VIII. Regulatory Alternatives
Chapter IX. Final Regulatory Flexibility Analysis
Chapter X. Environmental Impacts

Table VII–1 provides a summary of OSHA's best estimate of the costs and estimated benefits of the final rule using a discount rate of 3 percent. As shown, the final rule is estimated to prevent 642 fatalities and 918 silica-related illnesses annually once it is fully effective, and the estimated cost of the rule is $1,030 million annually. Also as shown in Table VII–1, the discounted monetized benefits of the final rule are estimated to be $8.7 billion annually, and the final rule is estimated to generate net benefits of $7.7 billion annually. Table VII–1 also presents the estimated costs and estimated benefits of the final rule using a discount rate of 7 percent.

Table VII-1: Annualized Benefits, Costs and Net Benefits of OSHA's Final Silica Standard of 50 µg/m³			
Discount Rate		**3%**	**7%**
Annualized Costs			
Engineering Controls (includes Abrasive Blasting)		$661,456,736	$673,898,234
Respirators		$32,884,224	$32,906,905
Exposure Assessment		$96,241,339	$97,697,836
Medical Surveillance		$96,353,520	$99,859,958
Familiarization and Training		$95,935,731	$101,603,066
Regulated Area		$2,637,136	$2,665,271
Written Exposure Control Plan		$44,273,091	$47,497,152
Total Annualized Costs (point estimate)		**$1,029,781,777**	**$1,056,128,421**
Estimated Annual Benefits: Number of Cases Prevented*			
Fatal Lung Cancers (midpoint estimate)	124		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	325		
Fatal Renal Disease	193		
Silica-Related Mortality	642	$6,398,159,903	$3,506,947,156
Silicosis Morbidity	918	$2,288,753,312	$1,304,866,992
Estimated Monetized Annual Benefits (midpoint estimate)*		**$8,686,913,216**	**$4,811,814,147**
Estimated Net Benefits*		**$7,657,131,439**	**$3,755,685,726**

*Results are estimates based on assumptions outlined in the benefits analysis.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, 2016.

The remainder of this section (Section VII) of the preamble is organized as follows:

B. Market Failure and the Need for Regulation

Employees in work environments addressed by the final silica rule are exposed to a variety of significant hazards that can and do cause serious injury and death. As described in Chapter II of the FEA in support of the final rule, OSHA concludes there is a failure of private markets to protect workers from exposure to unnecessarily high levels of respirable crystalline silica and that private markets, as well as information dissemination programs, workers' compensation systems, and

tort liability options, each may fail to protect workers from silica exposure, resulting in the need for a more protective OSHA silica rule.

After carefully weighing the various potential advantages and disadvantages of using a regulatory approach to improve upon the current situation, OSHA concludes that, in the case of silica exposure, the final mandatory standards represent the best choice for reducing the risks to employees. In addition, rulemaking is necessary in this case in order to replace older existing standards with updated, clear, and consistent health standards.

C. Profile of Affected Industries

Introduction

Chapter III of the FEA presents profile data for industries potentially affected by the final silica rule. The discussion below summarizes the findings in that chapter. As a first step, OSHA identifies the North American Industrial Classification System (NAICS) industries, both in general industry and maritime and in the construction sector, with potential worker exposure to silica. Next, OSHA provides summary statistics for the affected industries, including the number of affected entities and establishments, the number of workers whose exposure to silica could result in disease or death (''at-risk workers''), and the average revenue for affected entities and establishments.[12] Finally, OSHA presents silica exposure profiles for at-risk workers. These data are presented by sector and job category. Summary data are also provided for the number of workers in each affected industry who are currently exposed above the final silica PEL of 50 μg/m^3, as well as above an alternative PEL of 100 μg/m^3 for economic analysis purposes.

The methodological basis for the industry and at-risk worker data presented in this chapter comes from the PEA, the Eastern Research Group (ERG) analysis supporting the PEA (2007a, 2007b, 2008a, and 2008b),[13] and ERG's analytic support in preparing the FEA. The data used in this chapter come from the rulemaking record (Docket OSHA–2010–0034), the technological feasibility analyses presented in Chapter IV of the FEA, and from OSHA (2016), which updated its earlier spreadsheets to reflect the most recent industry data available. To do so, ERG first matched the BLS Occupational Employment Statistics (OES) survey occupational titles with the at-risk job categories, by NAICS industry. ERG then calculated the percentages of production employment represented by each at-risk job title within industry (see OSHA, 2016 for details on the calculation of employment percentages and the mapping of at-risk job categorizations into OES occupations).[14] ERG's expertise for identifying the appropriate OES occupations and calculating the employment percentages enabled OSHA to estimate the number of employees in the at-risk job categories by NAICS industry (Id.).

In the NPRM and PEA, OSHA invited the public to submit additional information and data that might help improve the accuracy and usefulness of the preliminary industry profile; the profile presented here and in Chapter III of the FEA reflects public comment.

Selection of NAICS Industries for Analysis

The technological feasibility analyses presented in Chapter IV of the FEA identify the general industry and maritime sectors and the construction activities potentially affected by the final silica standard.

General Industry and Maritime

Employees engaged in various activities in general industry and maritime routinely encounter crystalline silica as a molding material, as an inert mineral additive, as a component of fluids used to stimulate well production of oil or natural gas, as a refractory material, as a sandblasting abrasive, or as a natural component of the base materials with which they work. Some industries use various forms of silica for multiple purposes. As a result, employers are faced with the challenge of limiting worker exposure to silica in dozens of job categories throughout the general industry and maritime sectors.

Job categories in general industry and maritime were selected for analysis based on data from the technical industrial hygiene literature, evidence from OSHA Special Emphasis Program (SEP) results, and, in several cases, information from ERG site visit reports and public comment submitted into the record. These data sources provided evidence of silica exposures in numerous sectors. While the available data are not entirely comprehensive, OSHA believes that silica exposures in other sectors are quite limited.

The industry subsectors in the overall general industry and maritime application groups that OSHA identified as being potentially affected by the final silica standard are as follows:

- Asphalt Paving Products
- Asphalt Roofing Materials
- Hydraulic Fracturing
- Industries with Captive Foundries
- Concrete Products
- Cut Stone
- Dental Equipment and Supplies
- Dental Laboratories
- Flat Glass
- Iron Foundries
- Jewelry
- Mineral Processing
- Mineral Wool
- Nonferrous Sand Casting Foundries
- Non-Sand Casting Foundries
- Other Ferrous Sand Casting Foundries
- Other Glass Products
- Paint and Coatings
- Porcelain Enameling
- Pottery
- Railroads
- Ready-Mix Concrete
- Refractories
- Refractory Repair
- Shipyards
- Structural Clay

In some cases, affected industries presented in the technological feasibility analysis have been disaggregated to facilitate the cost and economic impact analysis. In particular, flat glass, mineral wool, and other glass products are subsectors of the glass industry described in Chapter IV, Section IV–9, of the FEA, and captive foundries,[15] iron foundries, nonferrous sand casting foundries, non-sand cast foundries, and other ferrous sand casting foundries are subsectors of the

[12] The Census Bureau defines an establishment as a single physical location at which business is conducted or services or industrial operations are performed. The Census Bureau defines a business firm or entity as a business organization consisting of one or more domestic establishments in the same state and industry that were specified under common ownership or control. The firm and the establishment are the same for single-establishment firms. For each multi-establishment firm, establishments in the same industry within a state will be counted as one firm; the firm employment and annual payroll are summed from the associated establishments. (US Census Bureau, Statistics of US Businesses, Definitions. 2015, *http://www.census.gov/econ/susb/definitions.html?cssp=SERP).*

[13] Document ID, 1709, 1608, 1431, and 1365, respectively.

[14] Production employment includes workers in building and grounds maintenance; forestry, fishing, and farming; installation and maintenance; construction; production; and material handling occupations.

[15] Captive foundries include establishments in other industries with foundry processes incidental to the primary products manufactured. ERG (2008b, Document ID 1365) provides a discussion of the methodological issues involved in estimating the number of captive foundries and in identifying the industries in which they are found. Since the 2008 ERG report, through comment in the public record and the public hearings, OSHA has gained additional information on the presence of captive foundries throughout general industry.

overall foundries industry presented in Chapter IV, Section IV–8, of the FEA.

As described in ERG (2008b, Document ID 1365) and updated in OSHA (2016), OSHA identified the six-digit NAICS codes for these subsectors to develop a list of industries potentially affected by the final silica standard. Table VII–2 presents the sectors listed above with their corresponding six-digit NAICS industries. The NAICS codes and associated industry definitions in the FEA are consistent with the 2012 NAICS edition.

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Table VII-2: General Industry and Maritime Application Groups and Industries Affected by OSHA's Final Silica Rule

Application Group	NAICS	Industry
Asphalt Paving Products	324121	Asphalt paving mixture and block manufacturing
Asphalt Roofing Materials	324122	Asphalt shingle and coating materials mfg.
Captive Foundries	331110	Iron and steel mills and ferroalloy mfg.
	331210	Iron and steel pipe and tube mfg. from purchased steel
	331221	Rolled steel shape manufacturing
	331222	Steel wire drawing
	331314	Secondary smelting and alloying of aluminum
	331420	Copper rolling, drawing, extruding, and alloying
	331492	Secondary smelting, refining, and alloying of nonferrous metal (except copper and aluminum)
	332111	Iron and steel forging
	332112	Nonferrous forging
	332117	Powder metallurgy part manufacturing
	332119	Metal crown, closure, and other metal stamping (except automotive)
	332215	Metal kitchen cookware, utensil, cutlery, and flatware (except precious) manufacturing
	332216	Saw blade and handtool manufacturing
	332439	Other metal container manufacturing
	332510	Hardware manufacturing
	332613	Spring manufacturing
	332618	Other fabricated wire product manufacturing
	332710	Machine shops
	332911	Industrial valve manufacturing
	332912	Fluid power valve and hose fitting mfg.
	332913	Plumbing fixture fitting and trim mfg.
	332919	Other metal valve and pipe fitting mfg.
	332991	Ball and roller bearing manufacturing
	332996	Fabricated pipe and pipe fitting mfg.
	332999	All other miscellaneous fabricated metal product manufacturing

Table VII-2: General Industry and Maritime Application Groups and Industries Affected by OSHA's Final Silica Rule (Continued)

Application Group	NAICS	Industry
Captive Foundries (contd.)	333318	Other commercial & service industry machinery mfg
	333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing
	333414	Heating Equipment (except Warm Air Furnaces) Manufacturing
	333511	Industrial Mold Manufacturing
	333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing
	333515	Cutting Tool and Machine Tool Accessory Manufacturing
	333517	Machine Tool Manufacturing
	333519	Rolling Mill and Other Metalworking Machinery Manufacturing
	333612	Speed changer, industrial high-speed drive, and gear manufacturing
	333613	Mechanical power transmission equipment manufacturing
	333911	Pump and pumping equipment manufacturing
	333912	Air & gas compressor manufacturing
	333991	Power-driven handtool manufacturing
	333992	Welding & soldering equipment manufacturing
	333993	Packaging machinery manufacturing
	333994	Industrial process furnace and oven mfg.
	333995	Fluid power cylinder and actuator mfg.
	333996	Fluid power pump and motor manufacturing
	333997	Scale and balance manufacturing
	333999	All other miscellaneous general purpose machinery manufacturing
	334519	Other measuring and controlling device manufacturing
	336111	Automobile manufacturing
	336112	Light truck and utility vehicle manufacturing

Table VII-2: General Industry and Maritime Application Groups and Industries Affected by OSHA's Final Silica Rule (Continued)

Application Group	NAICS	Industry
Captive Foundries (contd.)	336120	Heavy duty truck manufacturing
	336211	Motor vehicle body manufacturing
	336212	Truck trailer manufacturing
	336213	Motor home manufacturing
	336310	Motor vehicle gasoline engine and engine parts manufacturing
	336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing
	336330	Motor vehicle steering and suspension components (except spring) manufacturing
	336340	Motor vehicle brake system manufacturing
	336350	Motor vehicle transmission and power train parts manufacturing
	336370	Motor vehicle metal stamping
	336390	Other motor vehicle parts manufacturing
	336992	Military armored vehicle, tank, and tank component manufacturing
	337215	Showcase, partition, shelving, & locker mfg.
	339910	Jewelry and Silverware Manufacturing
Concrete Products	327331	Concrete block and brick manufacturing
	327332	Concrete pipe manufacturing
	327390	Other concrete product manufacturing
	327999	All other miscellaneous nonmetallic mineral product manufacturing
Cut Stone	327991	Cut stone and stone product manufacturing
	337110	Wood Kitchen Cabinet and Countertop Manufacturing
	444110	Home Centers
Dental Equipment and Supplies	339114	Dental equipment and supplies manufacturing
Dental Laboratories	339116	Dental laboratories
	621210	Offices of dentists
Engineered Stone Products	327991	Cut stone and stone product manufacturing

Table VII-2: General Industry and Maritime Application Groups and Industries Affected by OSHA's Final Silica Rule (Continued)

Application Group	NAICS	Industry
Ferrous Sand Casting Foundries	331511	Iron foundries
	331513	Steel foundries (except investment)
Fertilizer Manufacturing	325314	Fertilizer (mixing only) manufacturing
Flat Glass	327211	Flat glass manufacturing
Hydraulic Fracturing	213112	Support activities for oil and gas operations
Jewelry, Fine	339910	Jewelry and Silverware Manufacturing
Jewelry, Costume	339910	Jewelry and Silverware Manufacturing
Landscape Contracting	561730	Landscaping Services
Mineral Processing	327992	Ground or treated mineral and earth manufacturing
Mineral Wool	327993	Mineral wool manufacturing
Nonferrous Sand Casting Foundries	331524	Aluminum foundries (except die-casting)
	331529	Other nonferrous metal foundries (except die-casting)
Non-Sand Casting Foundries	331512	Steel investment foundries
Other Glass Products	327212	Other pressed and blown glass and glassware manufacturing
	327213	Glass container manufacturing
Paint and Coatings	325510	Paint & coating manufacturing
Porcelain Enameling	332323	Ornamental and architectural metal work manufacturing
	332812	Metal coating and allied services
	332999	All other miscellaneous fabricated metal product manufacturing
	335210	Small Electrical Appliance Manufacturing
	335221	Household cooking appliance manufacturing
	335222	Household refrigerator and home freezer manufacturing
	335224	Household laundry equipment manufacturing
	335228	Other major household appliance manufacturing
	339950	Sign manufacturing
Pottery	327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing

Table VII-2: General Industry and Maritime Application Groups and Industries Affected by OSHA's Final Silica Rule (Continued)

Application Group	NAICS	Industry
Railroads	482110	Rail transportation
Ready-Mix Concrete	327320	Ready-mix concrete manufacturing
Refractories	327120	Clay Building Material and Refractories Manufacturing
Refractory Repair	423840	Industrial supplies merchant wholesalers
Shipyards*	336611	Ship building and repairing
	336612	Boat building
Structural Clay	327120	Clay Building Material and Refractories Manufacturing

* The maritime industry encompasses the shipbuilding and repair industry (shipyards) as well as the marine cargo handling industry. Abrasive blasting with silica-containing abrasive is a widely-recognized source of silica exposure in the maritime industry and is addressed in this part of the analysis.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, 2016.

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Construction

The construction sector is an integral part of the nation's economy, accounting for approximately 4.5 percent of total private sector employment. Establishments in this industry are involved in a wide variety of activities, including land development and subdivision, homebuilding, construction of nonresidential buildings and other structures, heavy construction work (including roadways and bridges), and a myriad of special trades such as plumbing, roofing, electrical, excavation, and demolition work.

Construction activities were selected for analysis based on historical data of recorded samples of construction worker exposures from the OSHA Integrated Management Information System (IMIS) and the National Institute for Occupational Safety and Health (NIOSH). In addition, OSHA reviewed the industrial hygiene literature across the full range of construction activities and focused on dusty operations where silica sand was most likely to be fractured or abraded by work operations. These physical processes have been found to cause the silica exposures that pose the greatest risk of silicosis for workers.

The construction activities, by equipment or task, that OSHA identified as being potentially affected by the final silica standard are as follows:

- Earth drilling
- Heavy Equipment Operators and Ground Crew Laborers—I (Abrading or fracturing silica containing materials or demolishing concrete or masonry structures)
- Heavy Equipment Operators and Ground Crew Laborers—II (Grading and Excavating)
- Hole Drillers Using Handheld or Stand-Mounted Drills
- Jackhammers and Other Powered Handheld Chipping Tools
- Masonry and Concrete Cutters Using Portable Saws—I (Handheld power saws)
- Masonry and Concrete Cutters Using Portable Saws—II (Handheld power saws for cutting fiber-cement board)
- Masonry and Concrete Cutters Using Portable Saws—III (Walk-behind saws)
- Masonry and Concrete Cutters Using Portable Saws—IV (Drivable or ride-on concrete saws)
- Masonry and Concrete Cutters Using Portable Saws—V (Rig-mounted core saws or drills)
- Masonry Cutters Using Stationary Saws
- Millers Using Portable or Mobile Machines—I (Walk-behind milling machines and floor grinders)
- Millers Using Portable or Mobile Machines—II (Small drivable milling machine (less than half-lane))
- Millers Using Portable or Mobile Machines—III (Milling machines (half-lane and larger with cuts of any depth on asphalt only and for cuts of four inches in depth or less on any other substrate))
- Rock and Concrete Drillers—I (Vehicle-mounted drilling rigs for rock and concrete)
- Rock and Concrete Drillers—II (Dowel drilling rigs for concrete)
- Mobile Crushing Machine Operators and Tenders
- Tuckpointers and Grinders—I (Handheld grinders for mortar removal (*e.g.,* tuckpointing))
- Tuckpointers and Grinders—II (Handheld grinders for uses other than mortar removal)

As shown in OSHA (2016) and in Chapter IV of the FEA, these construction activities occur in the following industries and governmental bodies, accompanied by their four-digit NAICS codes: [16] [17]

- 2361 Residential Building Construction
- 2362 Nonresidential Building Construction

[16] ERG and OSHA used the four-digit NAICS codes for the construction sector both because the BLS's Occupational Employment Statistics survey only provides data at this level of detail ad because, unlike the case in general industry and maritime, job categories in the construction sector are task-specific, not industry-specific. Furthermore, as far as economic impacts are concerned, IRS data on profitability are reported only at the four-digit NAICS code level of detail.

[17] Some public employees in state and local governments are exposed to elevated levels of respirable crystalline silica. These exposures are included in the construction sector because they are the result of construction activities.

- 2371 Utility System Construction
- 2372 Land Subdivision
- 2373 Highway, Street, and Bridge Construction
- 2379 Other Heavy and Civil Engineering Construction
- 2381 Foundation, Structure, and Building Exterior Contractors
- 2382 Building Equipment Contractors
- 2383 Building Finishing Contractors
- 2389 Other Specialty Trade Contractors
- 2211 Electric Utilities
- 9992 State Government
- 9993 Local Government

Characteristics of Affected Industries

Table VII–3 provides an overview of the industries and estimated number of workers affected by the final rule. Included in Table VII–3 are summary statistics for each of the affected industries, subtotals for construction and for general industry and maritime, and grand totals for all affected industries combined.

The first five columns in Table VII–3 identify the NAICS code for each industry in which workers are routinely exposed to respirable crystalline silica and the name or title of the industry, followed by the total number of entities, establishments, and employees for that industry. Note that, while the industries are characterized by such exposure, not every entity, establishment, and employee in these affected industries engage in activities involving silica exposure.

The next three columns in Table VII–3 show, for each affected industry, the number of entities and establishments in which workers are actually exposed to silica and the total number of workers exposed to silica. The number of affected establishments was set equal to the total number of establishments in an industry (based on Census data) unless the number of affected establishments would exceed the number of affected employees in the industry. In that case, the number of affected establishments in the industry was set equal to the number of affected employees, and the number of affected entities in the industry was reduced so as to maintain the same ratio of entities to establishments in the industry.[18]

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[18] OSHA determined that removing this assumption would have a negligible impact on total costs and would reduce the cost and economic impact on the average affected establishment or entity.

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues per Establish-ment ($1,000)
Construction											
236100	Residential Building Construction	149,938	151,034	519,070	149,938	151,034	210,773	16,717	$190,342,871	$1,269	$1,260
236200	Nonresidential Building Construction	39,813	41,018	521,112	39,813	41,018	209,136	22,796	$280,695,881	$7,050	$6,843
237100	Utility System Construction	17,446	18,686	466,099	17,446	18,686	190,044	65,949	$118,254,327	$6,778	$6,328
237200	Land Subdivision	6,055	6,182	53,045	2,106	2,150	5,726	1,519	$40,050,602	$6,614	$6,479
237300	Highway, Street, and Bridge Construction	9,271	10,043	251,065	9,271	10,043	148,254	40,171	$100,657,731	$10,857	$10,023
237900	Other Heavy and Civil Engineering Construction	4,092	4,222	79,390	4,092	4,222	37,611	11,077	$24,201,269	$5,914	$5,732
238100	Foundation, Structure, and Building Exterior Contractors	85,082	85,801	657,508	85,082	85,801	324,954	56,183	$111,574,869	$1,311	$1,300
238200	Building Equipment Contractors	165,862	170,002	1,629,581	139,065	142,536	326,154	21,455	$304,014,454	$1,833	$1,788
238300	Building Finishing Contractors	101,727	102,700	608,945	76,597	77,330	140,813	17,985	$88,148,669	$867	$858
238900	Other Specialty Trade Contractors	62,522	63,214	475,127	62,522	63,214	259,906	87,322	$102,228,982	$1,635	$1,617
221100	Electric Utilities	1,831	10,401	509,704	821	4,662	6,541	2,363	$427,201,520	$233,316	$41,073
999200	State governments [c]	N/A	N/A	N/A	N/A	0	33,558	8,088	N/A	N/A	N/A
999300	Local governments [c]	N/A	N/A	N/A	N/A	0	123,946	36,084	N/A	N/A	N/A
	Subtotals - Construction	**643,639**	**663,303**	**5,770,646**	**586,752**	**600,695**	**2,017,417**	**387,710**	**$1,787,371,175**	**$2,777**	**$2,695**

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
General Industry and Maritime											
213112	Support Activities for Oil and Gas Operations	8,877	10,872	272,357	200	444	16,960	N/A	$17,396,813	$86,984	$39,182
324121	Asphalt Paving Mixture and Block Manufacturing	472	1,362	14,353	472	1,362	4,737		$13,137,706	$27,834	$9,646
324122	Asphalt Shingle and Coating Materials Manufacturing	132	223	9,074	132	223	3,158		$10,506,586	$79,595	$47,115
325510	Paint and Coating Manufacturing	971	1,161	35,328	646	772	2,511		$23,628,642	$24,334	$20,352
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	636	655	13,096	636	655	6,269		$2,131,885	$3,352	$3,255
327120	Clay Building Material and Refractories Manufacturing	417	586	20,985	417	586	7,893		$5,109,750	$12,254	$8,720
327211	Flat Glass Manufacturing	63	85	8,990	41	56	221		$3,168,243	$50,290	$37,273
327212	Other Pressed and Blown Glass and Glassware Manufacturing	407	442	13,434	157	171	674		$3,337,290	$8,200	$7,550
327213	Glass Container Manufacturing	33	74	13,684	28	62	686		$3,832,809	$116,146	$51,795
327320	Ready-Mix Concrete Manufacturing	2,115	5,377	66,196	2,115	5,377	27,123		$20,360,217	$9,627	$3,787
327331	Concrete Block and Brick Manufacturing	511	817	14,896	511	817	7,182		$3,891,212	$7,615	$4,763

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
327332	Concrete Pipe Manufacturing	157	352	8,229	157	352	3,967		$2,013,573	$12,825	$5,720
327390	Other Concrete Product Manufacturing	1,633	1,973	45,284	1,633	1,973	21,832		$8,640,490	$5,291	$4,379
327991	Cut Stone and Stone Product Manufacturing	1,801	1,859	24,537	1,801	1,859	9,429		$3,513,346	$1,951	$1,890
327992	Ground or Treated Mineral and Earth Manufacturing	153	249	7,129	153	249	5,432		$3,326,599	$21,742	$13,360
327993	Mineral Wool Manufacturing	175	269	13,925	113	174	789		$4,753,466	$27,163	$17,671
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	302	452	10,118	302	452	7,952		$4,045,718	$13,396	$8,951
331110	Iron and Steel Mills and Ferroalloy Manufacturing	414	562	105,309	206	280	594		$113,226,448	$273,494	$201,471
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	212	262	25,592	89	110	145		$14,371,958	$67,792	$54,855
331221	Rolled Steel Shape Manufacturing	150	167	7,836	37	41	44		$5,991,188	$39,941	$35,875
331222	Steel Wire Drawing	251	294	14,241	66	78	81		$5,654,358	$22,527	$19,233
331314	Secondary Smelting and Alloying of Aluminum	92	114	5,415	25	30	30		$5,623,100	$61,121	$49,325
331420	Copper Rolling, Drawing, Extruding, and Alloying	179	249	21,408	77	107	119		$23,357,388	$130,488	$93,805

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	228	261	10,913	51	58	62		$14,552,929	$63,829	$55,758
331511	Iron Foundries	361	407	38,286	361	407	13,583		$10,816,325	$29,962	$26,576
331512	Steel Investment Foundries	109	128	15,190	109	128	5,487		$3,728,493	$34,206	$29,129
331513	Steel Foundries (except Investment)	194	208	18,236	194	208	6,469		$4,536,694	$23,385	$21,811
331524	Aluminum Foundries (except Die-Casting)	383	406	15,446	383	406	5,601		$2,830,636	$7,391	$6,972
331529	Other Nonferrous Metal Foundries (except Die-Casting)	293	300	9,522	293	300	3,451		$2,412,855	$8,235	$8,043
332111	Iron and Steel Forging	315	356	24,030	110	125	136		$10,673,965	$33,886	$29,983
332112	Nonferrous Forging	54	62	6,182	25	29	35		$2,388,185	$44,226	$38,519
332117	Powder Metallurgy Part Manufacturing	121	133	8,160	42	46	46		$2,023,839	$16,726	$15,217
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	1,417	1,499	53,018	272	288	299		$11,816,815	$8,339	$7,883

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	178	188	7,374	35	37	42		$3,743,875	$21,033	$19,914
332216	Saw Blade and Handtool Manufacturing	935	1,012	27,852	136	147	157		$6,750,376	$7,220	$6,670
332323	Ornamental and Architectural Metal Work Manufacturing	2,175	2,214	29,694	39	40	40		$5,806,852	$2,670	$2,623
332439	Other Metal Container Manufacturing	298	346	11,749	53	62	66		$3,724,262	$12,498	$10,764
332510	Hardware Manufacturing	553	607	26,540	122	134	150		$7,494,634	$13,553	$12,347
332613	Spring Manufacturing	334	392	14,829	70	82	84		$3,595,394	$10,765	$9,172
332618	Other Fabricated Wire Product Manufacturing	829	911	24,626	124	137	139		$5,393,567	$6,506	$5,920
332710	Machine Shops	19,062	19,270	245,538	1,369	1,384	1,387		$38,834,064	$2,037	$2,015
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	2,314	2,518	49,911	1,488	1,620	4,113		$13,159,283	$5,687	$5,226
332911	Industrial Valve Manufacturing	401	517	35,657	138	177	201		$12,406,422	$30,939	$23,997

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
332912	Fluid Power Valve and Hose Fitting Manufacturing	303	371	34,663	114	139	196		$10,351,141	$34,162	$27,901
332913	Plumbing Fixture Fitting and Trim Manufacturing	108	121	7,567	32	36	43		$3,879,892	$35,925	$32,065
332919	Other Metal Valve and Pipe Fitting Manufacturing	224	243	14,260	69	75	80		$4,852,328	$21,662	$19,968
332991	Ball and Roller Bearing Manufacturing	118	176	22,522	66	99	127		$6,811,132	$57,721	$38,700
332996	Fabricated Pipe and Pipe Fitting Manufacturing	700	765	29,914	146	160	169		$8,539,434	$12,199	$11,163
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	3,483	3,553	70,118	388	396	405		$14,774,444	$4,242	$4,158
333318	Other Commercial and Service Industry Machinery Manufacturing	1,284	1,378	54,518	241	258	308		$17,379,403	$13,535	$12,612
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	414	491	24,138	110	131	136		$6,017,917	$14,536	$12,256
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	441	472	17,959	95	102	102		$5,305,649	$12,031	$11,241
333511	Industrial Mold Manufacturing	1,629	1,669	35,194	190	194	199		$6,097,671	$3,743	$3,653

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	2,444	2,477	42,810	233	236	242		$7,694,694	$3,148	$3,106
333515	Cutting Tool and Machine Tool Accessory Manufacturing	1,472	1,519	28,451	156	161	161		$5,277,212	$3,585	$3,474
333517	Machine Tool Manufacturing	662	689	24,322	124	129	137		$7,477,416	$11,295	$10,853
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	355	371	11,582	59	62	66		$3,166,299	$8,919	$8,534
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	213	246	16,072	66	76	91		$5,093,290	$23,912	$20,704
333613	Mechanical Power Transmission Equipment Manufacturing	206	245	15,545	69	82	88		$4,671,836	$22,679	$19,069
333911	Pump and Pumping Equipment Manufacturing	441	539	33,772	135	165	191		$15,242,314	$34,563	$28,279
333912	Air and Gas Compressor Manufacturing	262	306	21,225	85	99	120		$10,412,455	$39,742	$34,028
333991	Power-Driven Handtool Manufacturing	141	151	8,859	35	37	50		$4,253,527	$30,167	$28,169
333992	Welding and Soldering Equipment Manufacturing	325	344	15,781	55	58	89		$5,881,450	$18,097	$17,097

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
333993	Packaging Machinery Manufacturing	535	580	20,010	99	108	113		$5,690,862	$10,637	$9,812
333994	Industrial Process Furnace and Oven Manufacturing	327	352	11,009	58	62	62		$2,743,937	$8,391	$7,795
333995	Fluid Power Cylinder and Actuator Manufacturing	264	324	24,208	86	106	137		$6,560,865	$24,852	$20,250
333996	Fluid Power Pump and Motor Manufacturing	129	148	10,554	44	51	60		$4,065,318	$31,514	$27,468
333997	Scale and Balance Manufacturing	82	88	3,725	20	21	21		$969,400	$11,822	$11,016
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	1,590	1,654	51,495	251	261	291		$15,072,973	$9,480	$9,113
334519	Other Measuring and Controlling Device Manufacturing	858	905	34,604	155	164	196		$11,468,826	$13,367	$12,673
335210	Small Electrical Appliance Manufacturing	119	127	8,216	19	20	24		$3,412,551	$28,677	$26,870
335221	Household Cooking Appliance Manufacturing	95	98	10,408	14	15	30		$4,480,046	$47,158	$45,715
335222	Household Refrigerator and Home Freezer Manufacturing	23	30	9,374	8	11	27		$3,533,056	$153,611	$117,769
335224	Household Laundry Equipment Manufacturing	8	9	4,438	3	3	13		$912,032	$114,004	$101,337

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
335228	Other Major Household Appliance Manufacturing	30	36	9,059	10	12	26		$4,514,574	$150,486	$125,405
336111	Automobile Manufacturing	159	173	62,686	36	39	354		$103,913,316	$653,543	$600,655
336112	Light Truck and Utility Vehicle Manufacturing	63	78	56,524	22	27	319		$118,710,290	$1,884,290	$1,521,927
336120	Heavy Duty Truck Manufacturing	68	85	30,756	32	40	174		$30,162,164	$443,561	$354,849
336211	Motor Vehicle Body Manufacturing	656	741	40,544	168	190	229		$11,284,629	$17,202	$15,229
336212	Truck Trailer Manufacturing	374	421	28,304	108	121	160		$8,276,216	$22,129	$19,658
336213	Motor Home Manufacturing	54	62	7,395	14	16	42		$2,420,705	$44,828	$39,044
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	788	849	52,752	182	196	298		$31,854,605	$40,425	$37,520
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	618	678	50,017	183	200	283		$20,449,859	$33,090	$30,162
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	210	245	28,663	92	108	162		$11,779,510	$56,093	$48,080
336340	Motor Vehicle Brake System Manufacturing	156	195	21,859	80	100	123		$10,032,414	$64,310	$51,448

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	424	503	58,248	165	196	329		$34,304,884	$80,908	$68,201
336370	Motor Vehicle Metal Stamping	645	773	81,018	296	355	458		$31,438,874	$48,742	$40,671
336390	Other Motor Vehicle Parts Manufacturing	1,302	1,508	122,041	440	510	689		$58,108,630	$44,630	$38,534
336611	Ship Building and Repairing	604	689	108,311	309	353	3,038		$25,050,036	$41,474	$36,357
336612	Boat Building	836	871	28,054	301	313	787		$7,015,414	$8,392	$8,054
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	60	71	10,990	26	31	62		$5,815,339	$96,922	$81,906
337110	Wood Kitchen Cabinet and Countertop Manufacturing	6,795	6,862	76,052	204	206	223		$10,670,228	$1,570	$1,555
337215	Showcase, Partition, Shelving, and Locker Manufacturing	1,042	1,097	33,437	169	177	189		$6,526,548	$6,263	$5,949
339114	Dental Equipment and Supplies Manufacturing	706	727	15,835	706	727	4,956		$5,194,250	$7,357	$7,145
339116	Dental Laboratories	6,533	6,818	44,097	6,533	6,818	31,105		$4,606,911	$705	$676
339910	Jewelry and Silverware Manufacturing	2,102	2,119	24,436	2,102	2,119	6,772		$7,520,912	$3,578	$3,549

Table VII-3: Characteristics of Industries Affected by OSHA's Final Standards for Silica – All Entities (continued)

NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employ-ment [a]	Total Affected Entities [b]	Total Affected Establish-ments [b]	Total Affected Employ-ment [b]	Total FTE Affected Employ-ees [b]	Total Revenues ($1,000) [a]	Revenues Per Entity ($1,000)	Revenues Per Establishment ($1,000)
339950	Sign Manufacturing	5,405	5,499	69,051	357	363	384		$10,586,158	$1,959	$1,925
423840	Industrial Supplies Merchant Wholesalers	5,192	7,614	82,871	1,148	1,683	1,773		$64,188,699	$12,363	$8,430
444110	Home Centers	2,167	6,569	609,186	35	107	107		$13,942,008	$6,434	$2,122
482110	Rail transportation	N/A	N/A	N/A	N/A	N/A	16,895		N/A	N/A	N/A
561730	Landscaping Services	91,251	92,976	548,662	25,500	25,982	43,033		$52,657,318	$577	$566
621210	Offices of Dentists	125,151	133,107	873,172	8,015	8,525	8,525		$104,740,291	$837	$787
	Subtotals – General Industry and Maritime	**323,353**	**351,998**	**5,335,502**	**65,887**	**75,074**	**294,844**		**$1,475,562,403**	**$4,563**	**$4,192**
	Totals – All Industries	**966,992**	**1,015,301**	**11,106,148**	**652,639**	**675,770**	**2,312,261**	**387,710**	**$3,262,933,578**	**$3,374**	**$3,214**

[a] US Census Bureau, Statistics of US Businesses, 2012.
[b] OSHA estimates of employees potentially exposed to silica and associated entities and establishments. Affected entities and establishments constrained to be less than or equal to the number of affected employees. Full-time equivalent estimate does not apply to general industry and maritime.
Estimates of the numbers of affected employees in general industry and maritime are based on an assessment for each sector of the job categories of workers who perform tasks where silica exposures can occur. OSHA matched occupational titles from the 2012 BLS Occupational Employment Statistics (OES) survey with these at-risk job categories and then used OES occupational employment statistics to generate industry-specific estimates of the numbers of affected employees. To ensure data compatibility, OES occupational employment statistics were benchmarked to the 2012 County Business Pattern employment totals for each industry.
[c] State-plan states only. State and local governments are included under the construction sector because the silica risks for public employees are the result of construction-related activities.
[d] For NAICS 482110, Rail Transportation, data on entities, establishments and revenues were not available from the US Census Bureau. OSHA's final profile of rail transportation is drawn from supplementary government and industry sources; see Chapter VI in the FEA, Economic Feasibility Analysis and Regulatory Flexibility Determination.
Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, 2016.

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As shown in Table VII–3, OSHA estimates that a total of 652,600 entities (586,800 in construction; 65,900 in general industry and maritime), 675,800 establishments (600,700 in construction; 75,100 in general industry and maritime), and 2.3 million workers (2.0 million in construction; 0.3 million in general industry and maritime) would be affected by the final silica rule. Note that only 67 percent of the entities and establishments, and about 21 percent of the workers in affected industries,

actually engage in activities involving silica exposure.[19]

The ninth column in Table VII–3, with data only for construction, shows for each affected NAICS construction industry the number of full-time-equivalent (FTE) affected workers that corresponds to the total number of affected construction workers in the previous column.[20] This distinction is necessary because affected construction workers may spend large amounts of time working on tasks with no risk of silica exposure. As shown in Table VII–3, the 2.0 million affected workers in construction converts to approximately 387,700 FTE affected workers. In contrast, OSHA based its analysis of the affected workers in general industry and maritime on the assumption that they were engaged full time in activities with some silica exposure.

The last three columns in Table VII–3 show combined total revenues for all entities (not just affected entities) in each affected industry, and the average revenue per entity and per establishment in each affected industry. Because OSHA did not have data to distinguish revenues for affected entities and establishments in any industry, average revenue per entity and average revenue per affected entity (as well as average revenue per establishment and average revenue per affected establishment) are estimated to be equal in value.

[19] It should be emphasized that these percentages vary significantly depending on the industry sector and, within an industry sector, depending on the NAICS industry. For example, about 35 percent of the workers in construction, but only 6 percent of workers in general industry, actually engage in activities involving silica exposure. As an example within construction, about 35 percent of workers in highway, street, and bridge construction, but only 3 percent of workers in state and local governments, actually engage in activities involving silica exposure.

[20] FTE affected workers becomes a relevant variable in the estimation of control costs in the construction industry. The reason is that, consistent with the costing methodology, control costs depend only on how many worker-days there are in which exposures are above the PEL. These are the worker-days in which controls are required. For the derivation of FTEs, *see* Tables IV–8 and IV–22 and the associated text in ERG (2007a, Document ID 1709).

Silica Exposure Profile of At-Risk Workers

The technological feasibility analyses presented in Chapter IV of the FEA contain data and discussion of worker exposures to silica throughout industry. Exposure profiles, by job category, were developed from individual exposure measurements that were judged to be substantive and to contain sufficient accompanying description to allow interpretation of the circumstance of each measurement. The resulting exposure profiles show the job categories with current overexposures to silica and, thus, the workers for whom silica controls would be implemented under the final rule.

Chapter IV of the FEA includes a section with a detailed description of the methods used to develop the exposure profile and to assess the technological feasibility of the final standard. The final exposure profiles take the exposure data that were used for the same purpose in OSHA's PEA and build upon them, using new data in the rulemaking record. The sampling data that were used to identify the affected industries and to develop the exposure profiles presented in the PEA were obtained from a comprehensive review of the following sources of information: OSHA compliance inspections conducted before 2011, OSHA contractor (ERG) site visits performed for this rulemaking, NIOSH site visits, NIOSH Health Hazard Evaluation reports (HHEs), published literature, submissions by individual companies or associations and, in a few cases, data from analogous operations (Document ID 1720, pp. IV–2–IV–3). The exposure profiles presented in the PEA were updated for the FEA using exposure measurements from the OSHA Information System (OIS) that were taken during compliance inspections conducted between 2011 and 2014 (Document ID 3958). In addition, exposure data submitted to the record by rulemaking participants were used to update the exposure profiles. The criteria used for determining whether to include exposure data in the exposure profiles are described in Section IV–2—Methodology in Chapter IV of the FEA. As explained there, some of the original data are no longer used in the exposure profiles based on those selection or screening criteria. OSHA considers the exposure data relied upon for its analysis to be the best available evidence of baseline silica exposure conditions.

Table VII–4 summarizes, from the exposure profiles, the total number of workers at risk from silica exposure at any level, and the distribution of 8-hour TWA respirable crystalline silica exposures by job category for general industry and maritime sectors and for construction activities. Exposures are grouped into the following ranges: Less than 25 $\mu g/m^3$; $\geq$ 25 $\mu g/m^3$ and $\leq$ 50 $\mu g/m^3$; > 50 $\mu g/m^3$ and $\leq$ 100 $\mu g/m^3$; > 100 $\mu g/m^3$ and $\leq$ 250 $\mu g/m^3$; and greater than 250 $\mu g/m^3$. These frequencies represent the percentages of production employees in each job category and sector currently exposed at levels within the indicated range.

Table VII–5 presents data by NAICS code—for each affected general, maritime, and construction industry—on the estimated number of workers currently at risk from silica exposure, as well as the estimated number of workers at risk of silica exposure at or above 25 $\mu g/m^3$, above 50 $\mu g/m^3$, and above 100 $\mu g/m^3$. As shown, an estimated 1,249,250 workers (1,097,000 in construction; 152,300 in general industry and maritime) currently have silica exposures at or above the new action level of 25 $\mu g/m^3$; an estimated 948,100 workers (847,700 in construction; 100,400 in general industry and maritime) currently have silica exposures above the new PEL of 50 $\mu g/m^3$; and an estimated 578,000 workers (519,200 in construction; 58,800 in general industry and maritime) currently have silica exposures above 100 $\mu g/m^3$—an alternative PEL investigated by OSHA for economic analysis purposes.

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Table VII-4: Distribution of Silica Exposures by Application Group and Job Category or Activity – Final Profile

		Silica Exposure Range					
Application Group	Job Category/Activity	<25 µg/m^3	25-50 µg/m^3	50-100 µg/m^3	100-250 µg/m^3	>250 µg/m^3	Total[a]
Construction							
	Abrasive Blasters	21.1%	9.9%	15.5%	18.3%	35.2%	100.0%
	Drywall Finishers	86.7%	6.7%	6.7%	0.0%	0.0%	100.0%
	Heavy Equipment Operators	74.3%	17.1%	5.7%	2.9%	0.0%	100.0%
	Hole Drillers Using Hand-Held Drills	33.3%	19.0%	23.8%	19.0%	4.8%	100.0%
	Demolition Workers Using Jackhammers and Handheld Power Chipping Tools	24.6%	6.0%	15.7%	22.4%	31.3%	100.0%
	Masonry Cutters Using Portable Saws	54.4%	12.1%	7.3%	18.0%	8.3%	100.0%
	Masonry Cutters Using Stationary Saws	23.3%	26.7%	23.3%	3.3%	23.3%	100.0%
	Millers Using Portable or Mobile Machines	58.1%	16.3%	18.6%	2.3%	4.7%	100.0%
	Rock and Concrete Drillers	37.3%	15.7%	17.6%	15.7%	13.7%	100.0%
	Rock-Crushing Machine Operators and Tenders	37.5%	0.0%	25.0%	25.0%	12.5%	100.0%
	Tuckpointers and Grinders	12.5%	9.6%	13.3%	18.3%	46.3%	100.0%
	Underground Construction Workers	59.3%	18.5%	11.1%	7.4%	3.7%	100.0%
General Industry/Maritime							
Hydraulic Fracturing							
	Fracturing Sand Workers	8.6%	8.6%	14.3%	27.1%	41.4%	100.0%
	Ancillary Workers	25.0%	25.0%	12.5%	12.5%	25.0%	100.0%
	Remote/Intermittent Support Workers	38.9%	13.9%	25.0%	13.9%	8.3%	100.0%

Table VII-4: Distribution of Silica Exposures by Application Group and Job Category or Activity – Final Profile (Continued)

		Silica Exposure Range					
Application Group	Job Category/Activity	<25 µg/m^3	25-50 µg/m^3	50-100 µg/m^3	100-250 µg/m^3	>250 µg/m^3	Total[a]
Asphalt Paving Products		**80.0%**	**0.0%**	**20.0%**	**0.0%**	**0.0%**	**100.0%**
	Front-End Loader Operator	50.0%	0.0%	50.0%	0.0%	0.0%	100.0%
	Maintenance Worker	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Plant Operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Asphalt Roofing Materials		**0.0%**	**77.8%**	**11.6%**	**10.6%**	**0.0%**	**100.0%**
	Material Handler	0.0%	64.2%	21.5%	14.3%	0.0%	100.0%
	Production Operator	0.0%	80.0%	10.0%	10.0%	0.0%	100.0%
Captive Foundries		**45.3%**	**20.8%**	**13.2%**	**9.4%**	**11.3%**	**100.0%**
	Abrasive Blasting Operator	42.9%	14.3%	14.3%	0.0%	28.6%	100.0%
	Cleaning/Finishing Operator	60.0%	20.0%	20.0%	0.0%	0.0%	100.0%
	Coremaker	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Furnace Operator	66.7%	0.0%	33.3%	0.0%	0.0%	100.0%
	Housekeeping Worker	50.0%	50.0%	0.0%	0.0%	0.0%	100.0%
	Knockout Operator	66.7%	33.3%	0.0%	0.0%	0.0%	100.0%
	Maintenance Operator	50.0%	10.0%	0.0%	0.0%	40.0%	100.0%
	Molder	75.0%	25.0%	0.0%	0.0%	0.0%	100.0%
	Shakeout Operator	7.7%	30.8%	23.1%	38.5%	0.0%	100.0%
Concrete Products		**63.0%**	**11.0%**	**9.6%**	**9.6%**	**6.8%**	**100.0%**
	Abrasive Blasting Operator	11.8%	5.9%	23.5%	23.5%	35.3%	100.0%
	Finishing operator	52.0%	18.0%	8.0%	12.0%	10.0%	100.0%
	Forming Line operator	86.2%	6.2%	6.2%	1.5%	0.0%	100.0%
	Material Handler	56.5%	17.4%	13.0%	8.7%	4.3%	100.0%
	Mixer Operator	74.3%	5.7%	2.9%	14.3%	2.9%	100.0%
	Packaging Operator	33.3%	0.0%	33.3%	16.7%	16.7%	100.0%

Table VII-4: Distribution of Silica Exposures by Application Group and Job Category or Activity – Final Profile (Continued)

		Silica Exposure Range					
Application Group	Job Category/Activity	<25 µg/m^3	25-50 µg/m^3	50-100 µg/m^3	100-250 µg/m^3	>250 µg/m^3	Total[a]
Cut Stone		**38.3%**	**14.6%**	**15.8%**	**20.8%**	**10.4%**	**100.0%**
	Abrasive Blasting Operations	20.0%	30.0%	10.0%	20.0%	20.0%	100.0%
	Fabricator	48.9%	12.6%	11.9%	13.3%	13.3%	100.0%
	Machine Operator	16.7%	16.7%	22.2%	33.3%	11.1%	100.0%
	Sawyer	33.3%	16.7%	22.9%	20.8%	6.3%	100.0%
	Splitter/chipper	17.2%	13.8%	20.7%	48.3%	0.0%	100.0%
Dental Equipment and Supplies		**60.0%**	**0.0%**	**20.0%**	**20.0%**	**0.0%**	**100.0%**
	Production operator	60.0%	0.0%	20.0%	20.0%	0.0%	100.0%
Dental Laboratories		**83.3%**	**13.9%**	**2.8%**	**0.0%**	**0.0%**	**100.0%**
	Dental technician	83.3%	13.9%	2.8%	0.0%	0.0%	100.0%
Engineered Stone		**100.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**100.0%**
	Production Worker	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Glass		**28.6%**	**7.1%**	**28.6%**	**21.4%**	**14.3%**	**100.0%**
	Batch operations and Associated Workers	50.0%	0.0%	25.0%	12.5%	12.5%	100.0%
	Material handler	0.0%	16.7%	33.3%	33.3%	16.7%	100.0%
Ferrous Sand Casting Foundries		**21.6%**	**23.9%**	**25.4%**	**18.6%**	**10.5%**	**100.0%**
	Abrasive blasting operator	4.9%	27.9%	26.2%	29.5%	11.5%	100.0%
	Cleaning/Finishing operator	16.2%	18.9%	18.9%	22.4%	23.7%	100.0%
	Coremaker	28.7%	28.7%	29.6%	9.3%	3.7%	100.0%
	Furnace operator	54.5%	18.2%	0.0%	9.1%	18.2%	100.0%
	Housekeeping worker	18.2%	18.2%	54.5%	9.1%	00.0%	100.0%
	Knockout operator	14.3%	37.1%	22.9%	22.9%	2.9%	100.0%
	Maintenance operator	20.8%	25.0%	25.0%	8.3%	20.8%	100.0%
	Material handler	27.8%	22.2%	30.6%	19.4%	0.0%	100.0%
	Molder	34.2%	22.8%	26.6%	15.8%	0.6%	100.0%
	Pouring operator	30.0%	20.0%	20.0%	30.0%	0.0%	100.0%

Table VII-4: Distribution of Silica Exposures by Application Group and Job Category or Activity – Final Profile (Continued)

		Silica Exposure Range					
Application Group	Job Category/Activity	<25 µg/m^3	25-50 µg/m^3	50-100 µg/m^3	100-250 µg/m^3	>250 µg/m^3	Total[a]
Ferrous Sand Casting Foundries (contd.)	Sand systems operator	17.9%	19.6%	25.0%	25.0%	12.5%	100.0%
	Shakeout operator	13.3%	30.0%	34.4%	14.4%	7.8%	100.0%
Jewelry Industry		**63.6%**	**0.0%**	**0.0%**	**18.2%**	**18.2%**	**100.0%**
	Jewelers	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Jewelers (IMIS)	33.3%	0.0%	0.0%	33.3%	33.3%	100.0%
Landscape Contracting		**42.9%**	**28.6%**	**28.6%**	**0.0%**	**0.0%**	**100.0%**
	Landscape Worker	66.7%	33.3%	0.0%	0.0%	0.0%	100.0%
	Landscape Worker (IMIS)	25.0%	25.0%	50.0%	0.0%	0.0%	100.0%
Mineral Processing		**48.5%**	**30.3%**	**15.2%**	**6.1%**	**0.0%**	**100.0%**
	Production Worker (Before engineering improvements)	55.6%	22.2%	16.7%	5.6%	0.0%	100.0%
	Production Worker (With engineering controls)	66.7%	33.3%	0.0%	0.0%	0.0%	100.0%
	Production Worker (other conditions)	0.0%	50.0%	33.3%	16.7%	0.0%	100.0%
Mineral Wool		**28.6%**	**7.1%**	**28.6%**	**21.4%**	**14.3%**	**100.0%**
	Batch operator	50.0%	0.0%	33.3%	0.0%	16.7%	100.0%
	Material handler	0.0%	16.7%	33.3%	33.3%	16.7%	100.0%
Nonferrous Sand Casting Foundries		**64.3%**	**19.8%**	**13.1%**	**2.0%**	**0.8%**	**100.0%**
	Abrasive Blasting Operator	54.5%	36.4%	9.1%	0.0%	0.0%	100.0%
	Cleaning/Finishing Operator	50.0%	25.0%	22.7%	0.0%	2.3%	100.0%
	Coremaker	90.6%	5.7%	3.8%	0.0%	0.0%	100.0%
	Furnace Operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Knockout Operator	53.8%	30.8%	15.4%	0.0%	0.0%	100.0%
	Maintenance Operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Material Handler	50.0%	50.0%	0.0%	0.0%	0.0%	100.0%
	Molder	63.9%	21.3%	11.5%	1.6%	1.6%	100.0%

Table VII-4: Distribution of Silica Exposures by Application Group and Job Category or Activity – Final Profile (Continued)

		Silica Exposure Range					
Application Group	Job Category/Activity	<25 µg/m^3	25-50 µg/m^3	50-100 µg/m^3	100-250 µg/m^3	>250 µg/m^3	Total[a]
	Pouring Operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Nonferrous Sand Casting Foundries (contd.)	Sand Systems Operator	60.0%	20.0%	20.0%	0.0%	0.0%	100.0%
	Shakeout Operator	38.7%	25.8%	22.6%	12.9%	0.0%	100.0%
Non-Sand Casting Foundries		**55.6%**	**18.5%**	**11.3%**	**7.3%**	**7.3%**	**100.0%**
	Abrasive blasting operator	53.8%	7.7%	15.4%	7.7%	15.4%	100.0%
	Cleaning/Finishing operator	52.9%	32.4%	5.9%	5.9%	2.9%	100.0%
	Coremaker	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Furnace operator	75.0%	25.0%	0.0%	0.0%	0.0%	100.0%
	Housekeeping worker	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Knockout operator	26.7%	20.0%	33.3%	0.0%	20.0%	100.0%
	Maintenance operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Material handler	66.7%	0.0%	0.0%	33.3%	0.0%	100.0%
	Molder	55.2%	20.7%	13.8%	6.9%	3.4%	100.0%
	Pattern Assembler	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Pouring Operator	85.7%	0.0%	0.0%	14.3%	0.0%	100.0%
	Shakeout Operator	14.3%	14.3%	14.3%	28.6%	28.6%	100.0%
Paint and Coatings		**82.6%**	**4.3%**	**0.0%**	**4.3%**	**8.7%**	**100.0%**
	Material Handler	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Mixer Operator	66.7%	8.3%	0.0%	8.3%	16.7%	100.0%
Porcelain Enameling		**42.9%**	**14.3%**	**22.9%**	**5.7%**	**14.3%**	**100.0%**
	Enamel Preparer	20.0%	20.0%	40.0%	20.0%	0.0%	100.0%
	Porcelain Applicator	46.7%	13.3%	20.0%	3.3%	16.7%	100.0%
Pottery		**34.5%**	**21.8%**	**28.7%**	**8.0%**	**6.9%**	**100.0%**
	Coatings Operator (Automated spraying)	20.0%	20.0%	60.0%	0.0%	0.0%	100.0%

Table VII-4: Distribution of Silica Exposures by Application Group and Job Category or Activity – Final Profile (Continued)

		Silica Exposure Range					
Application Group	Job Category/Activity	<25 µg/m^3	25-50 µg/m^3	50-100 µg/m^3	100-250 µg/m^3	>250 µg/m^3	Total[a]
	Coatings Operator (Manual/semiautomatic spraying)	30.8%	15.4%	23.1%	23.1%	7.7%	100.0%
	Coatings Preparer	8.3%	8.3%	41.7%	8.3%	33.3%	100.0%
Pottery (contd.)	Finishing Operator	60.0%	20.0%	20.0%	0.0%	0.0%	100.0%
	Forming Line Operator (LEV in use)	50.0%	50.0%	0.0%	0.0%	0.0%	100.0%
	Forming Line Operator (No LEV)	25.0%	50.0%	25.0%	0.0%	0.0%	100.0%
	Forming Line Operator (No information about controls available)	42.9%	21.4%	28.6%	7.1%	0.0%	100.0%
	Material Handler (Fully or partially automated process)	50.0%	50.0%	0.0%	0.0%	0.0%	100.0%
	Material Handler (LEV in use)	0.0%	33.3%	66.7%	0.0%	0.0%	100.0%
	Material Handler (No LEV)	0.0%	0.0%	33.3%	33.3%	33.3%	100.0%
	Material Handler (No information about controls available)	66.7%	33.3%	0.0%	0.0%	0.0%	100.0%
Railroads		**31.7%**	**33.3%**	**16.7%**	**11.1%**	**7.1%**	**100.0%**
	Ballast dumper	50.0%	26.9%	7.7%	7.7%	7.7%	100.0%
	Machine Operator (Ballast Regulator)	21.1%	34.2%	21.1%	10.5%	13.2%	100.0%
	Machine Operator (Broom Operator)	9.5%	28.6%	33.3%	23.8%	4.8%	100.0%
	Machine Operator (Tamper Operator)	37.1%	40.0%	11.4%	8.6%	2.9%	100.0%
	Machine Operator (Other Operator)	66.7%	33.3%	0.0%	0.0%	0.0%	100.0%
Ready-Mix Concrete Industry		**69.7%**	**6.1%**	**12.1%**	**6.1%**	**6.1%**	**100.0%**
	Batch operator	87.5%	0.0%	12.5%	0.0%	0.0%	100.0%
	Maintenance operator	60.0%	20.0%	20.0%	0.0%	0.0%	100.0%
	Material handler	69.2%	7.7%	15.4%	7.7%	0.0%	100.0%
	Quality control technician	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Truck driver	0.0%	0.0%	0.0%	33.3%	67.7%	100.0%

Table VII-4: Distribution of Silica Exposures by Application Group and Job Category or Activity – Final Profile (Continued)

		Silica Exposure Range					
Application Group	Job Category/Activity	<25 µg/m^3	25-50 µg/m^3	50-100 µg/m^3	100-250 µg/m^3	>250 µg/m^3	Total[a]
Refractories		**52.4%**	**25.4%**	**11.1%**	**9.5%**	**1.6%**	**100.0%**
	Ceramic fiber furnace operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Finishing operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Forming operator	25.0%	62.5%	12.5%	0.0%	0.0%	100.0%
	Material handler	41.9%	19.4%	19.4%	16.1%	3.2%	100.0%
Refractories (contd.)	Packaging operator	50.0%	41.7%	0.0%	8.3%	0.0%	100.0%
Refractory Repair		**33.3%**	**33.3%**	**16.7%**	**16.7%**	**0.0%**	**100.0%**
	Production operator	33.3%	33.3%	16.7%	16.7%	0.0%	100.0%
Shipyards (Maritime) Industry		**22.2%**	**22.2%**	**11.1%**	**11.1%**	**33.3%**	**100.0%**
	Painter	33.3%	33.3%	0.0%	0.0%	33.3%	100.0%
	Painter's Helper	0.0%	0.0%	33.3%	33.3%	33.3%	100.0%
Structural Clay		**39.3%**	**13.3%**	**20.7%**	**17.8%**	**8.9%**	**100.0%**
	Forming Line Operators (Clay Powder Formers)	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
	Forming Line Operators (Coatings Applicators - Automated)	0.0%	22.2%	44.4%	33.3%	0.0%	100.0%
	Forming Line Operators (Coatings Applicators - Manual)	26.7%	6.7%	13.3%	26.7%	26.7%	100.0%
	Forming Line Operators (Coatings Blender)	20.0%	0.0%	50.0%	30.0%	0.0%	100.0%
	Forming Line Operators (Pug Mill operators)	0.0%	14.3%	14.3%	28.6%	42.9%	100.0%
	Forming Line Operators (Wet Clay Formers)	60.0%	30.0%	10.0%	0.0%	0.0%	100.0%
	Grinding Operator	23.5%	5.9%	23.5%	23.5%	23.5%	100.0%
	Material Handler/Loader Operator	42.9%	0.0%	42.9%	14.3%	0.0%	100.0%
	Material Handler/Post-Production Handlers	70.3%	18.9%	8.1%	2.7%	0.0%	100.0%
	Material Handler/Production Line Handlers	40.0%	15.0%	25.0%	15.0%	5.0%	100.0%

[a] Due to rounding, in each row the sum of the data may not equal the total.

Source: Technological feasibility analysis in Chapter IV in the FEA.

Table VII-5: Numbers of Workers Exposed to Silica (by Affected Industry and Exposure Level (μg/m³))

				Number of Employees Exposed to Silica				
NAICS	Industry	Number of Establishments	Number of Employees	>=0	>=25	>=50	>=100	>=250
Construction								
236100	Residential Building Construction	151,034	519,070	210,773	132,901	102,275	61,678	24,625
236200	Nonresidential Building Construction	41,018	521,112	209,136	117,311	91,266	56,168	24,155
237100	Utility System Construction	18,686	466,099	190,044	97,838	78,748	51,241	24,122
237200	Land Subdivision	6,182	53,045	5,726	3,061	2,414	1,616	831
237300	Highway, Street, and Bridge Construction	10,043	251,065	148,254	58,604	45,462	28,110	14,153
237900	Other Heavy and Civil Engineering Construction	4,222	79,390	37,611	18,389	14,994	9,837	4,739
238100	Foundation, Structure, and Building Exterior Contractors	85,801	657,508	324,954	216,714	167,943	113,372	65,852
238200	Building Equipment Contractors	170,002	1,629,581	326,154	212,327	152,945	77,880	17,104
238300	Building Finishing Contractors	102,700	608,945	140,813	89,565	67,634	40,922	16,650
238900	Other Specialty Trade Contractors	63,214	475,127	259,906	89,844	73,598	45,621	21,705
221100	Electric Utilities	10,401	509,704	6,541	3,050	2,133	1,088	238
999200	State governments [d]	Not Applicable	Not Applicable	33,558	12,743	10,889	7,418	3,514
999300	Local governments [d]	Not Applicable	Not Applicable	123,946	44,639	37,414	24,240	10,815
	Subtotals - Construction	**663,303**	**5,770,646**	**2,017,417**	**1,096,986**	**847,715**	**519,190**	**228,503**
General Industry and Maritime								
213112	Support Activities for Oil and Gas Operations	10,872	272,357	16,960	13,819	11,207	8,671	5,280
324121	Asphalt Paving Mixture and Block Manufacturing	1,362	14,353	4,737	48	48	0	0
324122	Asphalt Shingle and Coating Materials Manufacturing	223	9,074	3,158	3,158	1,410	672	0
325510	Paint and Coating Manufacturing	1,161	35,328	2,511	515	386	386	258
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	655	13,096	6,269	3,989	2,496	767	257
327120	Clay Building Material and Refractories Manufacturing	586	20,985	7,893	4,915	3,198	1,756	520
327211	Flat Glass Manufacturing	85	8,990	221	134	126	67	30
327212	Other Pressed and Blown Glass and Glassware Manufacturing	442	13,434	674	411	386	206	90

Table VII-5: Numbers of Workers Exposed to Silica (by Affected Industry and Exposure Level (μg/m³)) (continued)

				Number of Employees Exposed to Silica				
NAICS	Industry	Number of Establishments	Number of Employees	>=0	>=25	>=50	>=100	>=250
327213	Glass Container Manufacturing	74	13,684	686	419	394	209	92
327320	Ready-Mix Concrete Manufacturing	5,377	66,196	27,123	20,690	19,941	18,611	12,156
327331	Concrete Block and Brick Manufacturing	817	14,896	7,182	2,902	2,045	1,217	521
327332	Concrete Pipe Manufacturing	352	8,229	3,967	1,603	1,130	672	288
327390	Other Concrete Product Manufacturing	1,973	45,284	21,832	8,821	6,216	3,700	1,583
327991	Cut Stone and Stone Product Manufacturing	1,859	24,537	9,429	6,794	5,243	3,406	931
327992	Ground or Treated Mineral and Earth Manufacturing	249	7,129	5,432	2,798	1,152	329	0
327993	Mineral Wool Manufacturing	269	13,925	789	489	457	244	106
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	452	10,118	7,952	4,096	1,687	482	0
331110	Iron and Steel Mills and Ferroalloy Manufacturing	562	105,309	594	186	93	41	17
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	262	25,592	145	45	23	10	4
331221	Rolled Steel Shape Manufacturing	167	7,836	44	14	7	3	1
331222	Steel Wire Drawing	294	14,241	81	25	13	5	2
331314	Secondary Smelting and Alloying of Aluminum	114	5,415	30	10	5	2	1
331420	Copper Rolling, Drawing, Extruding, and Alloying	249	21,408	119	37	19	8	3
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	261	10,913	62	19	10	4	2
331511	Iron Foundries	407	38,286	13,583	10,089	6,876	3,583	1,173
331512	Steel Investment Foundries	128	15,190	5,487	1,729	962	589	203
331513	Steel Foundries (except Investment)	208	18,236	6,469	4,805	3,275	1,706	559
331524	Aluminum Foundries (except Die-Casting)	406	15,446	5,601	1,727	656	127	43
331529	Other Nonferrous Metal Foundries (except Die-Casting)	300	9,522	3,451	1,064	404	78	26
332111	Iron and Steel Forging	356	24,030	136	42	21	9	4
332112	Nonferrous Forging	62	6,182	35	11	5	2	1

Table VII-5: Numbers of Workers Exposed to Silica (by Affected Industry and Exposure Level (μg/m^3)) (continued)

				Number of Employees Exposed to Silica				
NAICS	Industry	Number of Establishments	Number of Employees	>=0	>=25	>=50	>=100	>=250
332117	Powder Metallurgy Part Manufacturing	133	8,160	46	14	7	3	1
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	1,499	53,018	299	93	47	20	9
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	188	7,374	42	13	6	3	1
332216	Saw Blade and Handtool Manufacturing	1,012	27,852	157	49	25	11	5
332323	Ornamental and Architectural Metal Work Manufacturing	2,214	29,694	40	21	16	8	7
332439	Other Metal Container Manufacturing	346	11,749	66	21	10	5	2
332510	Hardware Manufacturing	607	26,540	150	47	23	10	4
332613	Spring Manufacturing	392	14,829	84	26	13	6	2
332618	Other Fabricated Wire Product Manufacturing	911	24,626	139	43	22	9	4
332710	Machine Shops	19,270	245,538	1,387	433	216	95	40
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	2,518	49,911	4,113	2,205	1,654	823	678
332911	Industrial Valve Manufacturing	517	35,657	201	63	31	14	6
332912	Fluid Power Valve and Hose Fitting Manufacturing	371	34,663	196	61	31	13	6
332913	Plumbing Fixture Fitting and Trim Manufacturing	121	7,567	43	13	7	3	1
332919	Other Metal Valve and Pipe Fitting Manufacturing	243	14,260	80	25	13	5	2
332991	Ball and Roller Bearing Manufacturing	176	22,522	127	40	20	9	4
332996	Fabricated Pipe and Pipe Fitting Manufacturing	765	29,914	169	53	26	12	5
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	3,553	70,118	405	131	68	30	14
333318	Other Commercial and Service Industry Machinery Manufacturing	1,378	54,518	308	96	48	21	9
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	491	24,138	136	43	21	9	4
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	472	17,959	102	32	16	7	3

Table VII-5: Numbers of Workers Exposed to Silica (by Affected Industry and Exposure Level (μg/m³)) (continued)

				Number of Employees Exposed to Silica				
NAICS	Industry	Number of Establishments	Number of Employees	>=0	>=25	>=50	>=100	>=250
333511	Industrial Mold Manufacturing	1,669	35,194	199	62	31	14	6
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	2,477	42,810	242	75	38	16	7
333515	Cutting Tool and Machine Tool Accessory Manufacturing	1,519	28,451	161	50	25	11	5
333517	Machine Tool Manufacturing	689	24,322	137	43	21	9	4
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	371	11,582	66	21	10	4	2
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	246	16,072	91	28	14	6	3
333613	Mechanical Power Transmission Equipment Manufacturing	245	15,545	88	27	14	6	3
333911	Pump and Pumping Equipment Manufacturing	539	33,772	191	60	30	13	5
333912	Air and Gas Compressor Manufacturing	306	21,225	120	37	19	8	3
333991	Power-Driven Handtool Manufacturing	151	8,859	50	16	8	3	1
333992	Welding and Soldering Equipment Manufacturing	344	15,781	89	28	14	6	3
333993	Packaging Machinery Manufacturing	580	20,010	113	35	18	8	3
333994	Industrial Process Furnace and Oven Manufacturing	352	11,009	62	19	10	4	2
333995	Fluid Power Cylinder and Actuator Manufacturing	324	24,208	137	43	21	9	4
333996	Fluid Power Pump and Motor Manufacturing	148	10,554	60	19	9	4	2
333997	Scale and Balance Manufacturing	88	3,725	21	7	3	1	1
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	1,654	51,495	291	91	45	20	8
334519	Other Measuring and Controlling Device Manufacturing	905	34,604	196	61	31	13	6
335210	Small Electrical Appliance Manufacturing	127	8,216	24	13	10	5	4
335221	Household Cooking Appliance Manufacturing	98	10,408	30	16	12	6	5
335222	Household Refrigerator and Home Freezer Manufacturing	30	9,374	27	15	11	5	5
335224	Household Laundry Equipment Manufacturing	9	4,438	13	7	5	3	2
335228	Other Major Household Appliance Manufacturing	36	9,059	26	14	11	5	4

Table VII-5: Numbers of Workers Exposed to Silica (by Affected Industry and Exposure Level (μg/m^3)) (continued)

				Number of Employees Exposed to Silica				
NAICS	Industry	Number of Establishments	Number of Employees	>=0	>=25	>=50	>=100	>=250
336111	Automobile Manufacturing	173	62,686	354	111	55	24	10
336112	Light Truck and Utility Vehicle Manufacturing	78	56,524	319	100	50	22	9
336120	Heavy Duty Truck Manufacturing	85	30,756	174	54	27	12	5
336211	Motor Vehicle Body Manufacturing	741	40,544	229	72	36	16	7
336212	Truck Trailer Manufacturing	421	28,304	160	50	25	11	5
336213	Motor Home Manufacturing	62	7,395	42	13	7	3	1
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	849	52,752	298	93	46	20	9
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	678	50,017	283	88	44	19	8
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	245	28,663	162	51	25	11	5
336340	Motor Vehicle Brake System Manufacturing	195	21,859	123	39	19	8	4
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	503	58,248	329	103	51	22	9
336370	Motor Vehicle Metal Stamping	773	81,018	458	143	71	31	13
336390	Other Motor Vehicle Parts Manufacturing	1,508	122,041	689	215	107	47	20
336611	Ship Building and Repairing	689	108,311	3,038	2,633	2,228	1,620	1,013
336612	Boat Building	871	28,054	787	682	577	420	262
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	71	10,990	62	19	10	4	2
337110	Wood Kitchen Cabinet and Countertop Manufacturing	6,862	76,052	223	114	86	59	28
337215	Showcase, Partition, Shelving, and Locker Manufacturing	1,097	33,437	189	59	29	13	5
339114	Dental Equipment and Supplies Manufacturing	727	15,835	4,956	1,983	1,983	991	0
339116	Dental Laboratories	6,818	44,097	31,105	5,184	864	0	0
339910	Jewelry and Silverware Manufacturing	2,119	24,436	6,772	2,455	2,434	2,422	1,210
339950	Sign Manufacturing	5,499	69,051	384	217	163	77	56

Table VII-5: Numbers of Workers Exposed to Silica (by Affected Industry and Exposure Level (µg/m³)) (continued)

				Number of Employees Exposed to Silica				
NAICS	Industry	Number of Establishments	Number of Employees	>=0	>=25	>=50	>=100	>=250
423840	Industrial Supplies Merchant Wholesalers	7,614	82,871	1,773	1,182	591	591	591
444110	Home Centers	6,569	609,186	107	55	41	29	13
482110	Rail transportation	Not Applicable	Not Applicable	16,895	10,668	5,340	2,948	1,233
561730	Landscaping Services	92,976	548,662	43,033	24,747	12,612	497	156
621210	Offices of Dentists	133,107	873,172	8,525	1,421	237	0	0
	Subtotals – General Industry and Maritime	**351,998**	**5,335,502**	**294,844**	**152,263**	**100,375**	**58,779**	**29,718**
	Totals – All Industries	**1,015,301**	**11,106,148**	**2,312,261**	**1,249,249**	**948,090**	**577,969**	**258,221**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on Table VII-4 and the technological feasibility analysis presented in Chapter IV of the FEA.

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D. Technological Feasibility

In Chapter IV of OSHA's FEA, OSHA assesses the technological feasibility of the standard in all affected industry sectors and application groups. The analysis presented in this chapter is organized by industry sectors in general industry and maritime and by application groups in the construction industry. Employee exposures were analyzed at the operation, job category or task/activity level to the extent that the necessary data were available.

OSHA collected exposure data to characterize current (baseline) exposures and to identify the tasks, operations, and job categories for which employers will need to either improve their process controls or implement additional controls to reduce respirable crystalline silica exposures to 50 μg/m^3 or below. In the few instances where there were insufficient exposure data, OSHA used analogous operations to characterize these operations.

The technological feasibility analysis informed OSHA's selection of the rule's permissible exposure limit (PEL) of 50 μg/m^3 respirable crystalline silica, consistent with the requirements of the Occupational Safety and Health Act (''OSH Act''), 29 U.S.C. 651 *et seq.* Section 6(b)(5) of the OSH Act requires that OSHA ''set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity'' (29 U.S.C. 655(b)(5)). In fulfilling this statutory directive, OSHA is guided by the legal standard expressed by the Court of Appeals for the D.C. Circuit for demonstrating the technological feasibility of reducing occupational exposure to a hazardous substance:

> OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations. . . . The effect of such proof is to establish a presumption that industry can meet the PEL without relying on respirators. . . . Insufficient proof of technological feasibility for a few isolated operations within an industry, or even OSHA's concession that respirators will be necessary in a few such operations, will not undermine this general presumption in favor of feasibility. Rather, in such operations firms will remain responsible for installing engineering and work practice controls to the extent feasible, and for using them to reduce . . . exposure as far as these controls can do so *(United Steelworkers of Am, AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1980)).

Additionally, the D.C. Circuit explained that ''[f]easibility of compliance turns on whether exposure levels at or below [the PEL] can be met in most operations most of the time . . . '' (*Am. Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 990 (D.C. Cir. 1991)); (*see* Section II, Pertinent Legal Authority).

Consistent with the legal standard described above, Chapter IV of the FEA, which can be found at *www.regulations.gov* (docket OSHA–2010–0034), describes OSHA's examination of the technological feasibility of this rule on occupational exposure to respirable crystalline silica. The chapter provides a description of the methodology and data used by OSHA to analyze the technological feasibility of the standard, as well as a discussion of the accuracy and reliability of current methods used for the sampling and analysis of respirable crystalline silica. Chapter IV contains OSHA's analyses, for 21 general industry sectors, 1 maritime sector, and 12 construction industry application groups, of the technological feasibility of meeting the rule's requirements for reducing exposures to silica. For each sector and application group, OSHA addresses the extent to which the evidence in the record indicates that engineering and work practice controls can reduce respirable crystalline silica exposures to the PEL or below and maintain them at that level. These individual technological feasibility analyses form the basis for OSHA's overall finding that employees' exposures can be reduced to the rule's PEL or below in most of the affected sectors' operations. Throughout Chapter IV, OSHA describes and responds to issues raised in the comments and testimony it received from interested parties during the comment periods and public hearing OSHA held on the proposed rule. The material below summarizes the detailed discussion and presentation of OSHA's findings contained in Chapter IV of the FEA.

1. Methodology

As noted above, OSHA's technological feasibility analysis for this rule largely involved describing engineering and work practice controls that OSHA concludes can be expected to control respirable crystalline silica exposures to the PEL or below. For this portion of the analysis, OSHA relied on information and exposure measurements from many different sources, including OSHA's inspection database (OSHA Information System (OIS)), OSHA inspection reports, National Institute of Occupational Safety and Health (NIOSH) reports, site visits by NIOSH and OSHA's contractor, Eastern Research Group, Inc. (ERG), and materials from other federal agencies, state agencies, labor organizations, industry associations, and other groups. In addition, OSHA reviewed studies from the published literature that evaluated the effectiveness of engineering controls and work practices in order to estimate the reductions from current, baseline exposures to silica that can be achieved through wider or improved implementation of such controls. Finally, OSHA considered the extensive testimony and numerous comments regarding the feasibility of implementing engineering and work practice controls, including circumstances that preclude the use of controls in certain situations. In total, OSHA's feasibility analysis is based on hundreds of sources of information in the record, constituting one of the largest databases of information OSHA has used to evaluate the feasibility of a health standard.

The technological feasibility chapter of the FEA describes the industry sectors and application groups affected by the rule, and identifies the sources of exposure to respirable crystalline silica for each affected job category or task. The technological feasibility analysis subdivides the general industry and maritime workplaces into 24 industry sectors.[21] General industry sectors are identified primarily based on the type of product manufactured (*e.g.,* concrete products, pottery, glass) or type of process used (*e.g.,* foundries, mineral processing, refractory repair). Where sufficiently detailed information was available, the Agency further divided general industry sectors into specific job categories on the basis of common factors such as materials, work processes, equipment, and available exposure control methods. OSHA notes that these job categories are intended to represent job functions; actual job titles and responsibilities might differ depending on the facility or industry practice.

For the construction industry, OSHA identified application groups based on construction activities, tasks, or equipment that are commonly recognized to create silica exposures; these tasks involve the use of power tools (*e.g.,* saws, drills, jackhammers) or larger equipment that generates silica-containing dust (*e.g.,* milling machines, rock and concrete crushers, heavy equipment used in demolition or earthmoving). The technological feasibility analysis for the construction industry addresses 12 different application groups, defined by common construction tasks or activities. OSHA organized construction workers by application groups, rather than by industry sector or job titles, because construction workers often perform multiple activities and job titles do not always coincide with the sources of exposure; likewise, the same equipment,

[21] OSHA's technological feasibility analysis in the FEA is divided into 22 sections, one for each of the general industry and maritime sectors. However, separate technological feasibility findings are made for three different foundry sectors (ferrous, nonferrous, and non-sand casting foundries), making a total of 24 sectors for which separate analyses and findings are made (*see* Table VII–8).

tool or task may be called by different names throughout construction and its various subspecialties. By organizing construction activities this way, OSHA was able to create exposure profiles for employees who perform the same activities in any segment of the construction industry.

OSHA developed exposure profiles for each sector and application group in order to characterize the baseline exposures and conditions for each operation or task (*see* sections 4 and 5 of Chapter IV of the FEA). The sample results included in the exposure profiles presented in the Preliminary Economic Analysis (PEA) were obtained primarily from OSHA compliance inspection reports and from NIOSH Health Hazard Evaluation and control technology assessments. Samples were also obtained from state plan case files, contractor site visits, published literature and other sources. To ensure the exposure profiles were based on the best available data, the exposure profiles were updated by removing samples collected prior to 1990 (n = 290), leaving 2,512 samples from exposure profiles presented in the PEA from 1990 through 2007. More recent samples submitted by commenters during the rulemaking (n = 153), primarily from 2009 through 2014, and samples obtained from the OIS database (n = 699) from OSHA compliance inspections from 2011 to 2014 were added to exposure profiles, resulting in a total of 3,364 samples (2,483 for general industry and 881 for construction) in the final exposure profiles. In total, these were obtained from 683 source documents (*see* Table VII–6).

The exposure profiles characterize what OSHA considers to be the baseline, or current, exposures for each job category or application group. Where sufficient information on control measures was available, the exposure profiles were subdivided into sample results with and without controls and the controls were discussed in the baseline conditions section. OSHA also discusses the sampling results associated with specific controls in the baseline conditions section. In these cases, the exposure profiles include exposures associated with a range of controlled and uncontrolled exposure scenarios.

Table VII-6. Number of Source Documents and Samples Used to Develop the Final Exposure Profiles

	No. of Documents	**No. of Samples**
OSHA SEP Reports[22]	204	910
NIOSH Reports	98	1,174
State Plans Case Files	63	225
Publications	26	165
Site Visits (ERG)	6	39
Other Reports	20	152
OIS Data	266	699
Total	**683**	**3,364**

(Source: Supplemental data file submitted to the docket along with the FEA that includes results of all 3364 samples used in the exposure profiles)

The exposure profiles include silica exposure data only for employees in the United States. Information on international exposure levels is occasionally referenced for perspective or in discussions of control options. The rule covers three major polymorphs of crystalline silica (*i.e.,* quartz, cristobalite, and tridymite). However, the vast majority of crystalline silica encountered by employees in the United States is in the quartz form, and the terms crystalline silica and quartz are often used interchangeably. Unless specifically indicated otherwise, all silica exposure data, samples, and results discussed in the technological feasibility analysis refer to personal breathing zone (PBZ) measurements of respirable crystalline silica.

In general industry and maritime, the exposure profiles in the technological feasibility analysis consist mainly of full-shift samples, collected over periods of 360 minutes or more (*see*

[22] OSHA silica Special Emphasis Program (SEP) inspection reports are from inspections conducted by OSHA compliance safety and health officers (CSHOs) under the silica National Emphasis Program between 1993 and 2000.

Table IV–02–G in the FEA). By using this criterion, OSHA ensured that the samples included in the exposure profiles were collected for at least three-quarters of a typical 8-hour shift and therefore captured most activities involving exposure to silica at which the employee spends a substantial amount of time (Document ID 0845, pp. 38–40; *see* Table IV–02–G in the FEA). Due to the routine nature of most job activities in general industry, OSHA assumed that, for the partial shift samples of less than 480 minutes, the same level of exposure as measured during the sampled portion of the shift continued during the smaller, unsampled portion. OSHA considers the 6-hour (360-minute) sampling duration to be a reasonable criterion for including a sample because it limits the extent of uncertainty about general industry/maritime employees' true exposures, as no more than 25 percent of an 8-hour shift would be unsampled. The sample result is therefore assumed to be representative of an 8-hour time-weighted average (TWA). Moreover, by relying primarily on sampling results 360 minutes or greater, OSHA minimized the number of results included in the profiles reported as below the limit of detection (LOD). The LOD for an analytical method refers to the smallest mass of silica that can be detected on the filter used to collect the air sample. Many laboratories currently report an LOD of 10 μg or lower for quartz samples (Document ID 0666). As discussed in the Methodology section of Chapter IV of the FEA, relying primarily on samples with a duration of 360 minutes or greater allows OSHA to draw the conclusion that any sample results reported as non-detect for silica are at most 16 μg/m^3, and well below the action level of 25 μg/m^3.

In the construction industry, approximately 43 percent of the sampling data used in the exposure profiles also consisted of samples collected over periods of 360 minutes or more. Most of the samples (approximately 70%, or an additional 27%) in the construction industry exposure profiles were collected over periods of 240 minutes or more (*see* Table IV–02–G in the FEA). This allows OSHA to draw the conclusion that any sample results reported as non-detect are below the action level of 25 μg/m^3 (*see* Table IV–2–F in the FEA). Construction workers typically spend their shifts working at multiple discrete tasks and do not normally engage in any one task for the entire duration of a shift; these varied tasks can include tasks that generate exposure to respirable crystalline silica (Document ID 0677). Consequently, for construction, OSHA assumed zero exposure during the unsampled portion of the employee's shift unless there was evidence that silica exposures continued for the entire shift. For example, if a sample measured an average of 100 μg/m^3 over 240 minutes (4 hours), the result would be recorded as 50 μg/m^3 TWA for a full 8-hour shift (480 minutes).

The Construction Industry Safety Coalition (CISC), comprised of 25 trade associations, was critical of several aspects of OSHA's feasibility analysis. CISC objected to the assumption of zero exposure for the unsampled portion of the work shift when calculating 8-hour TWAs for the construction exposure profiles. It claimed that assuming zero exposure underestimated TWA exposure levels when compared with the alternative assumption used for general industry that the exposure level measured during the sampled time period remained at the same level during the unsampled period (Document ID 2319, pp. 21–25). While there would be some uncertainty whichever assumption OSHA used, OSHA concludes that the no-exposure assumption for unsampled portions of a shift produces a more accurate result than the assumption of continued exposure at the same level because of the widely-recognized differences in work patterns between general industry and construction operations. In general industry, most operations are at a fixed location and involve manufacturing processes that remain relatively constant over a work shift. Also, most of the sample durations in general industry were 360 minutes or longer, and therefore were more likely to be representative of 8-hour TWA exposures. In contrast, construction work is much more variable with respect to the location of the work site, the number of different tasks performed, and the duration of tasks performed. As stated above, tasks that generate exposure to respirable crystalline silica in construction are often performed on an intermittent basis (*e.g.,* Document ID 0677).

OSHA's conclusion that the variability in sample durations for the samples taken by OSHA in the construction industry more accurately reflects the variability in exposure duration for these activities thus comports with empirical experience. An assumption that exposure levels during short-term tasks continued for the entire work shift would substantially overestimate the actual 8-hour TWA exposures. The Building and Construction Trades Department, AFL–CIO (BCTD) supported OSHA's assumptions on work patterns, stating ''OSHA correctly treated the unsampled time as having 'zero exposure' in its technological feasibility assessment'' (Document ID 4223, pp. 16–17). Its conclusion was based on research performed by The Center to Protect Workers' Rights, which developed a task-based exposure assessment model for the construction industry that combines air sampling with task observations and task durations in order to assess construction workers' exposure to workplace hazards (Susi, *et al.,* 2000, Document ID 4073, Attachment 8c). This model, when applied to masonry job sites, found that employees spent much of their shifts performing non-silica-generating tasks, both before and after the task involving silica exposure (Document ID 4223, p. 16; 4073, Attachment 3a, pp. 1–2). BCTD indicated that it was reasonable to assume these types of work patterns would be similar for other construction tasks (Document ID 4223, pp. 16–17).

CISC also commented that OSHA did not account for the varying amounts of crystalline silica that could exist in materials being disturbed by employees, and that OSHA did not account for differences in exposure results ''due solely to what part of the country the activity took place in'' (Document ID 2319, pp. 26–27). OSHA has determined that the sampling data relied on to establish baseline silica exposures are representative of the range of silica content in materials worked on by construction workers. Information on the percent silica content of the respirable dust sampled was available for 588 of the 881 samples used in the exposure profiles for construction tasks. The silica content in these samples ranged from less than 1 percent (non-detect) to 50 percent, with an average silica content of 9.1 percent. Thus, the sample results in the exposure profiles reflect the range in the silica content of the respirable dust sampled by OSHA at construction work sites. Similarly, the exposure profiles contain exposure results from many different construction tasks taken in a variety of locations around the country under different weather conditions. Therefore, OSHA concludes that the exposure data used in the exposure profiles are the best available evidence of actual exposures in construction representing nationwide weather patterns, and that these data reflect the broad range of silica exposures experienced by employees in the construction industry.

Each section in the technical feasibility analysis presented in Chapter

IV of the FEA begins with descriptions of the manufacturing or industrial process or construction activity that has potential exposure to respirable crystalline silica, each job category or construction task with exposure, and the major activities and sources of exposure. Exposure profiles based on the available sampling information are then presented and used to characterize the baseline exposures and conditions for each operation or task (including exposure controls currently in use). Based on the profile of baseline exposures, each section next includes a description of additional engineering and work practice controls that can be implemented to reduce employee exposures to at least the rule's PEL. In addition, comments and other evidence in the record relating to the description of the industry sector or application group, the exposure profile and baseline conditions, and the need for additional controls are discussed in each section. Finally, based on the exposure profile and assessment of available controls and other pertinent evidence in the record, each section includes a feasibility determination for each operation, task, or activity, including an overall feasibility determination where more than one operation, task, or activity is addressed in the section.

In particular, OSHA evaluated information and testimony from the record on the effectiveness of engineering and work practice controls and either: (1) Identified controls that have been demonstrated to reduce exposures to 50 μg/m^3 or below; or (2) evaluated the extent to which baseline exposures would be reduced to 50 μg/m^3 or below after applying the percent reduction in respirable silica or dust exposure that has been demonstrated for a given control in the operation or task under consideration or, in some cases, in analogous circumstances. In some cases, the evidence demonstrates that most exposures are already below the PEL. OSHA considers the evidence relied on in making its feasibility determinations to be the best available evidence on these issues.

For general industry and maritime, the additional engineering controls and work practices identified by OSHA consist of equipment and approaches that are widely available and are already used in many applications. In some cases, the same technology can be transferred or adapted to similar operations in other industry sectors covered under the scope of this rule. Such controls and work practices include implementing and maintaining local exhaust ventilation (LEV) systems with dust collection systems (such as integrated material transfer stations); enclosing a conveyor of silica-containing material or other containment systems; worker isolation; process modifications; dust suppression, systems such as water sprays; and housekeeping. In many cases, a combination of controls is necessary to control exposures to silica. In general industry, enclosed and ventilated equipment is often already in use. For example, most paint and coating production operations have switched from manual transfer of raw materials containing crystalline silica to integrated bag dumping stations equipped with well-ventilated enclosures and bag compactors (*e.g.,* Document ID 0199, pp. 9–10; 0943, p. 87; 1607 p. 10–19; 1720, p. IV–237). Where the evidence shows that a type of control like the material transfer system is already being used in a sector covered by the rule, OSHA is able to conclude that it can be used more widely in that sector as an additional control or can be adapted to other industry sectors for use during similar operations (*see* sections IV–15 Paint and Coatings, IV–16 Porcelain Enameling, IV–11 Glass, and IV–05 Concrete Products, of the FEA for additional information).

For construction, the exposure controls contained in Table 1 of the rule consist primarily of water-based dust suppression systems, and LEV systems that are integrated into hand tools and heavier equipment. As shown in Chapter IV of the FEA, such systems are commercially available from several vendors. In addition, equipment such as filtered, ventilated booths or cabs and water-based systems for suppressing fugitive dust generated by crushers and heavy equipment are available to control exposures of construction workers to respirable crystalline silica.

OSHA received numerous comments that disputed OSHA's preliminary conclusion in the Notice of Proposed Rulemaking (NPRM) that a PEL of 50 μg/m^3 TWA was technologically feasible. These comments addressed two general areas of concern: (1) Whether sampling and analytical methods are sufficiently accurate to reliably measure respirable crystalline silica concentrations at levels around the PEL and action level; and (2) whether engineering and work practice controls can reduce exposures from current levels to the lower levels required to comply with the new standards. These issues and OSHA's technological feasibility findings are discussed in the sections that follow. Much more detail can be found in Chapter IV of the FEA.

2. Feasibility Determination for Sampling and Analytical Methods

As explained in Pertinent Legal Authority (Section II of this preamble to the final rule), a finding that a standard is technologically feasible requires that ''provisions such as exposure measurement requirements must also be technologically feasible'' (*see Forging Indust. Ass'n* v. *Sec'y of Labor,* 773 F.2d 1436, 1453 (4th Cir. 1985)). Thus, part of OSHA's technological feasibility assessment of a new or revised health standard includes examining whether available methods for measuring worker exposures have sufficient sensitivity and precision to ensure that employers can evaluate compliance with the standard and that workers have accurate information regarding their exposure to hazardous substances. Consistent with the Supreme Court's definition of ''feasibility'', OSHA finds that it is feasible to measure worker exposures to a hazardous substance if achieving a reasonable degree of sensitivity and precision with sampling and analytical methods is ''capable of being done'' (*Am. Textile Mfrs. Inst., Inc.* v. *Donovan,* 452 U.S. 490, 509–510 (1981)). OSHA also notes that its analysis of the technological feasibility of the sampling and analysis of respirable crystalline silica must be performed in recognition of the fact that, as recognized by federal courts of appeals, measurement error is inherent to sampling (*Nat'l Min. Assoc.* v. *Sec'y, U.S. Dep't of Labor,* Nos. 14–11942, 14–12163, slip op. at 55 (11th Cir. Jan. 25, 2016); *Am. Mining Cong.* v. *Marshall,* 671 F.2d 1251, 1256 (10th Cir. 1982)). ''Since there is no perfect sampling method, the Secretary has discretion to adopt any sampling method that approximates exposure with reasonable accuracy.'' *Am. Mining Cong.* v. *Marshall,* 671 F.2d at 1256.

Since the late 1960s, exposures to respirable crystalline silica (hereinafter referred to as ''silica'') have typically been measured using personal respirable dust samplers coupled with laboratory analysis of the crystalline silica content of the collected airborne dust. The laboratory analysis is usually performed using X-ray diffraction (XRD) or infrared spectroscopy (IR). A colorimetric method of analysis that was used by a few laboratories has now been phased out (Harper *et al.,* 2014, Document ID 3998, Attachment 8, p. 1). OSHA has successfully used XRD analysis since the early 1970s to enforce its previous PELs for crystalline silica, which, for general industry, were approximately equivalent to 100 micrograms per cubic meter (μg/m^3) for quartz and 50 μg/m^3 for cristobalite and

tridymite (and within the range of about 250 μg/m³ to 500 μg/m³ for quartz in construction). There are no other generally accepted methods for measuring worker exposure to respirable crystalline silica.

The ability of current sampling and analytical methods to accurately measure worker exposures to respirable crystalline silica was a subject of much comment in the rulemaking record. In particular, the Chamber of Commerce (Chamber) and American Chemistry Council (ACC) submitted comments and testimony maintaining that existing methods do not measure respirable crystalline silica exposures with sufficient accuracy to support OSHA's proposal in the Notice of Proposed Rulemaking to reduce the PEL to 50 μg/m³ and establish the 25 μg/m³ action level (Document ID 2285; 2288, pp. 17–21; 2307, Attachment A, pp. 198–227; 4209, pp. 129–155; 3436, p. 8; 3456, pp. 18–19; 3460; 3461; 3462; 4194, pp. 17–21). Similar views were expressed by several other rulemaking participants (*e.g.,* Document ID 2056, p. 1; 2085, p. 3; 2174; 2185, pp. 5–6; 2195, Attachment 1, p. 37; 2276, pp. 4–5; 2317, p. 2; 2379, Comments, pp. 28–30; 4224, pp. 11–14; 4232, Attachment 1, pp. 3–24). Specifically, these commenters argue that, due to several asserted sources of error, current sampling and analytical methods do not meet the NIOSH accuracy criterion of ±25 percent (NIOSH Manual of Analytical Methods, *http://www.cdc.gov/niosh/docs/95-117/*). Their arguments include: (1) That there is sampling error attributed to bias against the particle-size selection criteria that defines the performance of the samplers and variation in performance between sampling devices; (2) that the accuracy and precision of the analytical method at the low levels of silica that would be collected at the revised PEL and action level is less than that in the range of the previous PELs for silica, particularly in the presence of interfering substances; and (3) variation between laboratories analyzing comparable samples adds an unacceptable degree of uncertainty. After considering all of the testimony and evidence in the record, OSHA rejects these arguments and, as discussed below, concludes that it is feasible to obtain measurements of respirable crystalline silica at the final rule's PEL and action level with reasonable accuracy.

OSHA is basing its conclusions on the following findings, which are described in detail in this section. First, although there is variation in the performance of respirable dust samplers, studies have demonstrated that, for the majority of work settings, samplers will perform with an acceptable level of bias (as defined by international standards) as measured against internationally recognized particle-size selection criteria that define respirable dust samplers. This means that the respirable dust mass collected by the sampler will be reasonably close to the mass that would be collected by an ideal sampler that exactly matches the particle-size selection criteria. In addition, OSHA finds that the measure of precision of the analytical methods for samples collected at crystalline silica concentrations equal to the revised PEL and action level is only somewhat higher (*i.e.,* somewhat less precise) than that for samples collected at concentrations equal to the previous, higher PELs. Further, the analytical methods can account for interferences such that, with few exceptions, the sensitivity and precision of the method are not significantly compromised. Studies of measurement variability between laboratories, as determined by proficiency testing, have demonstrated a significant decline in inter-laboratory variability in recent years. Improvements in inter-laboratory variability have been attributed to changes in proficiency test procedures as well as greater standardization of analytical procedures among laboratories. Finally, although measurement variability increases at low sample loads compared to sample loads in the range of the former PELs, OSHA finds, based on these studies, that the magnitude of this increase has also declined in recent years.

Several rulemaking participants commented that OSHA's analysis of the feasibility of sampling and analytical methods for crystalline silica was well supported and sound (Document ID 2080, pp. 3–4; 2244, p. 3; 2371, Attachment 1, p. 5; 3578, Tr. 941; 3586, Tr. 3284; 3577, Tr. 851–852; 4214, pp. 12–13; 4223, pp. 30–33). Gregory Siwinski, CIH, and Dr. Michael Lax, Medical Director of Upstate Medical University, an occupational health clinical center, commented that current laboratory methods can measure respirable crystalline silica at the 50 μg/m³ PEL and 25 μg/m³ action level, and that they have measured exposures below the action level (Document ID 2244, p. 3). Dr. Celeste Montforton of the George Washington School of Public Health testified that ''[i]ndustrial hygienists, company safety personnel, consultants, and government inspectors have been conducting for decades workplace sampling for respirable silica . . .'' and that some governments, such as Manitoba and British Columbia, are successfully collecting and analyzing samples to determine compliance with their occupational exposure limits of 25 μg/m³ (Document ID 3577, Tr. 851–852). Dr. Frank Mirer of the CUNY School of Public Health, formerly with the UAW and on behalf of the AFL–CIO, stated that ''[a]ir sampling is feasible at 25 μg/m³ and below for [a] full shift and even for part shift. It was dealt with adequately in the OSHA proposal'' (Document ID 3578, Tr. 941).

The ACC, Chamber, and others base their argument that sampling and analytical methods for respirable crystalline silica are insufficiently precise on strict adherence to NIOSH's accuracy criterion of ±25 percent at a 95-percent confidence level for chemical sampling and analysis methods (*http://www.cdc.gov/niosh/docs/95-117/*). The ACC pointed out that ''OSHA standards typically reflect the NIOSH Accuracy Criterion by requiring employers to use a method of monitoring and analysis that has an accuracy of plus or minus 25 percent . . . ,'' and cited a number of OSHA standards where the Agency has included such requirements (benzene, 29 CFR 1910.1028; lead (which requires a method accuracy of ±20%), 29 CFR 1910.1025; cadmium, 29 CFR 1910.1027; chromium (VI), 29 CFR 1910.1026) (Document ID 4209, p. 129). However, the NIOSH accuracy criterion is not a hard, bright-line rule in the sense that a sampling and analytical method must be rejected if it fails to meet this level of accuracy, but is rather a goal or target to be used in methods development. Where evidence has shown that a method does not meet the accuracy criterion at the PEL or action level, OSHA has stipulated a less rigorous level of accuracy to be achieved. For example, OSHA's acrylonitrile standard requires use of a method that is accurate to ±35 percent at the PEL and ±50 percent at the action level (29 CFR 1910.1045), and several OSHA standards require that ±35 percent accuracy be obtained at the action level (arsenic, 29 CFR 1910.1018; ethylene oxide, 29 CFR 1910.1047; formaldehyde, 29 CFR 1910.1048; 1,3-butadiene, 29 CFR 1910.1051; methylene chloride, 29 CFR 1910.1052). As discussed below, the precision of the sampling and analytical method for crystalline silica, as currently implemented using OSHA Method ID–142 for X-ray diffraction, is about ±21 percent for quartz and cristobalite.

In the remainder of this section, OSHA first describes available respirable dust sampling methods and

addresses comments and testimony related to the performance and accuracy of respirable dust samplers. Following that discussion, OSHA summarizes available analytical methods for measuring crystalline silica in respirable dust samples and addresses comments and evidence regarding analytical method precision, the presence of interfering materials, and reported variability between laboratories analyzing comparable samples.

a. Respirable Dust Sampling Devices

Respirable dust comprises particles small enough that, when inhaled, they are capable of reaching the pulmonary region of the lung where gas exchange takes place. Measurement of respirable dusts requires the separation of particles by size to assess exposures to the respirable fraction of airborne dusts. A variety of different industrial hygiene sampling devices, such as cyclones and elutriators, have been developed to separate the respirable fraction of airborne dust from the non-respirable fraction. Cyclones are the most commonly used size-selective sampling devices, or ''samplers,'' for assessing personal exposures to respirable dusts such as crystalline silica. The current OSHA (ID–142, revised December 1996, Document ID 0946) and NIOSH (Method 7500, Document ID 0901; Method 7602, 0903; Method 7603, *http://www.cdc.gov/niosh/docs/2003-154/pdfs/7603.pdf*) methods for sampling and analysis of crystalline silica specify the use of cyclones.

Although respirable dust commonly refers to dust particles having an aerodynamic diameter of 10 µm (micrometer) or less, it is more precisely defined by the collection efficiency of the respiratory system as described by a particle collection efficiency model. These models are often depicted by particle collection efficiency curves that describe, for each particle size range, the mass fraction of particles deposited in various parts of the respiratory system. These curves serve as the ''yardsticks'' against which the performance of cyclone samplers should be compared (Vincent, 2007, Document ID 1456). Figure VII–1 below shows particle collection efficiency curves for two particle size selection criteria: The criteria specified in the 1968 American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) for respirable dust, which was the basis for the prior OSHA general industry silica PEL, and an international specification by the International Organization for Standardization (ISO) and the Comité Européen de Normalisation (CEN) known as the ISO/CEN convention, which was adopted by ACGIH in 1994 and is the basis for the definition of respirable crystalline silica in the final rule. In addition to the curves, which cover the full range of particle sizes that comprise respirable dust, particle size collection criteria are also often described by their 50-percent respirable ''cut size'' or ''cut point.'' This is the aerodynamic diameter at which 50 percent of the particle mass is collected, *i.e.,* the particle size that the sampler can collect with 50-percent efficiency. Particles with a diameter smaller than the 50-percent cut point are collected with an efficiency greater than 50 percent, while larger-diameter particles are collected with an efficiency less than 50 percent. The cut point for the 1968 ACGIH specification is 3.5 µm and for the ISO/CEN convention is 4.0 µm (Lippman, 2001, Document ID 1446, pp. 107, 113).

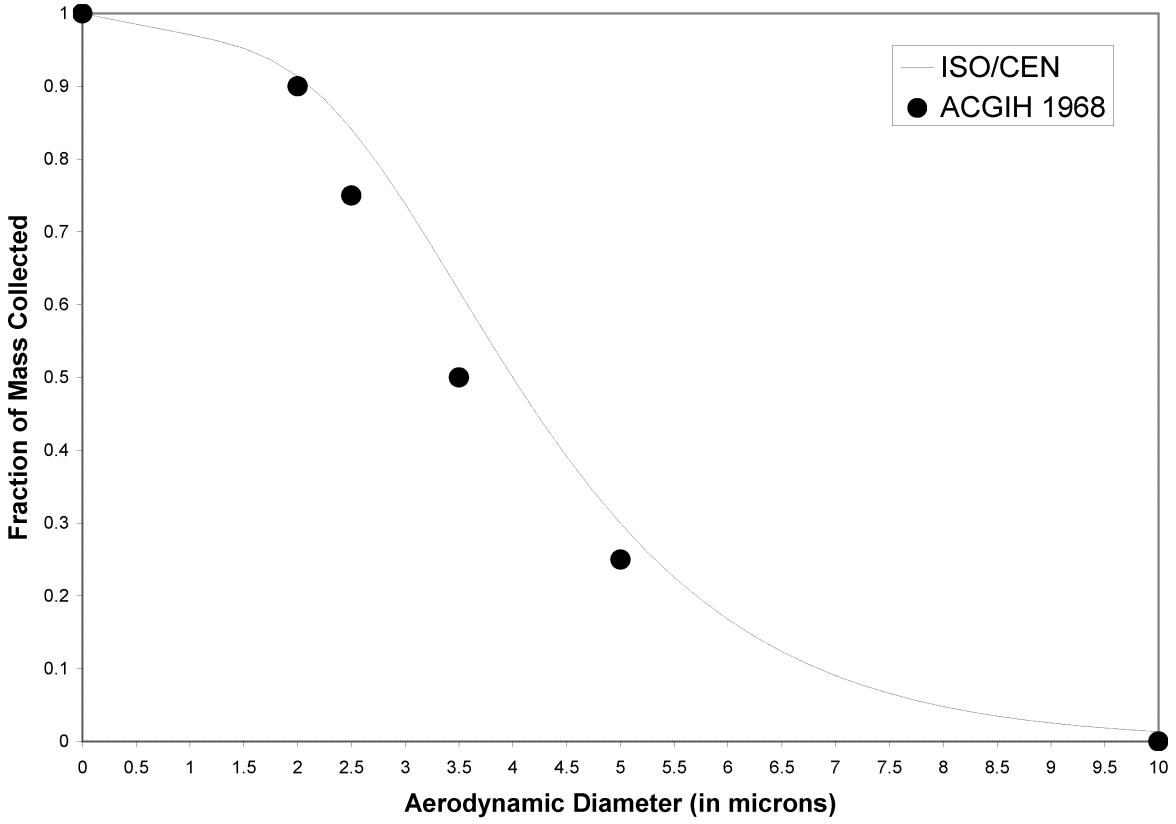

Figure VII-1. Comparison of the 1968 ACGIH and ISO/CEN Particle Size Collection Criteria
Source: Document ID 1720, p. IV-18

For most workplace conditions, the change in the criteria for respirable dust in the final rule would theoretically increase the mass of respirable dust collected over that measured under the previous criteria by an amount that depends on the size distribution of airborne particles in the workplace. Soderholm (1991, Document ID 1661) examined these differences based on 31 aerosol size distributions measured in various industrial workplaces (*e.g.,* coal mine, lead smelter, brass foundry, bakery, shielded metal arc [SMA] welding, spray painting, pistol range) and determined the percentage increase in the mass of respirable dust that would be collected under the ISO/CEN convention over that which would be collected under the 1968 ACGIH criteria. Soderholm concluded that, for all but three of the 31 size distributions that were evaluated, the increased respirable dust mass that would be collected using the ISO/CEN convention for respirable dust instead of the 1968 ACGIH criteria would be less than 30 percent, with most size distributions (25 out of the 31 examined, or 80 percent) resulting in a difference of between 0 and 20 percent (Document ID 1661, pp. 248–249, Figure 1). In the PEA, OSHA stated its belief that the magnitude of this effect does not outweigh the advantages of adopting the ISO/CEN convention. In particular, most respirable dust samplers on the market today are designed and calibrated to perform in a manner that closely conforms to the international ISO/CEN convention.

Incorporating the ISO/CEN convention in the definition of respirable crystalline silica will permit employers to use any sampling device that conforms to the ISO/CEN convention. There are a variety of these cyclone samplers on the market, such as the Dorr-Oliver, Higgins-Dewell (HD), GK2.69, SIMPEDS, and SKC aluminum. In the PEA, OSHA reviewed several studies demonstrating that these samplers collect respirable particles with efficiencies that closely match the ISO/CEN convention (Document ID 1720, pp. IV–21—IV–24). In addition to cyclone samplers, there are also personal impactors available for use at flow rates from 2 to 8 L/min that have been shown to conform closely with the ISO/CEN convention (Document ID 1834, Attachment 1). Cyclones and impactors both separate particles by size based on inertia. When an airstream containing particles changes direction, smaller particles remain suspended in the airstream and larger ones impact a surface and are removed from the airstream. Cyclones employ a vortex to separate particles centrifugally, while impactors use a laminar airflow around a flat surface such that particles in the desired size range impact onto the surface.

The current OSHA sampling method for crystalline silica, ID–142, is the method used by OSHA to enforce the silica PELs and is used by some employers as well. It specifies that a respirable sample be collected by drawing air at 1.7 ± 0.2 liters/minute (L/min) through a Dorr-Oliver 10 millimeter (mm) nylon cyclone attached to a cassette containing a 5-µm pore-size, 37-mm diameter polyvinyl chloride (PVC) filter (Document ID 0946). NIOSH sampling and analysis methods for crystalline silica (Method 7500, Method 7602, Method 7603) have also adopted the ISO/CEN convention with flow rate specifications of 1.7 L/min for the Dorr-Oliver 10-mm nylon cyclone and 2.2 L/min for the HD cyclone (Document ID 0901; 0903). Method 7500 also allows for the use of an aluminum cyclone at 2.5 L/min. NIOSH is revising its respirable dust method to include any sampler designed to meet the ISO/CEN criteria (Document ID 3579, Tr. 218).

The devices discussed above, when used at the appropriate flow rates, are capable of collecting a quantity of respirable crystalline silica that exceeds the quantitative detection limit for quartz (the principle form of crystalline silica) of 10 µg for OSHA's XRD method (Document ID 0946). For several scenarios based on using various devices and sampling times (8-hour, 4-hour, and 1-hour samples), OSHA calculated the amount of respirable quartz that would be collected at quartz concentrations equal to the existing general industry PEL, the proposed (and now final) rule's PEL, and the proposed (and now final) rule's action level. As seen in Table IV.3–A, computations show that the 10-mm nylon Dorr-Oliver operated at an optimized flow rate of 1.7 L/min, the aluminum cyclone operated at 2.5 L/min, the HD cyclone operated at 2.2 L/min, and the GK2.69 operated at 4.2 L/min will all collect enough quartz during an 8-hour or 4-hour sampling period to meet or exceed the 10 µg quartz limit of quantification for OSHA Method ID–142. Therefore, each of the commercially available cyclones is capable of collecting a sufficient quantity of quartz to exceed the limit of quantification when airborne concentrations are at or below the action level, provided that at least 4-hour air samples are taken. Table VII–7 also shows that the samplers can collect enough silica to meet the limit of quantification when the airborne respirable silica concentration is below the action level of 25 µg/m^3, in one case as low as 5 µg/m^3.

Table VII-7
Amount of Quartz Collected by Various Personal Cyclones by Respirable Quartz Concentration and Sampling Time

Cyclone Sampler	Lowest Detectable Concentration ($\mu g/m^3$)[a]		25 $\mu g/m^3$ (Action Level)		50 $\mu g/m^3$ (PEL)		100 $\mu g/m^3$ (Previous PEL)	
	4 hr	8 hr	4 hr	8 hr	4 hr	8 hr	4 hr	8 hr
Dorr Oliver 10 mm nylon (at 1.7 L/min)	25	12	10	20	20	41	41	82
HD (at 2.2 L/min)	19	9.5	13	26	26	53	53	106
Aluminum (at 2.5 L/min)	17	8	15	30	30	60	60	120
GK2.69 (at 4.2 L/min)	10	5	25	50	50	101	101	202

[a] The lowest concentration of airborne respirable crystalline silica that will result in the collection, over the specified sampling period, of at least 10 µg, which is the limit of quantification for quartz for OSHA Method ID-142. Calculated as (1,000 L/m^3 X 10 µg) / (flow rate (L/min) X Duration (min))

* Shaded boxes represent scenarios that will allow for the collection of enough quartz to meet or exceed the 10 µg limit of quantification for OSHA Method ID-142 (revised December 1996).

Source: Adapted from Document ID 1720, Table IV.B-2, pp. IV-24 - IV-25.

A comment from the National Rural Electric Cooperative Association (NRECA) stated that the current OSHA and NIOSH analytical methods require sampling to collect a minimum of 400 liters of air, and that at the flow rates specified for current samplers, sampling would have to be performed for approximately 2.5 to 4 hours; however, this is considerably longer than most construction tasks performed in electrical transmission and distribution work, which tend to last 2 hours or less (Document ID 2365, pp. 2, 6–7). OSHA does not view this discrepancy to be a problem. The minimum sampling times indicated in the OSHA and NIOSH methods contemplate that exposure occurs over most of the work shift. Construction operations frequently involve shorter-term tasks after which there is no further exposure to respirable crystalline silica. In those situations, OSHA often does not itself continue sampling during inspections and does not expect employers to continue sampling when there is no exposure to silica, and considers the sampling result that is obtained from shorter-term task sampling to be sufficient to represent a worker's 8-hour time-weighted-average (TWA) exposure, which can be calculated assuming no exposure for the period of the shift that is not sampled. If the airborne concentration of silica for the task is low, the sampling result would likely be below the limit of quantification. In that case, it would be safe for the employer to assume that the exposure is below the action level.

Transition to ISO–CEN Criteria for Samplers

In the final rule, OSHA is adopting the ISO/CEN particle size-selective criteria for respirable dust samplers used to measure exposures to respirable crystalline silica. Under the ISO/CEN convention, samplers should collect 50 percent of the mass of particles that are 4 µm in diameter (referred to as the cut point), with smaller particles being collected at higher efficiency and larger particles being collected at lower efficiency. Particles greater than 10 µm in diameter, which are not considered to be respirable, are to be excluded from the sample based on the ISO/CEN convention (Document ID 1446, pp. 112–113).

Several rulemaking participants supported OSHA's proposed adoption of the ISO/CEN criteria for respirable dust samplers (Document ID 1730; 1969; 3576, Tr. 290; 3579, Tr. 218–219; 4233, p. 4). For example, a representative of SKC, Inc., which manufactures samplers used to collect respirable crystalline silica, stated that:

> Adoption of the ISO/CEN performance standard for respirable dust samplers by OSHA will bring the U.S. regulatory standards in line with standards/guidelines established by other occupational health and safety agencies, regulatory bodies, and scientific consensus organizations around the world. It will also align OSHA performance criteria for respirable dust samplers to that of NIOSH (Document ID 1730, pp. 1–2).

As discussed above, OSHA's previous (and currently enforceable) general industry PEL for crystalline silica was based on a 1968 ACGIH definition, which specified a model with a cut point of 3.5 µm. Based on available studies conducted over 40 years ago, the Dorr-Oliver 10-mm cyclone was thought to perform closely to this specification. As such, it is the sampling device specified in OSHA's respirable dust sampling and analytical methods, including Method ID–142 for respirable crystalline silica (Document ID 0946). For most sizes of respirable particles, the ISO/CEN convention specifies a greater efficiency in particle collection than does the 1968 ACGIH model; consequently, samplers designed to meet the ISO/CEN convention will capture somewhat greater mass of airborne particle than would a sampler designed to the 1968 ACGIH model, with the magnitude of the increased mass dependent on the distribution of particle sizes in the air. For most particle size distributions encountered in workplaces, the increase in dust mass theoretically collected under the ISO/CEN convention compared to the ACGIH model would be 25 percent or less (Soderholm, 1991, Document ID 1661).

Several rulemaking participants commented that moving from the 1968 ACGIH model to the ISO/CEN convention effectively decreased the PEL and action level below the levels intended, since more dust would be collected by samplers that conform to

the ISO/CEN convention than by those that conform to the 1968 ACGIH model (Document ID 2174; 2195, p. 30; 2285, pp. 3–4; 2307, Attachments 10, p. 19, and 12, p. 3; 2317, p. 2; 3456, p. 10; 4194, pp. 15–16). For example, the Chamber commented that adopting the ISO/CEN specification ''can result in citations for over exposure to quartz dust where none would have been issued prior to the adoption of this convention'' (Document ID 2288, p. 16). OSHA disagrees with this assessment because, based on more recent evaluations (Bartley *et al.,* 1994, Document ID 1438, Attachment 2; Lee *et al.,* 2010, 3616; 2012, 3615), the Dorr-Oliver 10-mm cyclone that has been used by the Agency for enforcement of respirable dust standards for decades has been found to perform reasonably closely (*i.e.,* with an acceptable level of bias) to the ISO/CEN specification when operated at the 1.7 L/min flow rate specified by OSHA's existing method. Consequently, OSHA and employers can continue to use the Dorr-Oliver cyclone to evaluate compliance against the final PEL of 50 μg/m^3 without having to change equipment or procedures, and thus would not be collecting a greater quantity of dust than before. Furthermore, OSHA notes that other ISO/CEN-compliant samplers, such as the SKC 10-mm aluminum cyclone and the HD cyclone specified in the NIOSH Method 7500, are already widely used by investigators and employers to evaluate exposures to respirable crystalline silica against benchmark standards. Therefore, the change from the ACGIH convention to the ISO/CEN convention is more a continuation of the status quo than a drastic change from prior practice.

Other rulemaking participants argued that moving to the ISO/CEN convention effectively invalidates OSHA's risk and feasibility analyses since the exposure data that underlie these analyses were obtained using devices conforming to the 1968 ACGIH specification. For example, Thomas Hall, testifying for the Chamber, stated that moving to the ISO/CEN convention ''would produce a difference in [current] exposure results from . . . historical measurements that have been used in the risk assessments'' (Document ID 3576, Tr. 435). Similarly, in its pre-hearing comments, the ACC argued that:

> When OSHA conducted technological feasibility studies for attaining the proposed 50 μg/m^3 PEL, the Agency based its decisions on samples collected using the current ACGIH method, not the proposed ISO/CEN method. Thus, the switch to the ISO/CEN definition will have two impacts on feasibility. First, it will add uncertainty regarding OSHA's technological feasibility determination because greater reductions in exposure will be required to achieve a 50 μg/m^3 PEL measured by the ISO/CEN definition than by the ACGIH definition that OSHA applied. Second, OSHA's use of the ACGIH definition to estimate compliance costs causes the Agency to underestimate the costs of achieving the 50 μg/m^3 PEL because OSHA did not account for the additional workers whose exposures would exceed the proposed PEL under the ISO/CEN definition but who would be exposed below the proposed PEL if measured under the ACGIH definition (Document ID 2307, Attachment 8, p. 9).

OSHA rejects these arguments for the following reasons. First, with respect to the risk information relied on by the Agency, exposure data used in the various studies were collected from employer records reflecting use of several different methods. Some studies estimated worker exposures to silica from particle counts, for which the sampling method using impingers does not strictly conform to either the ACGIH or ISO/CEN conventions (*e.g.*, Rice *et al.*, Document ID 1118; Park *et al.*, Document ID 0405; Attfield and Costello, Document ID 0285; Hughes *et al.*, Document ID 1060). Other studies used measurements taken using cyclone samplers and modern gravimetric methods of silica analysis (*e.g.*, Rice *et al.* and Park *et al.*, data obtained from cyclone pre-separator up through 1988, Document ID 1118, 0405; Hughes *et al.*, data from 10-mm nylon cyclone through 1998, Document ID 1060). OSHA believes it likely that exposure data collected using cyclones in these studies likely conformed to the ISO/CEN specification since flow rates recommended in the OSHA and NIOSH methods were most likely used. The studies by Miller and MacCalman (Document ID 1097) and by Buchanan *et al.* (Document ID 0306) used exposure measurements made with the MRE 113A dust sampler, which does conform reasonably well with the ISO/CEN specification (Gorner *et al.*, Document ID 1457, p. 47). The studies by Chen *et al.* (2001, Document ID 0332; 2005, Document ID 0985) estimated worker exposures to silica from total dust measurements that were converted to respirable silica measurements from side-by-side comparisons of the total dust sampling method with samples taken using a Dorr-Oliver cyclone operated at 1.7 L/min, which is consistent with the ISO/CEN convention (*see* Section V, Health Effects, of this preamble and OSHA's Preliminary Review of Health Effects Literature and Preliminary Quantitative Risk Assessment, Document ID 1711). Thus, it is simply not the case that the exposure assessments conducted for these studies necessarily reflect results from dust samples collected with a device conforming to the 1968 ACGIH particle size-selective criteria, and OSHA finds that no adjustment of OSHA's risk estimates to reflect exposure measurements consistent with the ISO/CEN convention is warranted.

Second, with respect to the feasibility analysis, OSHA relied on exposure data and constructed exposure profiles based principally on measurements made by compliance officers using the Dorr-Oliver cyclone operated at 1.7 L/min, as the Agency has done since Method ID–142 was developed in 1981, well before the 1990 cut-off date for data used to construct the exposure profiles. As explained earlier in the section, recent research shows that the Dorr-Oliver cyclone operated at this flow rate performs in a manner consistent with the ISO/CEN specification. Other data relied on by OSHA comes from investigations and studies conducted by NIOSH and others who used various cyclones that conform to the ISO/CEN specification. Thus, OSHA finds that the exposure profiles being relied on to evaluate feasibility and costs of compliance do not reflect sample results obtained using the 1968 ACGIH model. Instead, the vast majority of sample results relied upon were collected in a manner consistent with the requirements of the final rule. NIOSH supported this assessment, stating that, given the Dorr-Oliver sampler operated at a flow rate of 1.7 L/min conforms closely to the ISO/CEN convention, ''there is continuation with historic exposure data'' (Document ID 4233, p. 4). For these reasons, OSHA finds that it is appropriate to rely on the feasibility and cost analyses and underlying exposure data without adjustment to account for the final rule's adoption of the ISO/CEN specification for respirable dust samplers.

Sampling Error

Several commenters raised issues concerning the accuracy of respirable dust samplers in relation to the ISO/CEN criteria, asserting that sampling respirable dust is uncertain and inaccurate, and that there are numerous sources of error. Chief among these were Dr. Thomas Hall of Industrial Hygiene Specialty Resources, LLC, testifying for the Chamber, and Paul K. Scott of ChemRisk, testifying for the ACC.

The Chamber's witnesses and others referenced studies showing that all samplers were biased against the ISO/CEN particle-size selection convention. This means that the sampler would collect more or less mass of respirable particulate than would an ideal sampler

that exactly conforms to the ISO/CEN convention. OSHA discussed this issue in the PEA, noting that most samplers tend to over-sample smaller particles and under-sample larger particles, compared to the ISO/CEN convention, at their optimized flow rates. This means that, for particle size distributions dominated by smaller particles, the sampler will collect more mass than would be predicted from an ideal sampler that exactly conforms to the ISO/CEN convention. For particle size distributions dominated by larger particles in the respirable range, less mass would be collected than predicted. In the PEA, OSHA evaluated several studies that showed that several cyclone samplers exhibited a bias of 10 percent or less for most particle size distributions encountered in the workplace. Some of these studies found biases as high as ±20 percent but only for particle size distributions having a large mass median aerodynamic diameter (MMAD) (*i.e.*, 20 µm or larger) and narrow distribution of particle sizes (*i.e.*, a geometric standard deviation (GSD) of 2 or less) (Document ID 1720, pp. IV–21—IV–24). Such particle size distributions are infrequently seen in the workplace; for well-controlled environments, Frank Hearl of NIOSH testified that the GSD for typical particle size distributions would be about 2 (Document ID 3579, Tr. 187). Dr. Hall (Document ID 3576, Tr. 502) testified, similarly, that it would be around 1.8 to 3 for well-controlled environments and higher for uncontrolled environments (*see also* Liden and Kenny, 1993, Document ID 1450, p. 390, Figure 5; Soderholm, 1991,1661, p. 249, Figure 1). Furthermore, a particle size distribution with a large MMAD and small GSD would contain only a very small percentage (< 10%) of respirable dust that would be collected by a sampler optimized to the ISO/CEN criteria (Soderholm, 1991, Document ID 1661, p. 249, Figure 2). According to Liden and Kenny (1993), ''samplers will perform reasonably well providing the absolute bias in sampling is kept to within 10 percent . . . this aim can be achieved . . . over the majority of size distributions likely to be found in field sampling'' (Document ID 1450, p. 390).

Dr. Hall commented that ''sampling results differ depending on the choice of sampler used'' and that published evaluations have shown that they ''have different collection efficiencies, specifically with respect to particle collection in aerosol clouds with large [MMADs greater than] 10 µm'' (Document ID 2285, p. 16). He cited the work of Gorner *et al.* (2001, Document ID 1457), who noted that the cut points achieved by different samplers varied considerably and that flow rates were optimized to bring their respective cut points closer to the ISO/CEN convention, as evidence that commercial samplers do not provide consistently similar results. However, OSHA interprets the findings of Gorner *et al.* as actually providing evidence of samplers' consistency with the ISO/CEN convention for most particle size distributions encountered in the workplace. This study, which was reviewed in OSHA's PEA, evaluated 15 respirable dust samplers, most of them cyclones, against 175 different aerosol size distributions and evaluated the bias and accuracy of sampler performance against the ISO/CEN convention.[23] Gorner *et al.* found that most of the samplers they tested met the international criteria for acceptable bias and accuracy (described by Bartley *et al.*, 1994, Document ID 1438, Attachment 2 and Gorner *et al.*, 2001, 1457); under those criteria, bias is not to exceed 10 percent and inaccuracy is not to exceed 30 percent for most of the size distributions tested (Document ID 1457, pp. 49, 52; Document ID 1438, Attachment 2, p. 254). Gorner *et al.* concluded that the samplers ''are therefore suitable for sampling aerosols within a wide range of particle size distributions'' (Document ID 1457, p. 52). Gorner *et al.* also stated that sampler performance should be evaluated by examining bias and accuracy rather than simply comparing cut points and slopes against the ISO/CEN convention (Document ID 1457, p. 50), as Dr. Hall did in his comments.

The ACC's witness, Mr. Scott, noted several potential sources of sampling error in addition to the conventional 5-percent pump flow rate error that is included in OSHA's estimate of sampling and analytical error (SAE, discussed further in Section IV–3.2.4—Precision of Measurement). These included variation in performance of the same cyclone tested multiple times (estimated at 6 percent) and variation between different cyclones tested in the same environment (estimated at 5 percent) (Document ID 2308, Attachment 6, pp. 7–8). Based on published estimates of the magnitude of these kinds of errors, Mr. Scott estimated a total sampling error of 9.3 percent after factoring in pump flow rate error, inter-sampler error, and intra-sampler error; this would increase the SAE by 4 percent, for example, from 15 to 19 percent at 50 µg/m^3 (Document ID 2308, pp. 8–9). This means that, if all sampler error were factored into the SAE, an employer would be considered out of compliance with the PEL for an exposure exceeding 59.5 µg/m^3, rather than at 57.5 µg/m^3 if only pump error were considered, a difference of only 2 µg/m^3 in silica concentration. OSHA therefore concludes that intra- and inter-sampler error of the types described by Mr. Scott do not materially change how OSHA would enforce, or how employers should evaluate, compliance with the final rule PEL.

As described above, many different respirable dust samplers have been evaluated against the ISO/CEN convention for different particle size distributions and, in general, these biases are small for the vast majority of particle size distributions encountered in the workplace. OSHA concludes that Mr. Scott's estimate likely overstates the true total sampling error somewhat because the measurements of sampler bias against the ISO/CEN criteria involve accurately measuring and maintaining consistent pump flow rates during the testing of the samplers; therefore, adding pump flow rate error to estimates of inter- and intra-sampler measurement error is redundant. Furthermore, if an employer relies on a single type of cyclone sampler, as is OSHA's practice, there would be no inter-sampler variability between different field samples. If an employer is concerned about this magnitude of uncertainty, he or she can choose simply to use the same sampling device as OSHA (*i.e.*, the Dorr-Oliver cyclone operated at a flow rate of 1.7 L/min, as specified in Method ID–142) and avoid any potential measurement uncertainties associated with use of different sampling devices.

The American Foundry Society (AFS) commented that the ASTM Standard D4532 for respirable dust sampling includes errors for sampling, weighing, and bias, none of which is included in OSHA's pump flow rate error (Document ID 2379, p. 29). This ASTM standard describes procedures for sampling respirable dust using a 10-mm cyclone, HD cyclone, or aluminum cyclone in a manner identical to that prescribed in the OSHA and NIOSH methods for sampling and analysis of silica. Thus, the kinds of errors identified by AFS are the same as those reflected in Mr. Scott's testimony described above, which, as OSHA has

[23] Bias means the difference in particle mass collected by a sampler as compared to the mass that would be collected by a hypothetical ideal sampler that exactly matched the ISO/CEN convention. Accuracy includes bias and other sources of error related to the testing procedure (*e.g.*, errors in flow rate and particle mass analysis)(Document ID 1457, p. 49).

shown, do not result in substantial uncertainties in exposure measurement.

OSHA further observes that the kinds of sampling errors described by rulemaking participants are independent of where the PEL is established and are not unique to silica; these biases have existed since OSHA began using the Dorr-Oliver cyclone to enforce the previous PELs for crystalline silica, as well as many other respirable dust standards, over 40 years ago. OSHA also believes that sampling error within the range quantified by Mr. Scott would be unlikely to change how an employer makes risk management decisions based on monitoring results. One Chamber witness, Gerhard Knutson, President of Knutson Ventilation, testified that the type of cyclone used to obtain exposure measurements for crystalline silica was not typically a consideration in designing industrial ventilation systems (Document ID 3576, Tr. 521–522). Dr. Hall, another Chamber witness, also testified that he has used all three sampling devices listed in the NIOSH Method 7500 and has not historically made a distinction between them, though he might make different decisions today based on the aerosol size distribution encountered in a particular workplace (Document ID 3576, Tr. 522–523). In his pre-hearing submission, Dr. Hall cited the Gorner *et al.* (2001, Document ID 1457) study as recommending that ''rough knowledge of the aerosol size distribution can guide the choice of an appropriate sampling technique'' (Document ID 2285, p. 8). OSHA concludes it unlikely that, in most instances, it is necessary to obtain such data to minimize sampling bias for risk management purposes, given the overall magnitude of the bias as estimated by Mr. Scott (*i.e.*, an error of less than 10 percent).

High Flow Samplers

OSHA's PEA also described high-flow samplers, in particular the GK2.69 from BGI, Inc., which is run at a flow rate of 4.2 L/min in contrast to 1.7 L/min for the Dorr-Oliver and 2.5 L/min for the aluminum cyclone. High-flow devices such as this permit a greater amount of dust to be collected in low-dust environments, thus improving sensitivity and making it more likely that the amount of silica collected will fall within the range validated by current analytical methods. For example, a Dorr-Oliver run at 1.7 L/min where the silica concentration is 50 μg/m^3 would collect 41 μg of silica over 8 hours, compared to the GK2.69 run at 4.2 L/min, which would collect 101 μg of silica (*see* Table IV.3–A), well within the validation range of the OSHA method (*i.e.*, the range over which precision is determined, 50 to 160 μg) (Document ID 0946, p. 1). Several rulemaking participants supported OSHA's proposal to permit use of high-flow samplers that conform to the ISO/CEN convention (Document ID 2256, Attachment 3, p. 12; 3578, Tr. 941; 3586, Tr. 3286–3287; 4233, p. 4). For example, William Walsh, representing the American Industrial Hygiene Association (AIHA) Laboratory Accreditation Programs, stated that he could measure concentrations of silica at the 25 μg action level with sufficient precision by using a high-flow device (Document ID 3586, Tr. 3287).

The performance of high-flow samplers has been extensively studied, particularly by Lee *et al.* (2010, Document ID 3616; 2012, 3615), Stacey *et al.* (2013, Document ID 3618), and Kenny and Gussman (1997, Document ID 1444). The Kenny and Gussman study, which was reviewed in OSHA's PEA, found the GK2.69 had good agreement with the ISO/CEN convention at the 4.2 L/min flow rate, with a cut point of 4.2 μm and a collection efficiency curve that was steeper than the ISO/CEN (*i.e.*, it was more efficient for smaller particles and less so for larger particles). For particle size distributions up to an MMAD of 25 μm and GSD of 1.5 to 3.5, bias against the ISO/CEN convention was generally between +5 and −10 percent. Bias was greater (−20 percent) for particle size distributions having an MMAD above 10 μm and a low GSD which, according to the authors, are not likely to be encountered (Document ID 1444, p. 687, Figure 7).

The Lee *et al.* (2010, Document ID 3616; 2012, 3615) and Stacey (2013, Document ID 3618) studies of high-flow sampler performance are the product of a collaborative effort between NIOSH and the United Kingdom's Health and Safety Executive (HSE) that examined the performance of three high-flow samplers; these were the GK2.69, the CIP10–R (Arelco ARC, France), and the FSP10 (GSA, Germany). The FSP10 runs at a flow rate of 10 L/min and the combination of large cyclone and heavy-duty pump may be burdensome for workers to wear. The CIP–10 also runs at 10 L/min and is much smaller and lighter, but uses a collection technology different from cyclones, which may be unfamiliar to users. According to NIOSH, cyclones operating around 4 L/min ''offer a current compromise'' for obtaining higher flow rates without the need to use larger personal samplers that may be difficult for workers to wear (Document ID 2177, Attachment B, p. 13; 3579, Tr. 163).'' For this reason, OSHA's review of these studies focuses on the performance of the GK2.69 cyclone.

Lee *et al.* (2010, Document ID 3616) tested the GK2.69 against 11 sizes of monodisperse aerosol and found that, at the 4.2 L/min flow rate, the estimated bias against the ISO/CEN convention was positive for all particle size distributions (*i.e.*, the sampler collected greater mass of particulate than would be predicted from an ideal sampler that exactly conformed to ISO/CEN), with a 10-percent efficiency for collecting 10 μm particles, compared to 1 percent for the ISO/CEN convention. The authors estimated a bias of +40 percent for a particle size distribution having a MMAD of 27.5 μm. However, adjustment of the flow rate to 4.4 L/min resulted in biases of less than 20 percent for most particle size distributions and the collection efficiency for 10 μm particles was much closer to the ISO/CEN convention (2.5 percent compared to 1 percent). The authors concluded that, at the higher flow rate, the GK2.69 cyclone met the international standard for sampler conformity to relevant particle collection conventions (European Committee for Standardization, EN 13205, cited in Lee *et al.*, 2010, Document ID 3616), and would provide relatively unbiased measurements of respirable crystalline silica (Document ID 3616, pp. 706, 708, Figure 5(a)).

Lee *et al.* (2012, Document ID 3615) performed a similar evaluation of the same samplers using coal dust but included analysis of crystalline silica by both XRD and IR. The GK2.69 runs at a flow rate of 4.4 L/min collected somewhat more respirable dust and crystalline silica than would be predicted from differences in flow rates, compared to the 10-mm nylon cyclone, but nearly the same as the Higgins-Dewell cyclone. The authors found that the GK2.69 ''showed non-significant difference in performance compared to the low-flow rate samplers'' (Document ID 3615, p. 422), and that ''the increased mass of quartz collected with high-flow rate samplers would provide precise analytical results (*i.e.*, significantly above the limit of detection and/or the limit of quantification) compared to the mass collected with low-flow rate samplers, especially in environments with low concentrations of quartz . . .'' (Document ID 3615, p. 413). Lee *et al.* concluded that ''[a]ll samplers met the [EN 13205] requirements for accuracy for sampling the ISO respirable convention'' (Document ID 3615, p. 424).

Stacey *et al.* (2013, Document ID 3618) used Arizona road dust aerosols

to evaluate the performance of high-flow samplers against the Safety In Mines Personal Dust Sampler (SIMPEDS), which is the low-flow sampler used to measure respirable crystalline silica in the U.K. For the GK2.69, use of a flow rate of 4.2 L/min or 4.4 L/min made little difference in the respirable mass collected, and there was closer agreement between the GK2.69 and SIMPEDS sampler when comparing respirable crystalline silica concentration than respirable dust concentration, and the difference was not statistically significant (Document ID 3618, p. 10). According to NIOSH, the findings by Stacey *et al.* (2013) corroborate those of Lee *et al.* (2010 and 2012) that the GK2.69 meets the ISO/CEN requirements for cyclone performance and that either the 4.2 L/min or 4.4 L/min flow rate ''can be used to meet the ISO convention within acceptable limits'' (Document ID 2177, p. 13).

Mr. Scott testified that the high-flow samplers (including the GK2.69) studied by Lee *et al.*, (2010 and 2012), ''tended to have a substantial bias towards collecting more respirable particulates than the low-flow samplers, collecting between 12 percent and 31 percent more mass'' because high-flow samplers tend to collect a higher proportion of larger particles (Document ID 3582, Tr. 1984). In his written testimony, he noted that Lee *et al.* (2010) reported a nearly 10-fold higher collection efficiency for 10 µm particles compared to the ISO/CEN standard. However, Mr. Scott's testimony ignores Lee *et al.*'s findings that the oversampling of larger particles seen at a flow rate of 4.2 L/min was not apparent at the higher 4.4 L/min flow rate and that Lee *et al.* (2010) concluded that agreement with the ISO/CEN convention was achieved at the higher flow rate (Document ID 3616, pp. 706, 708). In addition, oversampling of larger particles at the 4.2 L/min flow rate was not reported by Lee *et al.* (2012, Document 3615) or Stacey *et al.* (2013, Document ID 3618).

Dr. Hall expressed a similar concern as Mr. Scott. He cited Lee *et al.* (2010) as stating that the GK2.69 would collect significantly more aerosol mass for particle size distributions having an MMAD of more than 6 µm. He also cited Lee *et al.* (2010 and 2012) for the finding that the GK2.69 collects from 1.8 to 3.84 times as much aerosol mass as the Dorr-Oliver or Higgins-Dewell cyclones (Document ID 2285, p. 12). In his pre-hearing comment, Dr. Hall stated that ''[f]or aerosol clouds with a [MMAD] greater than 10 µm, the expected absolute bias can range be (sic) between 20 and 60%'' and ''the total variability for the method SAE can be as large as 85–90%'' (Document ID 2285, pp. 15–16).

OSHA notes that both Dr. Hall and Mr. Scott focus their comments regarding the performance of high-flow samplers on environments where the particle size distribution is characterized by larger particles and small variance (GSD). The findings by Lee *et al.* (2010) show that, at a flow rate of 4.2 L/min, under this experimental system, there were large positive biases (>20 percent) against the ISO/CEN convention for nearly all particle size distributions having MMAD of 5 to 10 µm (Document ID 3616, pp. 704–706, Figure 3(b)). However, when the flow rate was adjusted to 4.4 L/min, bias exceeding 20 percent was found to occur primarily with particle size distributions having GSDs under 2.0 and MMAD greater than 10 µm (Document ID 3616, p. 707, Figure 5(a)). As discussed above, it is rare to encounter particle size distributions having relatively large MMADs and small GSDs, so the high variability attributed to high-flow samplers by Dr. Hall and Mr. Scott should not be of concern for most workplace settings. Further, sampler performance is considered acceptable if the bias and accuracy over at least 80 percent of the remaining portion of the bias map are within acceptable limits, which are no more than 10 and 30 percent, respectively (Document ID 1457, pp. 49, 52). The Lee *et al.* studies (2010 and 2012) concluded that the high-flow samplers tested met these international requirements for accuracy for sampling the ISO/CEN convention, and the Stacey *et al.* (2013) study found that their results compared favorably with those of Lee *et al.* (2012). Therefore, OSHA finds that the uncertainties characterized by Dr. Hall and Mr. Scott are exaggerated for most workplace situations, and that there is substantial evidence that high-flow samplers, in particular the GK2.69 cyclone, can be used to collect respirable crystalline silica air samples in most workplace settings without introducing undue bias.

Mr. Scott, testifying for the ACC, was of the opinion that, although high-flow samplers have been evaluated by Gorner *et al.* (2001, Document ID 1457) and Lee *et al.* (2010, Document ID 3616; 2012, 3615) with respect to their sampling efficiencies as compared to the ISO/CEN convention and their performance compared to low-flow samplers, none of the studies evaluated the accuracy and precision using methods recommended in NIOSH's Guidelines for Air Sampling and Analytical Method Development and Evaluation (1995, *http://www.cdc.gov/niosh/docs/95-117/*) (Document ID 2308, Attachment 6, p. 18). OSHA understands Mr. Scott to contend that the sampler must be tested against a generated atmosphere of respirable crystalline silica and that the precision of the sampling and analytical method must be determined overall from these generated samples.

OSHA does not agree with the implication that, until high-flow samplers have been evaluated according to the NIOSH (1995) protocol, the findings from the studies described above are not sufficient to permit an assessment of sampler performance. The NIOSH Guidelines cited by Mr. Scott state that ''[a]n experimental design for the evaluation of sampling and analytical methods has been suggested. If these experiments are not applicable to the method under study, then a revised experimental design should be prepared which is appropriate to fully evaluate the method'' (*http://www.cdc.gov/niosh/docs/95-117/*, p. 1). These guidelines contemplate the development of entirely new sampling and analytical methods. Because the analytical portion of the sampling and analytical method for respirable crystalline silica was already fully evaluated before the GK2.69 was developed (Kenny and Gussman, 1997, Document ID 1444), it was only necessary to evaluate the performance of the GK2.69 high-flow sampler. As described above, the studies by Lee *et al.* (2010, Document ID 3616; 2012, 3615) and Stacey *et al.* (2013, Document ID 3618) reflect a collaborative effort between NIOSH in the U.S. and HSE in the U.K. to evaluate the performance of high-flow respirable dust samplers. The Lee *et al.* (2010, 2012) studies were conducted by NIOSH laboratories in Morgantown, West Virginia with peer review by HSE scientists, and the Stacey *et al.* (2013) study was conducted by HSE at the Health and Safety Laboratory at Buxton in the U.K. Both Lee *et al.* (2012) and Stacey *et al.* (2013) concluded that high-flow samplers studied, including the GK2.69, met the EN 13205 requirements for accuracy for sampling against the ISO/CEN convention, demonstrating that results from these two national laboratories compared favorably. OSHA concludes these peer-reviewed studies, performed by NIOSH and HSE scientists, meet the highest standards for effective methods evaluation and therefore does not agree with the suggestion that additional work following NIOSH's protocol is necessary. Comments submitted by NIOSH indicate that the Lee *et al.* (2010, 2012) and Stacy *et al.* (2013) studies are

sufficient to establish the GK2.69 high-flow sampler as acceptable for sampling respirable crystalline silica under the ISO/CEN convention (Document ID 2177, Attachment B; 4233, p. 4).

URS Corporation, on behalf of the ACC, commented that precision will not be improved by the use of high-flow samplers because filter loadings of interferences will increase along with the amount of crystalline silica; this would, in URS's opinion, necessitate additional sample handling procedures, such as acid washing, that erode precision. URS also argued that such samples may require analysis of multiple peaks and that overall X-ray intensity may be diminished due to increased filter load (Document ID 2307, Attachment 12, p. 3). In its post-hearing brief, the ACC stated that the use of high-volume samplers ''in addition to traditional Dorr-Oliver sampler'' would reduce inter-laboratory precision (*i.e.,* the extent to which different laboratories achieve similar results for the same sample) due to the use of multiple sampler types (Document ID 4209, p. 154).

OSHA finds that these arguments are unsupported. Although the high-flow sampler will collect more dust than lower-flow samplers in the same environment, the relative proportion of any interfering materials collected to the amount of crystalline silica collected would remain unchanged. Thus, there should be no increased effect from the interfering materials relative to the silica. OSHA recognizes that, to prevent undue interference or diminished X-ray intensity, it is important to keep the dust load on the filter within reasonable limits. Both OSHA and NIOSH methods stipulate a maximum sample weight to be collected (3 mg for OSHA and 2 mg for NIOSH) (Document ID 0946, p. 5; 0901, p. 3), and in the event that excess sample is collected, the sample can be split into portions and each portion analyzed separately (Document ID 0946, p. 5). In environments where using a high-flow sampler is likely to collect more than the maximum sample size, use of a lower-flow sampler is advised. In response to the concern that permitting use of high-flow samplers will affect inter-laboratory variability, OSHA observes that employers are already using a variety of commercially available samplers, such as those listed in the NIOSH Method 7500, to obtain exposure samples; not everyone uses the Dorr-Oliver sampler. Thus, for the final rule, OSHA is permitting employers to use any sampling device that has been designed and calibrated to conform to the ISO/CEN convention, including higher-flow samplers such as the GK2.69. In effect, this is a continuation of well-studied current practice, not an untested departure from it.

b. Laboratory Analysis of Crystalline Silica

Crystalline silica is analyzed in the laboratory using either X-ray diffraction (XRD) or infrared spectroscopy (IR). A third method, colorimetric spectrophotometry, is no longer used (Document ID 3579, Tr. 211; Harper *et al.*, 2014, 3998, Attachment 8, p. 1). This section describes crystalline silica analysis by XRD and IR and responds to comments and testimony on the precision and accuracy of these methods for measuring crystalline silica concentrations in the range of the final rule's PEL and action level. As discussed below, both XRD and IR methods can detect and quantify crystalline silica in amounts collected below the final rule's 25 µg action level.

X-Ray Diffraction

For XRD, a dust sample that has been collected by a sampler is deposited on a silver-membrane filter and scanned by the X-ray beam, where X-rays diffract at specific angles. A sensor detects these diffracted X-ray beams and records each diffracted beam as a diffraction peak. Unique X-ray diffraction patterns are created when the diffraction peaks are plotted against the angles at which they occur. The intensity of the diffracted X-ray beams depends on the amount of crystalline silica present in the sample, which can be quantified by comparing the areas of the diffraction peaks obtained with those obtained from scanning a series of calibration standards prepared with known quantities of an appropriate reference material. Comparing multiple diffraction peaks obtained from the sample with those obtained from the calibration standards permits both quantitative and qualitative confirmation of the amount and type of crystalline silica present in the sample (*i.e.,* quartz or cristobalite). A major advantage of XRD compared with the other techniques used to measure crystalline silica is that X-ray diffraction is specific for crystalline materials. Neither non-crystalline silica nor the amorphous silica layer that forms on crystalline silica particles affects the analysis. The ability of this technique to quantitatively discriminate between different forms of crystalline silica and other crystalline or non-crystalline materials present in the sample makes this method least prone to interferences. Sample analysis by XRD is also non-destructive, meaning that samples can be reanalyzed if necessary (Document ID 1720, pp. IV–26—IV–27).

The OSHA Technical Manual lists the following substances as potential interferences for the analysis of crystalline silica using XRD: Aluminum phosphate, feldspars (microcline, orthoclase, plagioclase), graphite, iron carbide, lead sulfate, micas (biotite, muscovite), montmorillonite, potash, sillimanite, silver chloride, talc, and zircon (*https://www.osha.gov/dts/osta/otm/otm_ii/otm_ii_1.html*, Chapter 1, III.K). The interference from other minerals usually can be recognized by scanning multiple diffraction peaks quantitatively. Diffraction peak-profiling techniques can resolve and discriminate closely spaced peaks that might interfere with each other. Sometimes interferences cannot be directly resolved using these techniques. However, many interfering materials can be chemically washed away in acids that do not dissolve the crystalline silica in the sample. Properly performed, these acid washes can dissolve and remove these interferences without appreciable loss of crystalline silica (Document ID 1720, p. IV–27).

The nationally recognized analytical methods using XRD include OSHA ID–142, NIOSH 7500, and MSHA P–2 (Document ID 0946; 0901; 1458). All are based on the XRD of a redeposited thin-layered sample with comparison to standards of known concentrations (Document ID 0946, p. 1; 0901, p. 1; 1458, p. 1). These methods, however, differ on diffraction peak confirmation strategies. The OSHA and MSHA methods require at least three diffraction peaks to be scanned (Document ID 0946, p. 5; 1458, p. 13). The NIOSH method only requires that multiple peaks be qualitatively scanned on representative bulk samples to determine the presence of crystalline silica and possible interferences, and quantitative analysis of air samples is based on a single diffraction peak for each crystalline silica polymorph analyzed (Document ID 0901, pp. 3, 5).

Infrared Spectroscopy

Infrared spectroscopy is based on the principle that molecules of a material will absorb specific wavelengths of infrared electromagnetic energy that match the resonance frequencies of the vibrations and rotations of the electron bonds between the atoms making up the material. The absorption of IR radiation by the sample is compared with the IR absorption of calibration standards of known concentration to determine the amount of crystalline silica in the sample. Using IR can be efficient for routine analysis of samples that are well

characterized with respect to mineral content, and the technique, like XRD, is non-destructive, allowing samples to be reanalyzed if necessary. The three principle IR analytical methods for crystalline silica analyses are NIOSH 7602 (Document ID 0903), NIOSH 7603 (*http://www.cdc.gov/niosh/docs/2003-54/pdfs/7603.pdf*), and MSHA P–7 (Document ID 1462); NIOSH Method 7603 and MSHA P–7 were both specifically developed for the analysis of quartz in respirable coal dust. OSHA does not use IR for analysis of respirable crystalline silica.

Interferences from silicates and other minerals can affect the accuracy of IR results. The electromagnetic radiation absorbed by silica in the infrared wavelengths consists of broad bands. In theory, no two compounds have the same absorption bands; however, in actuality, the IR spectra of silicate minerals contain silica tetrahedra and have absorption bands that will overlap. If interferences enhance the baseline measurement and are not taken into account, they can have a negative effect that might underestimate the amount of silica in the sample. Compared with XRD, the ability to compensate for these interferences is limited (Document ID 1720, pp. IV–29—IV–30).

c. Sensitivity of Sampling and Analytical Methods

The sensitivity of an analytical method or instrument refers to the smallest quantity of a substance that can be measured with a specified level of accuracy, and is expressed as either the LOD or the ''Limit of Quantification'' (LOQ). These two terms have different meanings. The LOD is the smallest amount of an analyte that can be detected with acceptable confidence that the instrument response is due to the presence of the analyte. The LOQ is the lowest amount of analyte that can be reliably quantified in a sample and is higher than the LOD. These values can vary from laboratory to laboratory as well as within a given laboratory between batches of samples because of variation in instrumentation, sample preparation techniques, and the sample matrix, and must be confirmed periodically by laboratories.

At a concentration of 50 µg/m^3, the final rule's PEL, the mass of crystalline silica collected on a full-shift (480 minute) air sample at a flow rate of 1.7 L/min, for a total of 816 L of air, is approximately 41 µg (*see* Table VII–7). At a concentration of 25 µg/m^3, the final rule's action level, the mass collected is about 20 µg. The LOQ for quartz for OSHA's XRD method is 10 µg (Document ID 0946; 3764, p. 4), which is below the amount of quartz that would be collected from full-shift samples at the PEL and action level. Similarly, the reported LODs for quartz for the NIOSH and MSHA XRD and IR methods are lower than that which would be collected from full-shift samples taken at the PEL and action level (NIOSH Method 7500, Document ID 0901, p. 1; MSHA Method P–2, 1458, p. 2; NIOSH Method 7602, 0903, p. 1; NIOSH Method 7603, *http://www.cdc.gov/niosh/docs/2003-154/pdfs/7603.pdf*, p. 1; MSHA Method P–7, 1462, p. 1).

The rule's 50 µg/m^3 PEL for crystalline silica includes quartz, cristobalite, and tridymite in any combination. For cristobalite and tridymite, the previous general industry formula PEL was approximately 50 µg/m^3, so the change in the PEL for crystalline silica does not represent a substantive change in the PEL for cristobalite or tridymite when quartz is not present. OSHA Method ID–142 (Document ID 0946) lists a 30-µg LOQ for cristobalite; however, because of technological improvements in the equipment, the current LOQ for cristobalite for OSHA's XRD method as implemented by the OSHA Salt Lake Technical Center (SLTC) is about 20 µg (Document ID 3764, p. 10).

That XRD analysis of quartz from samples prepared from reference materials can achieve LODs and LOQs between 5 and 10 µg was not disputed in the record. Of greater concern to several rulemaking participants was the effect of interfering materials potentially present in a field sample on detection limits and on the accuracy of analytical methods at low filter loads when interferences are present. Although the Chamber's witness, Robert Lieckfield of Bureau Veritas Laboratories, did not dispute that laboratories could achieve this level of sensitivity (Document ID 3576, Tr. 485–486), the ACC took issue with this characterization of method sensitivity stating that ''the LOQ for real world samples containing interferences is likely to be higher than the stated LOQ's for analytical methods, which are determined using pure NIST samples with no interferences'' (Document ID 4209, p. 132). Both Mr. Lieckfield and Mr. Scott testified that the presence of interferences in samples can increase the LOQ and potential error of measurement at the LOQ (Document ID 2259, p. 7; 3460, p. 5).

Mr. Scott (Document ID 2308, Attachment 6, p. 5) cited a laboratory performance study by Eller *et al.* (1999a, Document ID 1687), in which laboratories analyzing samples with and without interfering materials present reported a range of LOD's from 5 µg to 50 µg. Mr. Scott believed that this study provided evidence that interfering materials present in crystalline silica samples adversely affected laboratories' reported LODs. OSHA disagrees with this interpretation. The Agency reviewed this study in the PEA (Document ID 1720, p. IV–33) and believes that the variability in reported LODs reflected differences in laboratory practices with respect to instrument calibration and quality control procedures. These factors led Eller *et al.* (1999b, Document ID 1688, p. 24; 1720, p. IV–42) to recommend changes in such practices to improve laboratory performance. Thus, OSHA finds that the variation in reported LODs referred to by Mr. Scott cannot be attributed primarily to the presence of interfering materials on the samples.

The presence of interferences can adversely affect the sensitivity and precision of the analysis, but typically only when the interference is so severe that quantification of crystalline silica must be made from secondary and tertiary diffraction peaks (Document ID 0946, p. 6). However, OSHA finds no evidence that interferences usually present serious quantification problems. First, there are standard protocols in the OSHA, NIOSH, and MSHA methods that deal with interferences. According to OSHA Method ID–142,

> Because of these broad selection criteria and the high specificity of the method for quartz, some of the listed interferences may only present a problem when a large amount of interferent is present. . . . Interference effects are minimized by analyzing each sample for confirmation using at least three different diffraction peaks so as to include peaks where the quartz and cristobalite results are in good agreement and where the interferent thus causes no problem. Bulk samples or a description of the process being sampled are useful in customizing a chemical cleanup procedure for any interference found difficult to resolve by software. Even so, the presence of an interference rarely jeopardizes the analysis (Document ID 0946, p. 5).

Software developed by instrument manufacturers and techniques such as acid washing of the sample when interferences are suspected to be present are also useful in resolving interferences. The Chamber's expert witness, Mr. Lieckfield, acknowledged that it was also their practice at his lab to chemically treat samples from the start to remove interfering materials and to analyze multiple diffraction peaks to resolve interferences (Document ID 3576, Tr. 533, 542). According to OSHA's representative from the SLTC, it is ''nearly always possible'' to eliminate interferences and is it no more difficult to obtain precise measurements when

interferences are present than when they are not (Document ID 3579, Tr. 48).

ACC also cites the results of a round-robin performance study that it commissioned, in which five laboratories were provided with crystalline silica samples with and without interfering materials (Document ID 4209, p. 132). These laboratories reported non-detectable levels of silica for 34 percent of the filters having silica loadings of 20 µg or more. However, as discussed below in the section on inter-laboratory variability (Section IV–3.2.5—Measurement Error Between Laboratories), OSHA has determined that this study is seriously flawed and, in particular, that there was systematic bias in the results, possibly due to sample loss. This could explain the high prevalence of reported non-detectable samples by the laboratories, rather than the presence of interferences *per se*.

Furthermore, OSHA's review of the several hundred inspection reports relied on to evaluate the technological feasibility of the final rule's PEL in many industry sectors does not show that investigators have particular difficulty in measuring respirable crystalline silica concentrations below the PEL. Sections IV–4 and IV–5 of this chapter contain hundreds of exposure measurement results in a wide variety of workplace settings that were detected and reported by a laboratory as being above detectable limits but below the PEL or action level. If, as ACC suggests, interferences have a profound effect on the ability to measure concentrations in this range, many of these samples might have been reported as ''less than the LOD,'' with the reported LOD in the range of 25 µg to 50 µg. Examination of the exposure data described in Sections IV–4 and IV–5 of this chapter shows clearly that this is not the case (*see* exposure profiles for Concrete Products, Section IV–4.3; Cut Stone, Section IV–4.4; Foundries (Metal Casting), Section IV–4.8; Mineral Processing, Section IV–4.12; Porcelain Enameling, Section IV–4.14; Ready Mix Concrete, Section IV–4.17; Refractories, Section IV–4.18). In addition, the United Steelworkers reported receiving exposure data from 17 employers with samples in this same range, indicating that sampling of exposures below the final PEL and action level is feasible and already being utilized by employers (Document ID 4214, pp. 12–13; Document ID 4032, Attachment 3).

Therefore, OSHA finds that the presence of interfering substances on field samples will not, most of the time, preclude being able to detect concentrations of respirable crystalline silica in the range of the PEL and action level, and that such instances where this might occur are rare. Accordingly, even when the presence of interfering substances is taken into account, worker exposure is capable of being measured with a reasonable degree of sensitivity and precision.

d. Precision of Measurement

All analytical methods have some random measurement error. The statistics that describe analytical error refer to the amount of random variation in measurements of replicate sets of samples containing the same quantity of silica. This variation is expressed as a standard deviation about the mean of the measurements. The relative standard deviation (RSD), a key statistic used to describe analytical error, is calculated by dividing the standard deviation by the mean for a data set. The RSD is also known as the coefficient of variation (CV).

When random errors are normally distributed, a 95-percent confidence interval can be calculated as $\bar{X} \pm (1.96 \times CV)$, where $\bar{X}$ is the mean. This statistic is termed the ''precision'' of the analytical method and represents a 2-sided confidence interval in that, for a particular measurement, there is a 95-percent chance that the ''true'' value, which could be higher or lower than the measurement, lies within the confidence interval. The measure of analytical precision typically also includes a term to represent error in sampler pump flow, which is conventionally taken to be 5 percent. The better the precision of an analytical method, the lower its value (*i.e.,* a method having a precision of 17 percent has better precision than one with a precision of 20 percent).

OSHA also uses a statistic called the Sampling and Analytical Error (SAE) to assist compliance safety and health officers (CSHOs) in determining compliance with an exposure limit. The estimate of the SAE is unique for each analyte and analytical method, and must be determined by each laboratory based on its own quality control practices. At OSHA's Salt Lake Technical Center (SLTC), where analytical methods are developed and air samples taken for enforcement purposes are analyzed, the SAE is based on statistical analysis of results of internally prepared quality control samples. Sampling and analytical components are assessed separately, where CV_1 reflects analytical error that is estimated from the analysis of quality control samples, and CV_2 is the sampling error, assumed to be 5 percent due to variability in sampling pump flow rates that can affect sample air volume. Analytical error is combined with sampling pump error, and the SAE is calculated as a one-sided 95-percent confidence limit with the following formula:

$$SAE = 1.645 \times \sqrt{CV_1^2 + CV_2^2}$$

The current SLTC SAE for crystalline silica is approximately 0.17, according to testimony from a representative of SLTC (Document ID 3579, Tr. 95). OSHA uses the SAE in its enforcement of PELs, where the PEL times the SAE is added to the PEL for a substance and compared to a sample result (*see* Section II, Chapter 1 of the OSHA Technical Manual, *https://www.osha.gov/dts/osta/otm/otm_toc.html*). A sample result is considered to have definitively exceeded the PEL if the result is greater than the sum of the PEL and the PEL times the SAE. For example, with the PEL at 50 µg/m^3 and an SAE of 17 percent, an air sample result would have to be greater than 58.5 µg/m^3 (*i.e.,* $50 + (50 \times 0.17)$) to be considered to have definitively exceeded the PEL. This policy gives employers the benefit of the doubt, as it assumes that the actual exposure was below the PEL even when the result is above the PEL but below the PEL plus the SAE; the effect is that OSHA does not cite an employer for an exposure above the PEL unless the Agency has obtained a sample measurement definitively above the PEL after accounting for sampling and analytical error.

OSHA's quality control samples, which were prepared and analyzed at SLTC, demonstrate that the XRD method has acceptable precision, even at the low range of filter loads (50 µg). For the period April 2012 through April 2014, SLTC's analysis of 348 quality control samples, with a range of filter loads of about 50 to 250 µg crystalline silica, showed average recovery (*i.e.,* the measurement result as compared to the reference mean value for the sample) of 0.98 with an RSD of 0.093 and precision of 20.8 percent (Document ID 3764, Attachment 1). Among those samples, there were 114 with a target filter load of 50 µg (range of actual filter load was 50 to 51.6 µg); these samples showed an average recovery of 1.00 with an RSD of 0.093 and precision of 20.7 percent (Document ID 3764, Attachment 1). Thus, OSHA's experience with quality control standards shows that the XRD method for quartz is as precise in the low range of method validation as it is over the full range.

The ACC raised several questions regarding OSHA's Method ID–142 and

its validation. First, a paper they submitted by Sandra Wroblewski, CIH, of Computer Analytical Solutions notes that OSHA's stated Overall Analytical Error is 26 percent, higher than the 25-percent level ''OSHA states is necessary to ensure that a PEL can be feasibly measured,'' and that the method had not been validated for cristobalite (Document ID 2307, Attachment 10, pp. 13–14). In addition, the ACC stated that OSHA's method specifies a precision and accuracy validation range of 50–160 µg quartz per sample, above the quantity that would be collected at the PEL and action level (assuming use of a Dorr-Oliver sampler at 1.7 L/min) and that the method has not been tested for validation at a range corresponding to the PEL and action level (Document ID 2307, Attachment 10, p. 14). ACC also argued that OSHA's method does not comply with the Agency's Inorganic Methods Protocol, which requires the CV_1 to be 0.07 or less and the detection limit to be less than 0.1 times the PEL (Document ID 2307, Attachment A, p. 202). The Edison Electric Institute (Document ID 2357, pp. 20–21) and Ameren Corporation (Document ID 2315, p. 2) expressed similar concerns about the detection limit.

While OSHA's published Method ID–142 reports an Overall Analytical Error of 26 percent, OSHA no longer uses this statistic (it is in the process of revising Method ID–142); the Agency provides measures of precision and SAE instead. The Overall Analytical Error, which is described in Method ID–142, published in 1996, included a bias term that is now corrected for in the data used to determine method precision, so there is no longer a need to include a bias term in the estimation of analytical error. As described above, the precision of Method ID–142 is about 21 percent based on recent quality control samples.[24] OSHA's Inorganic Methods Protocol, to which the ACC referred, has been replaced by evaluation guidelines for air sampling methods using spectroscopic or chromatographic analysis, published in 2005 (*https://www.osha.gov/dts/sltc/methods/spectroguide/spectroguide.html*) and 2010 (*https://www.osha.gov/dts/sltc/methods/chromguide/chromguide.html*), respectively. These more recent publications no longer reflect the guidance contained in the Inorganic Methods Protocol, and OSHA's Method ID–142 is consistent with these more recent guidelines. Finally, although the published method did not include validation data for filter loads below 50 µg or data for cristobalite, OSHA has conducted studies to characterize the precision that is achieved at low filter loads for quartz and cristobalite; these studies are in the rulemaking record (Document ID 1670, Attachment 1; 1847, Attachment 1; 3764, pp. 15–16) and are discussed further below.

In comments submitted on behalf of the Chamber, Mr. Lieckfield cited the NIOSH Manual of Analytical Methods, Chapter R, as stating that ''current analysis methods do not have sufficient accuracy to monitor below current exposure standards'' (Document ID 2259, p. 1). However, this is contradicted by NIOSH's own post-hearing submission, which stated that, although method variability was assessed based on the exposure limits at that time (*i.e.*, 1983, *see* Document ID 0901, pp. 1, 7), ''it was known from an intra-laboratory study that an acceptable variability would likely be at least 20 µg on-filter, and so 20 µg was given as the lower range of the analytical method'' (Document ID 4233, p. 3). Furthermore, in Chapter R of NIOSH's Manual, NIOSH goes on to say that the GK2.69 high-flow sampler ''has promise for potentially lowering the levels of silica that can be measured and still meet the required accuracy'' (*http://www.cdc.gov/niosh/docs/2003-154/pdfs/chapter-r.pdf*, p. 265). This chapter was published in 2003, well before the studies by Lee *et al.* (2010, 2012) and Stacey *et al.* (2013), discussed above, which demonstrate that the GK2.69 sampler has acceptable performance. NIOSH concluded in its post-hearing comment that ''current methods of sampling and analysis for respirable crystalline silica have variability that is acceptable to demonstrate compliance with the proposed PEL and action level'' (Document ID 4233, p. 4).

At the time of the proposal, there was little data characterizing the precision of analytical methods for crystalline silica at filter loads in the range of the PEL and action level (*i.e.*, with prepared samples of 40 µg and 20 µg crystalline silica, which are the amounts of silica that would be collected from full-shift sampling at the PEL and action level, respectively, assuming samples are collected with a Dorr-Oliver cyclone at a flow rate of 1.7 L/min). To characterize the precision of OSHA's Method ID–142 at low filter loads, SLTC conducted studies in 2010 and again in 2013 (the latter of which was presented in the PEA; *see* Document ID 1720, p. IV–35). For these studies, the lab prepared 10 replicate samples each of quartz and cristobalite from NIST standard reference material and determined the precision of the analytical method; a term representing pump flow rate error was included in the precision estimate. In the 2010 test (Document ID 1670, Attachment 1), the precision for quartz loads equating to the PEL and action level was 27 and 33 percent, respectively. For cristobalite loads equating to the PEL and action level, the precision was 23 and 27 percent, respectively. The results from the 2013 test (Document ID 1847, Attachment 1; 3764, pp. 15–16; Document ID 1720, p. IV–35) showed improvement in the precision; for quartz, precision at loads equating to the PEL and action level was 17 and 19 percent, respectively, and for cristobalite, precision at loads equating to the PEL and action level was 19 and 19 percent, respectively. Both the 2010 and 2013 tests were conducted using the same NIST standards, same instrumentation, and same sample preparation method (OSHA Method ID–142) with the exception that the 2013 test used automatic pipetting rather than manual pipetting to prepare the samples (Document ID 1847). OSHA believes it likely that this change in sample preparation reduced variation in the amount of silica loaded onto the filters, which would account for at least some of the increased precision seen between 2010 and 2013 (*i.e.*, imprecision in preparing the samples would make the analytical precision for 2010 appear worse than it actually was). Based on these studies, particularly the 2013 study, OSHA preliminarily determined that the XRD method was capable of accurately measuring crystalline silica concentrations at the PEL and action level.

The ACC believed that OSHA's reliance on the 2013 study was ''misplaced'' because the results were not representative of ''real world'' samples that contain interfering minerals that could increase analytical error, and because the studies did not account for inter-laboratory variability (Document ID 4209, pp. 135–137; 2308, Attachment 6, p. 10). The ACC also believed that variability would have been depressed in this study because the samples were analyzed in close temporal proximity by the same analyst and using the same instrument calibration, and the study involved only 10 samples at each filter load (Document ID 4209, pp. 137–138; 2308,

[24] OSHA also wishes to point out that the guideline for achieving a method precision of 25 percent was never an OSHA requirement for determining method feasibility, but is drawn from the NIOSH Accuracy Criterion (*http://www.cdc.gov/niosh/docs/95-117/*), which was used for the purpose of developing and evaluating analytical methods. Nevertheless, OSHA's Method ID–142 now meets that guideline.

Attachment 6, p. 10). The ACC's witness, Mr. Scott, also commented that the study failed to take into account the effect of particle sizes on the analysis of crystalline silica and believed that SLTC's evaluation could not reflect differences in precision between the XRD and IR methods (Document ID 2308, Attachment 6, p. 10).

Despite the criticism that OSHA's investigation involved a small number of samples analyzed at the same time, the results obtained were comparable to OSHA's analysis of quality control samples at somewhat higher filter loads (between 50 and 51.6 µg) analyzed over a two-year period (Document ID 3764, Attachment 1). These results, described above, showed a precision of 20.7 percent, compared to 17 and 19 percent for quartz filter loads of 40 and 20 µg, respectively (Document ID 1847, Attachment 1; Document ID 3764). From these results, OSHA concludes that any effect on analytical error from performing a single study using the same analyst and instrument calibration is modest.

OSHA also concludes that Mr. Scott's argument that particle size effects were not taken into account is without merit. The samples prepared and analyzed in OSHA's study, like any laboratory's quality control samples, use standard materials that have a narrow range in particle size. Although large (non-respirable) size particles can result in an overestimate of crystalline silica content, in practice this is not typically a serious problem with air samples and is more of a concern with analyzing bulk samples. First, as discussed above, respirable dust samplers calibrated to conform to the ISO/CEN convention are collecting respirable particulate and excluding larger particles (Document ID 3579, Tr. 219). In analyzing field samples, OSHA uses microscopy to identify whether larger particles are present and, if they are, the results are reported as a bulk sample result so as not to be interpreted as an airborne exposure (Document ID 3579, Tr. 213). Additionally, OSHA's Method ID–142 calls for grinding and sieving bulk samples to minimize particle size effects in the analysis (Document ID 0946, p. 13). OSHA also notes that the Chamber's witness, Mr. Lieckfield, testified that his laboratory does not check for oversized particles (Document ID 3576, p. 483).

With regard to interferences, as discussed above, there are procedures that have been in place for many years to reduce the effect of interfering materials in the analysis. The presence of interferences does not typically prevent an analyst from quantifying crystalline silica in a sample with reasonable precision. As to the claim regarding XRD versus IR, a recent study of proficiency test data, in which multiple laboratories are provided comparable silica samples, both with and without interfering materials added, did not find a meaningful difference in precision between laboratories using XRD and those using IR (Harper *et al.*, 2014, Document ID 3998, Attachment 8). In addition, as discussed above, NIOSH's and OSHA's measures of precision of the XRD method at low filter loads were comparable, despite differences in equipment and sample preparation procedures. Therefore, OSHA finds that the studies it carried out to evaluate the precision of OSHA Method ID–142 at low filter loads provide a reasonable characterization of the precision of the method for analyzing air samples taken at concentrations equal to the final PEL and action level under the respirable crystalline silica rule.

With respect to the ACC's and Mr. Scott's reference to inter-laboratory variation in silica sample results, OSHA discusses data and studies that have evaluated inter-laboratory variance in analytical results in the next section.

e. Measurement Error Between Laboratories

The sources of random and systematic error described above reflect the variation in sample measurement experienced by a single laboratory; this is termed intra-laboratory variability. Another source of error that affects the reliability of results obtained from sampling and analytical methods is inter-laboratory variability, which describes the extent to which different laboratories may obtain disparate results from analyzing the same sample. Inter-laboratory variability can be characterized by using data from proficiency testing, where laboratories analyze similarly-prepared samples and their results are compared. In practice, however, it is difficult to separate intra- and inter-laboratory variability because each laboratory participating in a proficiency test provides analytical results that reflect their own degree of intra-laboratory variability. Thus, use of proficiency test data to compare performance of laboratories in implementing an analytical method is really a measure of total laboratory variability.

The best available source of data for characterizing total variability (which includes an inter-laboratory variability component) of crystalline silica analytical methods is the AIHA Industrial Hygiene Proficiency Analytical Testing (PAT) Program. The AIHA PAT Program is a comprehensive testing program that provides an opportunity for laboratories to demonstrate competence in their ability to accurately analyze air samples through comparisons with other labs. The PAT program is designed to help consumers identify laboratories that are deemed proficient in crystalline silica analysis.

Crystalline silica (using quartz only) is one of the analytes included in the proficiency testing program. The AIHA PAT program evaluates the total variability among participating laboratories based on proficiency testing of specially prepared silica samples. The AIHA contracts the preparation of its crystalline silica PAT samples to an independent laboratory that prepares four PAT samples in the range of about 50 to 225 µg (Document ID 3586, Tr. 3279–3280) and one blank sample for each participating laboratory per round. Each set of PAT samples with the same sample number is prepared with as close to the same mass of crystalline silica deposited on the filter as possible. However, some variability occurs within each numbered PAT sample set because of small amounts of random error during sample preparation. Before the contract laboratory distributes the round, it analyzes a representative lot of each numbered set of samples to ensure that prepared samples are within ±10 percent (Document ID 3586, Tr. 3276). The samples are distributed to the participating laboratories on a quarterly basis (Document ID 1720, p. IV–36). The PAT program does not specify the particular analytical method to be used. However, the laboratory is expected to analyze the PAT samples using the methods and procedures it would use for normal operations.

The results of the PAT sample analysis are reported to the AIHA by the participating laboratories. For each PAT round, AIHA compiles the results and establishes upper and lower performance limits for each of the four sample results based on the mean and RSD of the sample results. For each of the four samples, a reference value is defined as the mean value from a selected set of reference laboratories. The RSD for each of the four samples is determined from the results reported by the reference labs after correcting for outliers (generally clear mistakes in analysis or reporting, particularly those that are order-of-magnitude errors) (Document ID 4188, p. 2). A participating laboratory receives a passing score if at least three out of the four sample results reported are within 20 percent of the reference mean for the sample (Document ID 3586, Tr. 3291).

Two or more results reported by a lab in a given round that are outside the limits results in the lab receiving an unsatisfactory rating. An unsatisfactory rating in 2 of the last 3 rounds results in revocation of the lab's AIHA accreditation for the analysis of crystalline silica. Participation in the PAT program is a prerequisite for accreditation through the AIHA Industrial Hygiene Laboratory Accreditation Program (IHLAP).

In the PEA, OSHA presented PAT results from its SLTC for the period June 2005 through February 2010 (PAT Rounds 160–180) (Document ID 1720, pp. IV–40–41). The mean recovery was 99 percent, with a range of 55 to 165 percent. Eighty-one percent of the samples analyzed over this period were within ±25 percent of the reference mean and the RSD for this set of samples was 19 percent, showing reasonable agreement with the reference mean. OSHA also evaluated PAT data from all participating laboratories for the period April 2004 through June 2006 (PAT Rounds 156–165) (Document ID 1720, pp. IV–37—IV–40). Overall, the mean lab RSD was 19.5 percent for the sample range of 49 to 165 µg. Beginning with Round 161, PAT samples were prepared by liquid deposition rather than by sampling a generated silica aerosol, in order to improve consistency and reduce errors in sample preparation. The improvement was reflected in the results, with the mean lab RSD declining from 21.5 percent to 17.2 percent after the change to liquid deposition, demonstrating the improved consistency between PAT samples.

In the time since OSHA analyzed the PAT data, Harper *et al.* (2014, Document ID 3998, Attachment 8) evaluated more recent data. Specifically, Harper *et al.* (2014, Document ID 3998, Attachment 8, p. 3) evaluated PAT test results for the period 2003–2014 (Rounds 152 through 194) and found that variation in respirable crystalline silica analysis has improved substantially since the earlier data from 1990 to 1998 was studied by Eller *et al.* (1999a, Document ID 1687). A total of 9,449 sample results were analyzed after removing re-test results, results where the method of analysis was not identified, and results that were more than three standard deviations from the reference mean. There was a clear improvement in overall variation in the newer data set compared with that of Eller *et al.* (1999a, Document ID 1687), with the mean laboratory RSD declining from about 28.7 percent to 20.9 percent (Document ID 3998, Attachment 8, Figure 1). Both the older and newer data sets showed that analytical variation increased with lower filter loadings, but the more recent data set showed a much smaller increase than did the older. At a filter load of 50 µg, the mean lab RSD of the more recent data was less than 25 percent, whereas it was almost 35 percent with the older data set (Document ID 3998, Attachment 8, Figure 1). It was also clear that the change in sample preparation procedure (*i.e.*, from aerosol deposition to liquid deposition starting in Round 161) explained at least some of the improvement seen in the more recent PAT results, with the mean lab RSD declining from 23.6 percent for all rounds combined to 19.9 percent for Rounds 162–194.

Despite the improvement seen with the change in deposition method, it is important to understand that the observed variation in PAT results between labs still reflects some sample preparation error (limited to ±10 percent as explained above), a source of error not reflected in the analysis of field samples. Other factors identified by the investigators that account for the improved performance include the phasing out of the colorimetric method among participating labs, use of more appropriate calibration materials (*i.e.*, NIST standard reference material), calibration to lower mass loadings, stricter adherence to published method procedures, and possible improvements in analytical equipment. There was also only a small difference (2 percent) in mean lab RSD between labs using XRD and those using IR (Document ID 3998, Attachment 8, p. 9). The increase in variance seen with lower filter loads was not affected either by analytical method (XRD vs. IR) or by the composition of interfering minerals added to the matrix (Document ID 3998, Attachment 8, p. 4).

OSHA finds that this study provides substantial evidence that employers will obtain reliable results from analysis of respirable crystalline silica most of the time for the purpose of evaluating compliance with the PEL. From Round 162 through 194 (after the deposition method was changed), and over the full range of PAT data, only about 7 out of the 128 (5 percent) lab RSD values reported were above 25 percent (Document ID 3404, Figure 2). For filter loads of 75 µg or less, only 3 lab RSD values out of about 30 reported, were above 25 percent. As stated above, the mean RSD at a filter load of 50 µg was less than 25 percent and agreement between labs improved substantially compared to earlier PAT data.

Summary data for PAT samples having a target load of less than 62.5 µg were provided by AIHA in a post-hearing comment (Document ID 4188) and compared with the findings reported by Harper *et al.* (2014, Document ID 3998, Attachment 8). For PAT rounds 155–193 (from 1999 to 2013), there were 15 sets of samples in the range of 41.4 to 61.8 µg distributed to participating laboratories. Lab RSDs from results reported for these samples ranged from 11.2 to 26.4 percent, with an average RSD of 17.1 percent, just slightly above the average RSD of 15.9 percent for all samples across the entire range of filter loads from those rounds. Taken together, the results of the analysis performed by Harper *et al.* (2014, Document ID 3998, Attachment 8) and the summary data provided by AIHA (Document ID 4188) suggest that sample results from participating labs will be within 25 percent of the crystalline silica filter load most of the time.

In its post hearing comments, the National Stone, Sand & Gravel Association (NSSGA) contended that analytical laboratories cannot provide adequately precise and accurate results of silica samples (Document ID 4232). NSSGA provided a detailed analysis of low-load samples from the same 15 PAT rounds as examined by AIHA (Document ID 4188) and concluded that ''employers and employees cannot rely on today's silica sampling and analytical industry for consistently accurate sample results necessary to achieve or surpass compliance requirements'' (Document ID 4232, p. 26). The NSSGA compared individual labs' sample results to the reference mean for each sample and found, from the AIHA PAT data, that 76–84 percent of the results were within 25 percent of the reference mean, and the range of results reported by laboratories included clear outliers, ranging from zero to several-fold above the target filter load (Document ID 4232, p. 8, Table 1, rows 1–6). NSSGA concluded from this that ''[i]t is of little value to employers that a given lab's results meet the NIOSH Accuracy Criterion while other labs' results cannot, particularly since employers almost certainly won't know which labs fall into which category'' (Document ID 4232, p. 10). NSSGA's point appears to be that the outliers in the PAT data erode an employer's ability to determine if they are receiving accurate analytical results, without which they have little ability to determine their compliance status with respect to the PEL or action level. Further, NSSGA suggests that OSHA's analysis of the PAT data, discussed above, is not adequate to demonstrate the performance of an individual

laboratory that may be chosen by an employer.

In response to NSSGA's criticism, OSHA points out that its analysis of the PAT data was part of its analysis of technological feasibility in which the Agency's legal burden is to show that employers can achieve compliance in most operations most of the time. It may be an unavoidable fact that lab results may be inaccurate some of the time, but that does not render the standard infeasible or unenforceable. OSHA contends that its analysis has satisfied that burden and nothing in the NSSGA's comments suggests otherwise.

NSSGA further suggests that employers have no means of determining, based on a laboratory's PAT proficiency rating alone, whether that individual laboratory is likely to produce erroneously high or low results. OSHA concurs that selecting a laboratory based on accreditation, price, and turnaround time, as NSSGA suggests (Document ID 4232, p. 5), is common but may be inadequate to determine whether an individual laboratory is capable of producing results of consistently high quality. Employers and their industrial hygiene consultants can, and should, ask additional questions and request additional assurances of quality from the laboratories they consider using. For example, employers can ask to review the laboratory's individual PAT results over time, focusing on and questioning any significant outliers in the laboratory's results. While NSSGA suggests that the PAT results are treated as confidential by the AIHA–PAT program (Document ID 4232, p. 6), there is nothing stopping a laboratory from sharing its PAT data or any other information related to its accreditation with their clients or prospective clients.

Further, laboratories routinely perform statistical analyses of their performance in the context of analyzing known samples they use for equipment calibration, and often perform statistical comparisons among the various technicians they employ. Review of these statistics can shed light on the laboratory's ability to provide consistent analysis. Finally, as employers conduct exposure monitoring over time, and come to understand what results are typically seen in their workplaces, clear outliers should become more identifiable; for example, if employee exposures are usually between the action level and PEL, and a sample result shows an exposure significantly above the PEL without any clear change in workplace conditions or operations, employers should question the result and ask for a reanalysis of the sample. Employers could also request gravimetric analysis for respirable dust against which to compare the silica result to confirm that the silica content of the dust is consistent with past experience. For example, if, over time, an employer's consistent results are that the silica content of respirable dust generated in its workplace is 20 percent silica, and subsequently receives a sample result that indicates a significantly higher or lower silica content, it would be appropriate for the employer to question the result and request reanalysis. Therefore, OSHA rejects the idea that employers are at the mercy of random chance and have to simply accept a high degree of uncertainty in exposure measurements; rather, there are positive steps they can take to reduce that uncertainty.

Results from the AIHA PAT program were discussed at considerable length during the rulemaking proceeding. After considering all of the analyses of PAT data presented by Eller *et al.* (1999a, Document ID 1687), OSHA in its PEA, and Harper *et al.* (2014, Document ID 3404), the ACC concluded that ''PAT program results indicate that analytical variability as measured by precision is unacceptably high for silica loadings in the range of 50–250 µg'' and that the PAT data ''provide strong evidence that commercial laboratories will not be able to provide reliable measurements of . . . [respirable crystalline silica] exposures at the levels of the proposed PEL and action level'' (Document ID 4209, p. 144). OSHA disagrees with this assessment. First, OSHA's experience over the last 40 years in enforcing the preceding PEL that this standard supersedes is that analytical variability has not been an impediment to successful enforcement of the superseded PEL, and there have been few, if any, challenges to such enforcement actions based on variability. Nor has OSHA been made aware of concerns from employers that they have been unable to evaluate their own compliance with the former PEL or make reasonable risk management decisions to protect workers. In fact, the Chamber's expert, Mr. Lieckfield, admitted that analytical variability for asbestos, another substance that has been regulated by OSHA over the Agency's entire history, ''is worse'' than that for crystalline silica (Document ID 3576, Tr. 531).

To support its contention that reliably measuring silica at the final rule's PEL and action level is not possible, the ACC cited Harper *et al.* (2014, Document ID 3998, Attachment 8) as stating that further increases in laboratory variance below the 40–50 µg range would have ''implications for the [working] range of the analytical methods,'' and that excessive variance might ''make it difficult to address for either method'' (Document ID 4209, p. 144). However, it is clear from Harper *et al.* (2014) that this is the basis for the authors' recommendation that the PAT program consider producing samples with filter loads as low as 20 µg to ''support the analysis of lower target concentration levels'' (Document ID 3404, p. 5). They also identify use of currently available higher-flow-rate sampling devices (discussed above) to increase the collected mass of silica, which would generate field samples in the filter load range currently used in the PAT program.

Finally, the ACC sponsored a performance testing study to assess inter-laboratory variability at crystalline silica filter loads at 40 and 20 µg (*i.e.,* the amount of silica collected at final rule's PEL and action level, respectively, assuming use of a Dorr-Oliver cyclone operated at a flow rate of 1.7 L/min) as well as at 80 µg (*i.e.,* the amount collected at the preceding PEL) (Document ID 2307, Attachment 14; 3461; 3462). The study was blinded in that participating laboratories were not aware that they were receiving prepared samples, nor were they aware that they were involved in a performance study. For this study, each of five laboratories was sent three replicate rounds of samples; each round consisted of three filters prepared with respirable crystalline silica (Min-U-Sil 5) alone, three of silica mixed with kaolin, three of silica mixed with soda-feldspar, and one blank filter. The samples were prepared by RJ Lee Group and sent by a third party to the laboratories as if they were field samples. All laboratories were accredited by AIHA and analyzed the samples by XRD.

The samples were initially prepared on 5 µm PVC filters; however, due to sample loss during preparation, RJ Lee changed to 0.8 µm PVC filters. It should be noted that the 2-propanol used to suspend the Min-U Sil sample for deposition onto the 0.8 µm filter dissolved between 50 and 100 µg of filter material, such that the amount of minerals deposited on the filter could not be verified from the post-deposition filter weights. In addition, two of the labs had difficulty dissolving these filters in tetrahydrofuran, a standard method used to dissolve PVC filters in order to redeposit the sample onto silver membrane filters for XRD analysis. These labs were replaced by two laboratories that used muffle furnaces to ash the filters before redeposition, as

did the other three labs originally selected.

Results reported from the labs showed a high degree of both intra- and inter-laboratory variability as well as a systematic negative bias in measured vs. applied silica levels, with mean reported silica values more than 30 percent lower than the deposited amount. Across all laboratories, mean results reported for filter loads of 20, 40, and 80 µg were 13.36, 22.93, and 46.91 µg, respectively (Document ID 2307, Attachment 14, pp. 5–6). In addition, laboratories reported non-detectable results for about one-third of the silica samples (Document ID 2307, Attachment 14, p. 7) and two blank filters sent to the labs were reported to have silica present, in one case an amount of 52 µg (Document ID 2307, Attachment 14, pp. 9–10; 3582, Tr. 1995). Individual CVs for the labs ranged from 20 to 66 percent, up to more than 3 times higher than the CVs reported by OSHA or NIOSH for their respective methods. After examining variability in reported results, the investigators concluded that two-fold differences in filter load could not be reliably distinguished in the concentration range of 25 to 100 µg/m^3 (Document ID 2307, Attachment 14, p. 14).

OSHA identifies several deficiencies in this study; these deficiencies are sufficient to discredit the finding that high variability in silica results can be attributed to the inability of the analytical method to accurately measure crystalline silica at filter loads representative of concentrations at the action level and PEL set by this rule. Principally, the loss of filter material during deposition of the samples, combined with the lack of any verification of the actual amount of silica loaded onto the filters, makes it impossible to use the laboratory results to assess lab performance since the amount of silica on the filters analyzed by the labs cannot be known. The large negative bias in lab results compared to the target filter load implies that there was significant sample loss. In addition, the quality control employed by RJ Lee to ensure that filter loads were accurately known consisted only of an analysis of six separately prepared samples to evaluate the recovery from the 0.8 µm PVC filter and two sets of filters to evaluate recovery and test for shipping loss (Document ID 3461, Slides 8, 15, 16; 3582, Tr. 2090–2091). This is in stark contrast to the procedures used by the AIHA PAT program, which verifies its sample preparation by analyzing a statistically adequate number of samples prepared each quarter to ensure that sample variation does not exceed ±10 percent (Document ID 3586, Tr. 3276–3277). RJ Lee's use of the 0.8 µm PVC copolymer filter (Document ID 4001, Attachment 1) is also contrary to the NIOSH Method 7500 (Document ID 0901), which specifies use of the 5 µm PVC filter, and may have introduced bias. As stated at the hearing by Mary Ann Latko of the AIHA Proficiency Analytical Testing Programs, ''[a]ny variance from the NIOSH method should not be considered valid unless there's a sufficient quality control data provided to demonstrate the reliability of the modified method'' (Document ID 3586, Tr. 3278).

OSHA finds that the AIHA PAT data are a far more credible measure of inter-laboratory variation in crystalline silica measurement than the ACC-sponsored RJ Lee study. Strict procedures are used to prepare and validate sample preparation in accordance with ISO requirements for conformity assessment and competence of testing in calibration laboratories (Document ID 3586, Tr. 3275) and the database includes 200 rounds of silica testing since 2004, with 55 laboratories participating in each round (Document ID 3586, Tr. 3264–3265). By comparison, the RJ Lee study consisted of three rounds of testing among five laboratories.

One of the goals of the RJ Lee study was to conduct a double-blind test so that laboratories would not know they were analyzing prepared samples for proficiency testing; according to Mr. Bailey, a laboratory's knowledge that they are participating in a performance study, such as is the case with the AIHA PAT program, ''can introduce bias into the evaluation from the very beginning'' (Document ID 3582, Tr. 1989; Document ID 4209, p. 147). However, OSHA doubts that such knowledge has a profound effect on laboratory performance. Accredited laboratories participating in the PAT program undergo audits to ensure that analytical procedures are applied consistently whether samples are received from the field or from the PAT program. According to testimony from Mr. Walsh:

> [S]ite assessors [for the AIHA accreditation program] are very sensitive to how PAT samples are processed in the lab. It's a specific area that's examined, and if the samples are processed in any way other than a normal sample, the laboratory is cited as a deficiency (Document ID 3586, Tr. 3299–3300).

Therefore, after considering the evidence and testimony on the RJ Lee study and AIHA PAT Program data, OSHA concludes that the AIHA PAT data are the best available data on which to evaluate inter-laboratory variability in measuring respirable crystalline silica. The data evaluated by Harper *et al.* (2014) showed that laboratory performance has improved in recent years resulting in greater agreement between labs; mean RSD for the period 2003–2013 was 20.9 percent (Document ID 3998, Attachment 8, Figure 1). In addition, across the range of PAT filter loadings, only about 5 percent of the samples resulted in lab RSDs above 25 percent. At lower filter loads, 75 µg or less, about 10 percent of samples resulted in RSDs above 25 percent Document ID 3998, Attachment 8, Figure 2). OSHA concludes that these findings indicate general agreement between laboratories analyzing PAT samples.

Although laboratory performance has not been broadly evaluated at filter loads below 40 µg, particularly when interferences are present, OSHA's investigations show that the XRD method is capable of measuring crystalline silica at filter loads of 40 µg or less without appreciable loss of precision. The analysis of recent PAT data by Harper *et al.* (2014, Document ID 3998, Attachment 8) shows that the increase seen in inter-laboratory variation with lower filter loads (*e.g.,* about 50 and 70 µg) is modest compared to the increase in variation seen in the past from earlier PAT data, and the summary data provided by AIHA (Document ID 4188) show that the average lab RSD for samples with low filter loads is only a few percentage points above average lab RSD across the full range of filter loads used in the PAT program since 1999. OSHA finds that the studies of recent PAT data demonstrate that laboratories have improved their performance in recent years, most likely as a result of improving quality control procedures such as were first proposed by Eller *et al.* (1999b, Document ID 1688, pp. 23–24). Such procedures, including procedures concerning equipment calibration, use of NIST standard reference material for calibration, and strict adherence to published analytical methods, are required by Appendix A of the final standards (29 CFR 1910.1053 and 29 CFR 1926.1153). According to Dr. Rosa Key-Schwartz, NIOSH's expert in crystalline silica analysis, NIOSH worked closely with the AIHA laboratory accreditation program to implement a silica emphasis program for site visitors who audit accredited laboratories to ensure that these quality control procedures are being followed (Document ID 3579, Tr. 153). With such renewed emphasis being placed on

tighter procedures for crystalline silica analysis, OSHA finds that exposure monitoring results being received from laboratories are more reliable than was the case in years past and thus are deserving of greater confidence from employers and workers.

f. Conclusion

Based on the record evidence reviewed in this section, OSHA finds that current methods to sample respirable dust and analyze samples for respirable crystalline silica by XRD and IR methods are capable of reliably measuring silica concentrations in the range of the final rule's PEL and action level. This finding is based on the following considerations: (1) Several sampling devices are available that conform to the ISO/CEN specification for particle-size selective samplers with a level of bias and accuracy deemed acceptable by international convention, and moving to the ISO/CEN convention will maintain continuity with past practice, (2) both the XRD and IR methods can measure respirable crystalline silica with acceptable precision at amounts that would be collected by samplers when airborne concentrations are at or around the PEL and action level, and (3) laboratory proficiency data demonstrate that there is reasonable agreement between laboratories analyzing comparable samples most of the time.

There are several sampling devices that can collect respirable crystalline silica in sufficient quantity to be measured by laboratory analysis; some of these include the Dorr-Oliver nylon cyclone operated at 1.7 L/min air flow rate, the Higgins-Dewell cyclones (2.2 L/min), the SKC aluminum cyclone (2.5 L/min), and the GK2.69, which is a high-flow sampler (4.2 L/min). Each of these cyclones can collect the minimum amount of silica necessary, at the PEL and action level, for laboratories to measure when operated at their respective flow rates for at least four hours. In addition, each of these devices (as well as a number of others) has been shown to conform to the ISO/CEN convention with an acceptable bias and accuracy for a wide range of particle-size distributions encountered in the workplace. OSHA used the Dorr-Oliver at a flow rate of 1.7 L/min to enforce the previous PELs for respirable crystalline silica, so specifying the use of sampling devices conforming to the ISO/CEN convention does not reflect a change in enforcement practice. The modest error that is associated with using respirable dust samplers is independent of where the PEL is set, and these samplers have been used for decades both by OSHA, to enforce the preceding silica PEL (and other respirable dust PELs), and by employers in managing silica-related risks. Therefore, OSHA finds that these samplers are capable of and remain suitable for collecting respirable dust samples for crystalline silica analysis.

Both XRD and IR analytical methods are capable of quantifying crystalline silica with acceptable precision when air samples are taken in environments where silica concentrations are around the PEL and action level. OSHA's quality control samples analyzed by XRD over the past few years show the precision to be about 20 percent over the range of filter loads tested (about one-half to twice the former PEL). OSHA conducted studies to characterize the precision of its Method ID–142 at low filter loads representing the amounts that would be captured using the Dorr-Oliver cyclone at the action level and PEL (*i.e.,* 20 and 40 μg, respectively), and found the precision, for quartz and cristobalite, at both 20 and 40 μg to be comparable to the precision at the higher range of filter loads.

Evaluation of data from AIHA's Proficiency Analytical Testing Program shows that results from participating laboratories are in agreement (*i.e.,* within 25%) most of the time. Performance between laboratories has improved significantly in recent years, most likely due to adoption of many of the quality control practices specified by Appendix A of the final standards. Although precision declines as the amount of crystalline silica in samples declines, the rate of decline in precision with declining mass is less today than for prior years. OSHA expects that increasing emphasis on improved quality control procedures by the AIHA laboratory accreditation program (Document ID 3579, Tr. 153), the requirement in the final rule for employers to use laboratories that use XRD or IR analysis (not colorimetric) and that are accredited and conform to the quality control procedures of Appendix A of the final standards, and increased market pressure for laboratories to provide reliable results are likely to improve agreement in results obtained by laboratories in the future.

Inter-laboratory variability has not been well characterized at filter loads below 50 μg, which is slightly more than would be collected by a Dorr-Oliver cyclone sampling a silica concentration at the PEL over a full shift. However, OSHA concludes that the studies conducted by SLTC show that acceptable precision can be achieved by the XRD method for filter loads obtained by collecting samples with the Dorr-Oliver and similar devices at the action level and PEL. If employers are concerned about the accuracy that their laboratory would achieve at filter loads this low, samplers with higher flow rates could be used to collect an amount of silica that falls within the working range of the OSHA method and within the range of filter loads currently used by the PAT program (*i.e.,* 50 μg or more). For example, either the aluminum cyclone or HD will collect at least 50 μg or more of silica where concentrations are around the PEL, and the GK2.69 will collect a sufficient quantity of crystalline silica where concentrations are at least at the action level.

Based on the information and evidence presented in this section, OSHA is confident that current sampling and analytical methods for respirable crystalline silica provide reasonable estimates of measured exposures. Employers should be able to rely on sampling results from laboratories meeting the specifications in Appendix A of the final standards to analyze their compliance with the PEL and action level under the new silica rule; employers can obtain assurances from laboratories or their industrial hygiene service providers that such requirements are met. Similarly, employees should be confident that those exposure results provide them with reasonable estimates of their exposures to respirable crystalline silica. Thus, OSHA finds that the sampling and analysis requirements under the final rule are technologically feasible.

3. Feasibility Findings for the Final Permissible Exposure Limit of 50 $\mu g/m^3$

In order to demonstrate the technological feasibility of the final PEL, OSHA must show that engineering and work practices are capable of reducing exposures to the PEL or below for most operations most of the time. Substantial information was submitted to the record on control measures that can reduce employee exposures to respirable crystalline silica, including but not limited to LEV systems, which could include an upgrade of the existing LEV or installation of additional LEV; process enclosures that isolate the employee from the exposure; dust suppression such as wet methods; improved housekeeping; and improved work practices. Substantial information was also submitted to the record on the use of respiratory protection; while OSHA does not, as a rule, consider the use of respirators when deciding whether an operation is technologically

feasible, it does, when it finds a particular operation or task cannot achieve the PEL without respiratory protection, require appropriate respirator use as a supplementary control to engineering and work practice controls, when those controls are not sufficient alone to meet the PEL.

OSHA finds that many engineering control options are currently commercially available to control respirable dust (*e.g.,* Document ID 0199, pp. 9–10; 0943, p. 87; 1607, p. 10–19; 1720, p. IV–237; 3791, p. iii; 3585, p. 3073; 3585, p. 3072). These controls will reduce employees' exposures to respirable crystalline silica when the employees are performing the majority of tasks that create high exposures. OSHA's finding is based on numerous studies, conducted both in experimental settings in which the tools, materials and duration of the task are controlled by the investigator, and in observational field studies of employees performing their normal duties in the field. As detailed in Chapter IV of the FEA, more than 30 studies were submitted to the docket that report substantial reductions in exposure when using controls compared with uncontrolled situations. The specific reports that OSHA relied upon to estimate the range of reductions that can be achieved through the implementation of engineering controls are discussed in greater detail in the relevant sections of the technological feasibility analyses.

Table VII–8 lists the general industry sectors included in the technological feasibility analysis and indicates the numbers of job categories in each sector for which OSHA has concluded that the final PEL of 50 $\mu g/m^3$ is technologically feasible (*see* Chapter IV of the FEA). As this table shows, OSHA has determined that the final rule's PEL is feasible for all general industry sectors for the vast majority of operations in these affected industry sectors (87 out of 90). For only three general industry job categories, OSHA has concluded that exposures to silica will likely exceed the final rule's PEL even when all feasible controls are fully implemented; therefore, supplemental respiratory protection will be needed in addition to those controls to ensure that employees are not exposed in excess of the PEL for those three categories. Specifically, supplemental use of respiratory protection may be necessary for abrasive blasting operations in the concrete products industry sector, cleaning cement trucks in the ready mix concrete industry sector, and during abrasive blasting operations in shipyards. In addition, in foundries, while finding that compliance with the standard is overall feasible for all job categories, OSHA recognizes that supplemental use of respiratory protection may be necessary for the subset of employees who infrequently perform refractory lining repair; for the small percentage of shakeout operators, knockout operators, and abrasive blasters who work on large castings in circumstances where substitution to non-silica granular media is not feasible; and for maintenance operators performing refractory patching where reduced silica refractory patching products cannot be used.

Table VII-8. Summary of Technological Feasibility of Achieving the Final PEL by General Industry Sector

FEA Section	General Industry Sector	Total number of affected job categories	Number of job categories for which the PEL is achievable with engineering and work practice controls	Overall feasibility finding for industry sector
4.1	Asphalt Paving Products	3	3	Feasible
4.2	Asphalt Roofing Materials	2	2	Feasible
4.3	Concrete Products	6	5	Feasible
4.4	Cut Stone and Stone Products	5	5	Feasible
4.5	Dental Equipment	1	1	Feasible
4.6	Dental Laboratories and Supplies	1	1	Feasible
4.7	Engineered Stone Products	1	1	Feasible
4.8.1	Foundries – Ferrous	12	12	Feasible
4.8.2	Foundries - Nonferrous	12	12	Feasible
4.8.3	Foundries - Non-sand Casting	12	12	Feasible
4.9	Glass Products	2	2	Feasible
4.10	Jewelry	1	1	Feasible
4.11	Landscaping Services	1	1	Feasible
4.12	Mineral Processing	1	1	Feasible
4.13	Paint and Coatings	2	2	Feasible
4.14	Porcelain Enameling	2	2	Feasible
4.15	Pottery	5	5	Feasible
4.16	Railroads	2	2	Feasible
4.17	Ready Mix Concrete	5	4	Feasible
4.18	Refractories	5	5	Feasible
4.19	Refractory Repair	1	1	Feasible
4.20	Shipyards	2	1	Feasible
4.21	Structural Clay	3	3	Feasible
4.22	Hydraulic Fracturing	3	3	Feasible
	Total	**90**	**87**	

OSHA has determined that some engineering controls are already commercially available for the hydraulic fracturing industry, and other controls that have demonstrated promise are currently being developed. OSHA recognizes, however, that engineering controls have not been widely implemented at hydraulic fracturing sites, and no individual PBZ results associated with controls have been submitted to the record.

The available information indicates that controls for dust emissions occurring from the sand mover, conveyor, and blender hopper have been effective in reducing exposures. KSW Environmental reported that a commercially-available control technology reduced exposures in one test with all 12 samples below the NIOSH recommended exposure limit (REL) of 50 μg/m^3 (Document ID 4204, p. 35, Fn. 21). KSW Environmental also stated that four additional customer tests resulted in 76 PBZ samples, all below 100 μg/m^3 (Document ID 4204, p. 35, Fn. 21). Another manufacturer of a similar ventilation system (J&J Bodies) reported that there was significantly less

airborne dust during the loading of proppant onto the sand mover when its dust control system was used. This dust control system was used at 10 different hydraulic fracturing sites with reportedly good results (Document ID 1530, p. 5).

These findings indicate that, with good control of the major dust emission sources at the sand mover and along the conveyor to the blender hopper, exposures can be reduced to at least 100 μg/m^3. Use of other dust controls, including controlling road dust (reducing dust emissions by 40 to 95 percent), applying water misting systems to knock down dust released from partially-enclosed conveyors and blender hoppers (reducing dust emissions by more than half), providing filtered booths for sand operators (reducing exposure to respirable dust by about half), reducing drop height at transfer points and hoppers, and establishing regulated areas, will further reduce exposures to 50 μg/m^3 or below. Additional opportunities for exposure reduction include use of substitute proppant, where appropriate, and development and testing of dust suppression agents for proppant, such as that developed by ARG (Document ID 4072, Attachment 35, pp. 9–10). OSHA anticipates that once employers come into compliance with the preceding PEL, the additional controls to be used in conjunction with those methodologies to achieve compliance with the PEL of 50 μg/m^3 will be more conventional and readily available.

Therefore, OSHA finds that the PEL of 50 μg/m^3 can be achieved for most operations in the hydraulic fracturing industry most of the time. As shown in Table IV.4.22–B of the FEA, this level has already been achieved for almost one-third of all sampled workers (and nearly 1 in 5 sand fracturing workers, the highest exposed job category). OSHA expects that the growing availability of the controls needed to achieve the preceding PEL, along with further development of emerging technologies and better use and maintenance of existing controls, will reduce exposures to at or below the PEL for the remaining operations.

The American Petroleum Institute (API), the Marcellus Shale Coalition (MSC), and Halliburton questioned whether the analysis of engineering controls presented in the PEA was sufficient to demonstrate the technological feasibility of reducing exposures to silica at hydraulic fracturing sites to levels at or below 50 μg/m^3, in part because the analysis did not include industry-specific studies on the effectiveness of dust controls but largely relied instead on research from other industries (Document ID 2301, Attachment 1, pp. 29, 60–61; 2302, pp. 4–7; 2311, pp. 2–3). These stakeholders argued that OSHA needed to do significantly more data collection and analysis to show that the PEL of 50 μg/m^3 is feasible for hydraulic fracturing operations.

OSHA sought additional information on current exposures and dust control practices. Throughout the NPRM and hearings, OSHA, as well as other stakeholders, requested additional information on exposures and engineering controls (Document ID 3589, Tr. 4068–4070, 4074–4078, 4123–4124; 3576, Tr. 500, 534). Submissions to the record indicate that significant efforts are currently being made to develop more effective dust controls specifically designed for hydraulic fracturing (Document ID 1530; 1532; 1537; 1538; 1570; 4072, Attachments 34, 35, 36; 4204, p. 35, Fn. 21). However, industry representatives provided no additional sampling data to evaluate the effectiveness of current efforts to control exposures. Thus, NIOSH and OSHA provided the only detailed air sampling information for this industry, and summary data were provided by a few rulemaking participants (Document ID 4204, Attachment 1, p. 35, Fn. 21; 4020, Attachment 1, p. 4).

When evaluating technological feasibility, OSHA can consider engineering controls that are under development. Under section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b), OSHA is not bound to the technological status quo and can impose a standard where only the most technologically advanced companies can achieve the PEL even if it is only some of the operations some of the time. *Lead I (United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall, 647 F.2d 1189 (D.C. Cir. 1980)); Am. Iron & Steel Inst.* v. *OSHA, 577 F.2d 825 (3d Cir. 1978).* Relying on these precedents, the D.C. Circuit reaffirmed that MSHA and OSHA standards may be ''technology-forcing'' in *Kennecott Greens Creek Min. Co.* v. *MSHA,* 476 F.3d 946, 957, 960 (D.C. Cir. 2007), and that ''the agency is 'not obliged to provide detailed solutions to every engineering problem,' but only to 'identify the major steps for improvement and give plausible reasons for its belief that the industry will be able to solve those problems in the time remaining.' '' *Id.* (finding that MSHA provided ''more than enough evidence,'' including ''identif[ying] several types of control technologies that are effective at reducing . . . exposure,'' to conclude that the industry could comply with the two-year implementation date of a technology-forcing standard) (citing *Nat'l Petrochemical & Refiners Ass'n* v. *EPA,* 287 F.3d 1130, 1136 (D.C. Cir. 2002)).

OSHA concluded that these technologies will enable the industry to comply within five years. OSHA has described technologies that have been developed and tested, and that have demonstrated that the PEL is obtainable. These technologies have been developed to reduce exposures to the preceding PEL, but some of them appear also to have the capability to reduce some exposures to the PEL of 50 μg/m^3. KSW Environmental has provided data that indicate exposures can be achieved at or below the PEL (Document ID 1570, p. 22; 4204, Attachment 1, p. 35, Fn. 21; 4222, Attachment 2, p. 6), and NIOSH has presented concepts of ''mini-bag houses'' that can be retrofitted on existing equipment (Document ID 1537, p. 5; 1546, p. 10). SandBox Logistics, LLC, has developed a shipping container for bulk transport of sand specifically designed for hydraulic fracturing operations that eliminates the need for sand movers, a major source of exposure to silica at fracturing sites (Document ID 3589, Tr. 4148). OSHA views these and other advanced controls discussed above as on the ''horizon,'' but not currently widely available for operational use (*Am. Fed'n of Labor & Cong. of Indus. Organizations* v. *Brennan*, 530 F.2d 109, 121 (3d Cir. 1975)). Once they are deployed, as explained fully in Chapter IV of the FEA, more conventional adjustments and additional controls can be used with them to lower exposures to the new PEL or below.

Evidence in the record shows widespread recognition of silica exposure hazards on hydraulic fracturing sites and industry's efforts to address them primarily through the efforts of the National Service, Transmission, Exploration & Production Safety (STEPS) network's Respirable Silica Focus Group. The STEPS network initiated action to address exposure to silica at hydraulic fracturing sites in 2010, when NIOSH first conducted air sampling and then publicized the severity of hazardous silica exposures as part of its Field Effort to Assess Chemical Exposures in Gas and Oil Workers (Document ID 1541). Recognition of silica exposures in the industry well above the preceding PEL of 100 μg/m^3 prompted the development of engineering controls to reduce exposures to silica. While some companies in the hydraulic fracturing industry are able to obtain and implement controls to comply with the preceding PEL (*e.g.,* Document ID 4204,

Attachment 1, p. 35, Fn. 21), the technology is not currently widely available. Given the progress that has been made since 2010, OSHA concluded that these technologies will become more widely available and enable the industry to comply with the final PEL within five years. As noted by Kenny Jordan, the Executive Director of the Association of Energy Service Companies (AESC), his organization's participation on the National Occupational Research Agenda (NORA) NIOSH Oil and Gas Extraction Council enabled members to be ''at the forefront of building awareness of the silica at the well site issue, particularly among those working in fracking operations'' (Document ID 3589, Tr. 4059). In the five years since that time, the substantial progress in controlling silica exposures at fracking sites described above has occurred.

In June 2012, the STEPS network, in which AESC and many other industry, educational and regulatory entities participate, launched a respirable silica focus group to spread awareness, better characterize on-site silica exposures, and facilitate and evaluate the development of engineering controls (Document ID 3589, Tr. 4059; 1537). This enabled several manufacturers of engineering controls, such as KSW Environmental (formerly Frac Sand Dust Control and Dupre) who had developed a working model in 2009 (Document ID 1520), to collaborate and share information on various engineering controls. As a consequence, the silica control field has grown significantly during this period, including the development, testing and, in some cases, deployment of new technologies, including those from KSW Environmental, J&J Truck Bodies, SandBox Logistics, and NIOSH's baghouse. For example, John Oren, the co-inventor of the SandBox Logistics technology, said it had taken his company only three years to develop the product and make it commercially available (Document ID 3589, Tr. 4148). OSHA concludes that an additional five years will be more than enough time for these and other firms to complete development and increase manufacturing and sales capacity, and, simultaneously, for hydraulic fracturing employers to test, adopt and adapt these emerging technologies to their workplaces. Indeed, in light of the progress that has already been made, it may be more accurate to call the standard ''market-accelerating'' than ''technology-forcing.''

During the rulemaking, API touted the efforts of this industry to develop technology to protect workers against the hazards of silica (Document ID 4222, Attachment 2, p. 9). OSHA agrees with API that these efforts have been noteworthy and that more time is warranted to allow for continued development, commercialization, and implementation of these innovative technologies. OSHA is confident that with the innovation displayed by this industry to date, the hydraulic fracturing industry can further reduce worker exposures to the PEL if sufficient time is provided. Therefore, OSHA is providing an extra three years from the effective date of the standard—for a total of five years—to implement engineering controls for the hydraulic fracturing industry. OSHA concludes that this is ample time for this highly technical and innovative industry to come into compliance with the final PEL. This is consistent with, but longer than, the time frame OSHA granted for implementation of engineering controls for hexavalent chromium, where OSHA provided four years to allow sufficient time for some industries to coordinate efforts with other regulatory compliance obligations as well as gain experience with new technology and learn more effective ways to control exposures (71 FR 10100, 10372, Feb. 28, 2006). Thus, with the extra time provided for this industry to come into compliance, OSHA finds that the final PEL of 50 μg/m^3 is feasible for the hydraulic fracturing industry.

In the two years leading up to the effective date, the hydraulic fracturing industry will continue to be subject to the preceding PEL in 29 CFR 1910.1000 (Table Z). In order to meet the preceding PEL of 100 μg/m^3 during this interim period, such compliance will include adoption of the new engineering controls discussed above as they become widely available for field use.[25] As a result, OSHA expects many exposures in hydraulic fracturing to be at or near the 50 μg/m^3 level ahead of the five-year compliance date due to the expected efficacy of this new technology. Thus, with the extra time provided for this industry to come into compliance, OSHA finds that the standard is feasible for most workers in the Hydraulic Fracturing industry most of the time.

OSHA has determined that a PEL of 50 μg/m^3 is technologically feasible for the maritime industry. Although it is not feasible to reduce painters' exposures to 50 μg/m^3 when conducting abrasive blasting operations most of the time without the use of respirators, evidence in the record demonstrates that it is feasible to reduce painters' helpers' exposure to 50 μg/m^3 most of the time with HEPA-filtered vacuums. As noted in Chapter IV of the FEA, workers in the maritime industry may also be exposed during foundry activities; as explained in FEA Chapter IV. Section 4.8.4—Captive Foundries, OSHA has determined that it is feasible to reduce exposures during most operations in captive foundries to 50 μg/m^3, most of the time. The record evidence indicates that shipyard foundries face similar issues controlling silica as other typical small foundries (*e.g.,* cleaning the cast metal) and that shipyard foundries cast items in a range of sizes, from small items like a ship's plaque to large items like the bow structure for an aircraft carrier (Document ID 1145; 3584, Tr. 2607). OSHA did not receive comments indicating that foundries in shipyards would require any unique controls to reduce exposures, and therefore believes that exposures in shipyard foundries can also be reduced to 50 μg/m^3 in most operations, most of the time. Accordingly, OSHA has determined that 50 μg/m^3 is feasible for most silica-related activities performed in the maritime industry.

Even if captive foundries are excluded from consideration, OSHA considers the standard to be feasible for shipyards with the use of respirators by painters doing abrasive blasting. OSHA recognizes that, consistent with its hierarchy of controls policy for setting methods of compliance, respirator use is not ordinarily taken into account when determining industry-wide feasibility. Neither this policy nor the ''most operations most of the time'' formulation for technological feasibility is meant to place OSHA in a ''mathematical straitjacket'' (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.*, 448 U.S. 607, 655 (1980) (''*Benzene*'') (stated with respect to the ''significant risk'' finding, which the Supreme Court recognized is ''based largely on policy considerations'' (*Benzene*, 448 U.S. at 655 n.62)). No court has been confronted with a situation where an industry has two operations (or any even number), of which one can achieve the PEL through

[25] Compliance with Table Z requires implementing all feasible engineering and administrative controls to achieve the PEL before using protective equipment such as respirators. 29 CFR 1910.1000(e). OSHA acknowledges that the technologies to meet the PEL in Table Z are not currently widely available in the quantities needed for the entire industry to achieve compliance. Accordingly, as employers work toward implementing controls during the interim period, supplemental respiratory protection may be necessary to comply with the PEL of 100 μg/m^3. Likewise, during the additional three-year phase-in period, OSHA anticipates that many employers may need to use supplemental respiratory protection to comply with the PEL of 50 μg/m^3.

engineering controls and the other (or exactly half) can achieve it most of the time only with the use of respirators. However, the same court that formulated the ''most operations most of the time'' standard ''also noted that '[i]nsufficient proof of technological feasibility for a few isolated operations within an industry, or even OSHA's concession that respirators will be necessary in a few such operations, will not undermine' a showing that the standard is generally feasible'' (*Amer. Iron & Steel Inst.* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991) (*Lead II*), (quoting *United Steelworkers of Am. AFL–CIO–CLC* v. *Marshall*, 647 F.2d 1189, 1272 (D.C. Cir. 1980) (''*Lead I*'')). It further recognized the intended pragmatic flexibility of this standard by stating that ''[f]or example, if 'only the most technologically advanced plants in an industry have been able to achieve [the standard]—even if only in some of their operations some of the time,' then the standard is considered feasible for the entire industry'' (*Lead II*, 939 F. 2d at 980 (quoting *Lead I*, 647 F.2d at 1264)). In this instance, OSHA has determined that it makes sense to treat painters performing abrasive blasting in shipyards as an outlier for which the PEL established for all other covered industries is feasible, even conceding that respirators will be necessary. If abrasive blasting were the predominant activity that occurs in shipyards, there might be justification to set a separate, higher PEL for shipyards. But as in construction (for which supplemental respirator use is also contemplated for abrasive blasting operations), abrasive blasting is one of many activities that occurs; substitution of non-silica blasting materials is an option in many cases; few, if any, painters spend entire days or weeks doing blasting operations and thus needing respirators for the duration; and lowering the standard from 250 μg/m³ to 50 μg/m³ does not threaten the economic viability of the industry. Under these circumstances, OSHA concludes that it may find the standard feasible for shipyards rather than raise the PEL for this single industry because it can only achieve the uniform PEL with respirators or, alternatively, not be able to revise the previous PEL of 250 μg/m³ at all.

Table VII–9 lists the construction application groups included in the technological feasibility analysis and indicates the numbers of tasks in each application group. As this table shows, OSHA has determined that the rule's PEL is feasible for the vast majority of tasks (19 out of 23) in the construction industry. For those construction tasks listed in Table 1 of paragraph (c) of the construction standard, OSHA has determined that the controls listed on Table 1 are either commercially available from tool and equipment manufacturers or, in the case of jackhammers, can be fabricated from readily available parts. Therefore, OSHA has determined that these control requirements are technologically feasible and will, with few exceptions, achieve exposures of 50 μg/m³ or less most of the time. Furthermore, Table 1 in paragraph (c) of the standard for construction acts as a ''safe harbor'' in the sense that full and proper implementation of the specified controls satisfies the employer's duty to achieve the PEL, and the employer is under no further obligation to do an exposure assessment or install additional, non-specified controls. Thus, OSHA finds the operations listed in Table 1 to be technologically feasible for the vast majority of employers who will be following the table.

Where available evidence indicates that exposures will remain above this level after implementation of dust controls (*see* Chapter IV of the FEA), Table 1 requires that respiratory protection be used. OSHA has determined that available engineering and work practice controls cannot achieve exposure levels of 50 μg/m³ or less for only two activities: Handheld grinders used to remove mortar (*i.e.,* tuckpointing) and dowel drilling in concrete. For a few other activities, OSHA concludes that respiratory protection will not generally be needed unless the task is performed indoors or in enclosed areas, or the task is performed for more than four hours in a shift. Table 1 requires use of respiratory protection when using handheld power saws indoors or outdoors more than four hours per shift; walk-behind saws indoors; dowel drills in concrete; jackhammers or handheld powered chipping tools indoors or outdoors more than four hours per shift; handheld grinders for mortar removal; and handheld grinders for uses other than mortar removal when used indoors for more than four hours per shift.

OSHA has also evaluated the feasibility of three application groups that do not appear on Table 1: Underground construction, drywall finishing work, and abrasive blasting. For these operations, employers will be subject to the paragraph (d) requirements for alternative exposure control methods. Due in part to the complexity of excavating machines, dust controls, and the ventilation systems required to control dust for underground operations, OSHA decided not to include underground construction and tunneling operations in Table 1 of paragraph (c) of the construction standard. Nonetheless, OSHA has determined that the PEL is technologically feasible in underground construction because exposures can be reduced to 50 μg/m³ or less most of the time. Drywall finishing work was not included on Table 1 because silica-free drywall compounds are commercially available and can be used to eliminate exposure to silica when finishing drywall. In contrast to underground construction and drywall finishing, OSHA decided that abrasive blasting was not suited to the Table 1 approach because employers have several options in the control measures they can implement when abrasive blasting based on their particular application. For example, substitution to low-silica agent, use of wet blasting and process enclosures are all possible control options for abrasive blasting operations. Therefore, OSHA does not specify a specific control for abrasive blasting suitable for all applications, unlike the entries on Table 1 for tuckpointing and dowel drilling, where LEV is the only option accompanied by required supplemental respirator use. Furthermore, OSHA has existing requirements for abrasive blasting under the ventilation standard for construction (29 CFR 1926.57). In certain situations, that standard requires abrasive blasting operators to use abrasive blasting respirators approved by NIOSH for protection from dusts produced during abrasive blasting operations (29 CFR 1926.57(f)(5)(i) through (iii)). That standard also includes specifications for blast-cleaning enclosures (29 CFR 1926.57(f)(3)), exhaust ventilation systems (29 CFR 1926.57(f)(4)), air supply and air compressors (29 CFR 1926.57(f)(6)), and operational procedures (29 CFR 1926.57(f)(7)). OSHA also has similar requirements for abrasive blasting under the general industry standard (29 CFR 1910.94). Therefore, OSHA expects that respiratory protection will be required to be used during blasting operations under the paragraph (d) approach that employers must follow when employees are doing this task.

Table VII-9: Summary of Technological Feasibility by Application Group

FEA Section	Construction Application Group	Total number of tasks included in analysis	Number of tasks where 8-hour TWA of 50 µg/m^3 is achievable with engineering and work practice controls	Overall feasibility finding for application group
5.1	Abrasive Blasters	2	0	Infeasible
5.2	Drywall Finishers	1	1	Feasible
5.3	Heavy Equipment Operators and Ground Crew Laborers	3	3	Feasible
5.4	Hole Drillers Using Handheld or Stand-Mounted Drills	1	1	Feasible
5.5	Jackhammers and Other Powered Handheld Impact Tools	1	1	Feasible
5.6	Masonry and Concrete Cutters Using Portable Saws	5	5	Feasible
5.7	Masonry Cutters Using Stationary Saws	1	1	Feasible
5.8	Millers Using Portable or Mobile Machines	3	3	Feasible
5.9	Rock and Concrete Drillers	1	1	Feasible
5.9	Rock and Concrete Drillers – concrete dowel drilling	1	0	Infeasible
5.10	Mobile Crushing Machine Operators and Tenders	1	1	Feasible
5.11	Tuckpointers and Grinders – Grinders	1	1	Feasible
5.11	Tuckpointers and Grinders – Tuckpointers	1	0	Infeasible
5.12	Underground Construction Workers	1	1	Feasible
Total		23	19	

Note: Three of the application groups discussed in this table (abrasive blasting, drywall finishing, and underground construction) do not appear on Table 1 of paragraph (c) of the construction standard.

The American Chemistry Council's (ACC's) Crystalline Silica Panel contended that OSHA did not demonstrate that the proposed standard would be technologically feasible in all affected industry sectors because OSHA had failed to account for day-to-day environmental variability in exposures (Document ID 4209, Attachment 1, p. 97). ACC noted that OSHA enforces PELs as never-to-be-exceeded values and that an employer can be cited based

on a single measurement even if most exposures on most days are below the PEL. Therefore, they stated that to be ''reasonably confident of complying with OSHA's proposed PEL of 50 μg/m^3, the long-term average exposure in most workplaces likely would have to be maintained at a level below 25 μg/m^3 (or even below 20 μg/m^3)'' (Document ID 4209, p. 97; 2307, Attachment A, pp. 23–24, 160). Representatives from the American Foundry Society (AFS) and the Asphalt Roofing Materials Association (ARMA) made similar arguments (Document ID 2291, p. 5; 3584, Tr. 2654–2655; 3580, Tr. 1282–1284, 1289).

OSHA recognizes the existence of exposure variability due to environmental factors that can affect employee exposures, especially in the construction industry where work sites and weather conditions can change on a daily basis. OSHA has acknowledged this in past rulemakings where the same issue was raised (*e.g.,* benzene, 52 FR 34534; asbestos, 53 FR 35609; lead in construction, 58 FR 26590; formaldehyde, 57 FR 22290; cadmium, 57 FR 42102; and chromium (VI), 71 FR 10099). However, not all exposure variation is due to random environmental factors; rather, many high exposures are the result of predictable causes that the employer can readily identify and address in efforts to improve exposure control. Several studies were submitted to the docket that used multivariate statistical models to identify factors associated with increased exposure to silica during various construction activities (Document ID 3608, 3803, 3956, 3998 Attachment 5h). These studies reported that as much as 80 percent of the variability in respirable quartz exposures could be attributed to various exposure determinants included in the models, clearly indicating that not all variability in exposure is uncontrollable. This was also attested to at the hearing by Dr. Frank Mirer:

> Exposures go up and down not by magic but by particular conditions, differences in work methods, differences in control efficiency, differences in adjacent operations (Document ID 3578, Tr. 971).

OSHA concludes from the evidence in the record that the consistent use of engineering controls will reduce exposure variability. By improving or adding effective controls and work practices to reduce employee exposures to the PEL or below, employers will reduce exposure variability, and this reduction will provide employers with greater confidence that they are in compliance with the revised PEL. OSHA does, however, acknowledge that exposure controls cannot entirely eliminate variability. Some day-to-day variability in silica exposure measurements may remain, despite an employer's conscientious application and maintenance of all feasible engineering and work practice controls. Nonetheless, the legal standard for finding that a PEL is technologically feasible for an industry sector is whether most employers can implement engineering and work practice controls that reduce exposures to the PEL or below most of the time. As explained in Section XV, Summary and Explanation, in situations where exposure measurements made by OSHA indicate that exposures are above the PEL, and that result is clearly inconsistent with an employer's own exposure assessment, OSHA will use its enforcement discretion to determine an appropriate response. Moreover, for the vast majority of construction employers (and some general industry or maritime employers doing tasks that are ''indistinguishable'' from Table 1 tasks and choose to comply with the construction standard), full compliance with Table 1 will eliminate the risk that an employer will be subject to citation for exposures above the PEL, even when the employer has instituted all feasible controls that normally or typically maintain exposures below the PEL.

OSHA also received a number of general comments on the feasibility of wet methods and LEV, as well as comments on challenges faced when employing these dust control strategies in specific work settings. In general industry, several commenters indicated for specific industries that there was no one control that could obtain the PEL of 50 μg/m^3 (Document ID 2264, p. 36). CISC was also critical of several aspects of OSHA's feasibility analysis. CISC commented that OSHA failed to consider exposures from secondary or adjacent sources and that OSHA should factor this into its analysis (Document ID 2319, p. 30; 4217, p. 13). Dr. Mirer also stated that many employees' silica exposures are due to dust released from adjacent operations, but indicated that if these dust releases are controlled, the exposures of workers in adjacent areas will be substantially reduced (Document ID 4204, p. 104). In many industries, OSHA has shown that all sources of respirable crystalline silica should be controlled and that often a combination of controls may be needed to address potential sources of silica. Additionally, addressing each source of exposure also reduces exposures in adjacent areas, thus mitigating the concern about secondary exposures expressed by both industry and union stakeholders.

Other commenters addressed the use of water on construction sites; several commenters asserted that it is not always possible for employers to use water for dust suppression. For example, in its post-hearing submission, CISC discussed what it believed to be ''significant obstacles'' to using wet dust suppression technologies on construction sites. Such obstacles include freezing weather, which contraindicates water use, and a lack of running water onsite, which requires employers to deliver water, a practice which, according to CISC, is both ''costly and time consuming'' (Document ID 4217, pp. 18–19). However, many other participants commented that these barriers can be overcome. For example, Phillip Rice, of Fann Contracting, Inc., uses water trucks to haul water to sites and includes the cost of doing so in his bids. He added that ''when someone says they can't get water on their project there is something wrong'' (Document ID 2116, Attachment 1, p. 33). Representatives of the International Union of Bricklayers and Allied Craftworkers pointed out that water is essential for work in the masonry trades and without it, no mortar can be mixed to set materials (Document ID 3585, Tr. 3059–3060). They testified that, in their experience, it was rare to work on sites that did not have water or electricity available, but when they do, they bring in water trucks and gas-powered generators to run saws (Document ID 3585, Tr. 3061–3063). With respect to weather conditions, heated water or heated shelters can be used if construction work is being performed in sub-freezing temperatures (Document ID 3585, Tr. 3095–3096).

These comments and testimony indicate that the vast majority of the barriers to wet dust suppression raised by CISC have already been overcome in various construction settings. However, OSHA recognizes that there will be limited instances where the use of wet dust suppression is not feasible, particularly where its use can create a greater hazard. For example, water cannot be used for dust control in work settings where hot processes are present due to the potential for steam explosions (Document ID 2291, p. 13; 2298, p. 3), nor can it be used safely where it can increase fall hazards, such as on a roof (Document ID 2214, p. 2). Nevertheless, OSHA finds that many employers currently use wet dust suppression, that there are many commercially available products with integrated water systems for dust suppression, and that these products

can be used in most work settings to control exposures to respirable crystalline silica. In the limited cases where dust suppression is not feasible, OSHA discusses the use of alternative controls such as local exhaust ventilation and the supplemental use of respiratory protection, as needed.

Some commenters questioned whether OSHA had adequately considered the difficulties in complying with the PEL for maintenance activities. The National Association of Manufacturers, for example, quoted one of its members, who stated:

[t]here are occasional conditions where maintenance cleaning is performed inside conveyor enclosures where the enclosure is ordinarily a part of the dust control systems. This is just one example of where a control would have to be breached in order to properly maintain it as well as the operating equipment. It is simply not technically feasible to establish engineering controls for all possible maintenance activities (Document ID 2380, Attachment 2, p. 1).

OSHA has addressed maintenance activities in each sector's technological feasibility analysis, but the standard itself acknowledges the difficulties of some maintenance activities. Paragraph (g)(1)(ii) of the standard for general industry and maritime (paragraph (e)(1)(ii)(B) in construction) requires respiratory protection ''where exposures exceed the PEL during tasks, such as certain maintenance and repair tasks, for which engineering and work practice controls are not feasible'' (*see* the Summary and Explanation section on Respiratory Protection for more information).

CISC submitted comments suggesting that the technological feasibility analysis was incomplete because it did not cover every construction-related task for which there is the potential for exposure to silica dust. It listed more than 20 operations, including cement mixing, cutting concrete pavers, demolishing drywall or plaster walls/ceilings, overhead drilling, demolition of concrete and masonry structures, and grouting floor and wall tiles, that it stated OSHA must examine in order to establish feasibility, in addition to the application groups already covered by OSHA's analysis (Document ID 2319, pp. 19–21). CISC asserted that, because of the many types of silica-containing materials used in the construction industry, as well as the presence of naturally occurring silica in soil, additional data collection and analysis by OSHA should be conducted before promulgating a final rule (Document ID 2319, pp. 25–26; 4217, p. 3).

As explained in the NPRM, OSHA's analysis for construction focuses on tasks for which the available evidence indicates that significant levels of respirable crystalline silica may be created, due primarily to the use of powered tools or large equipment that generates visible dust. OSHA notes that many of the examples of tasks for which CISC requested additional analysis are tasks involving the tools and equipment already covered in this feasibility analysis. For example, overhead drilling is addressed in section IV–5.4 Hole Drillers Using Handheld or Stand-Mounted Drills, and the demolition of concrete and masonry structures is addressed in section IV–5.3 Heavy Equipment Operators. In other cases, such as for concrete mixing, there are no sampling data in the record to indicate that the task is likely to result in 8-hour TWA exposures above the action level. Exposure can occur when cleaning dried cement, and the feasibility of control measures to reduce exposures when cleaning out the inside of cement mixers is discussed in section IV–4.17 Ready Mix Concrete. Other tasks listed by CISC involve working with wet or intact concrete, which is unlikely to result in 8-hour TWA exposures above the action level. Further, CISC did not submit to the record any air monitoring data to support its assertion that these activities result in significant exposures. Therefore, OSHA has not added these additional activities to the feasibility analysis.

4. Feasibility Findings for an Alternative Permissible Exposure Limit of 25 μg/m³

In the NPRM, OSHA invited comment on whether it should consider a lower PEL because it determined there was still significant risk at the proposed PEL of 50 μg/m³ (78 FR 56288, September 12, 2013). OSHA has determined that the rule's PEL of 50 μg/m³ is the lowest exposure limit that can be found to be technologically feasible based on the rulemaking record. Specifically, OSHA has determined that the information in the rulemaking record either demonstrates that the proposed alternative PEL of 25 μg/m³ would not be achievable for most of the affected industry sectors and application groups or the information is insufficient to conclude that engineering and work practice controls can consistently reduce exposures to or below 25 μg/m³. Therefore, OSHA cannot find that the proposed alternative PEL of 25 μg/m³ is achievable for most operations in the affected industries, most of the time.

The UAW submitted comments and data to the record, maintaining that a PEL of 25 μg/m³ is technologically feasible. As evidence, it submitted exposure data from a dental equipment manufacturing plant and two foundries (Document ID 2282, Attachment 3, pp. 7–8; 4031, pp. 3–8) showing that exposures to silica in these establishments were consistently below 25 μg/m³ TWA. However, OSHA cannot conclude that exposure data from three facilities is representative of the wide array of facilities affected by the rule or sufficient to constitute substantial record evidence that a PEL of 25 μg/m³ is technologically feasible in most operations most of the time.

Although available exposure data indicate that exposures below 25 μg/m³ have already been achieved for most employees in some general industry sectors and construction application groups (*e.g.,* dental laboratories, jewelry, and paint and coatings in general industry, and drywall finishers and heavy equipment operators performing excavation in construction), the relatively low exposures can be attributed to the effective control of the relatively small amounts of dust containing silica generated by employees in these industries and application groups. Further extrapolation to other sectors or groups with higher baseline exposures or more challenging control situations is not warranted, however.

For most of the industries and application groups included in this analysis, a review of the sampling data indicates that an alternative PEL of 25 μg/m³ cannot be achieved with engineering and work practice controls. OSHA finds that engineering and work practice controls will not be able to consistently reduce and maintain exposures to an alternative PEL of 25 μg/m³ in the sectors that use large quantities of silica containing material, including foundries (ferrous, nonferrous, and non-sandcasting), concrete products, and hydraulic fracturing, or have high energy operations, such as jackhammering and crushing machines.

For instance, in the ferrous foundry industry, the baseline median exposure in the profiles exceeds 50 μg/m³ for 6 of the 12 job categories analyzed: Sand system operators, shakeout operators, abrasive blasting operator, cleaning/finishing operators, maintenance operators, and housekeeping employees. OSHA concluded that engineering and work practice controls can reduce TWA exposures to 50 μg/m³ or less for most of these operations most of the time. However, because large amounts of silica-containing sand is transported, used, and recycled to create castings, OSHA cannot conclude that available controls can reduce exposures to or below 25 μg/m³ in any step of the

production process. Additionally, high energy operations in foundries can create concentrations of respirable silica above 25 μg/m³. For example, the shakeout process is a high energy operation using equipment that separates castings from mold materials by mechanically vibrating or tumbling the casting. The dust generated from this process causes elevated silica exposures for shakeout operators and often contributes to exposures for other employees in a foundry. The effectiveness of dust controls on shakeout operations was demonstrated at three foundries that implemented various dust controls in the shakeout area (*e.g.,* shakeout enclosure added, ventilation system improved, conveyors enclosed and ventilated); full-shift samples taken by or for OSHA measured exposures for shakeout operators ranging from less than or equal to 13 μg/m³ to 41 μg/m³ (Document ID 1365, pp. 2–51; 1407, p. 20; 0511, p. 2). These readings were obtained in foundries that had made a systematic effort to identify and abate all sources of dust emission with the establishment of an abatement team consisting of an engineer, maintenance and production supervisors, and employees. TWA exposures for the shakeout operators were reduced to less than 50 μg/m³, but two of the four measurements in this well-controlled facility exceeded 25 μg/m³ (*see* Chapter IV 4.8.1 of the FEA). Other industry sectors that use substantial quantities of crystalline silica as a raw material include refractories, glass products, mineral processing, structural clay and cement products. OSHA finds that the available evidence on exposures at facilities in these industries in which controls have been implemented indicates most exposures are typically between 25 μg/m³ and 50 μg/m³.

For other general industry sectors, OSHA has insufficient data to demonstrate that engineering and work practice controls will reduce exposures to or below 25 μg/m³ most of the time (*see* Chapter IV of the FEA). For example, it is not evident that exposures can be reduced to 25 μg/m³ for four out of five jobs analyzed in the pottery sector, for two out of three job categories in the structural clay sector, and for two jobs in the porcelain enameling sector.

OSHA has also determined that application groups in construction that use large quantities of silica containing material or involve high energy operations will not be able to consistently achieve 25 μg/m³ (*e.g.* tuck pointing/grinding and rock and concrete drilling). These operations cause employees to have elevated exposures even when available engineering and work practice controls are used. Examples include using jackhammers during demolition of concrete and masonry structures, grinding concrete surfaces, using walk-behind milling machines, operating rock and concrete crushers, and using portable saws to cut concrete block. For instance, jackhammering is a high energy operation and OSHA finds that when employees perform this operation for four hours or less in a shift, most employees using jackhammers outdoors experience levels at or below 50 μg/m³ TWA but not reliably at or below 25 μg/m³. The use of portable cut-off saws (a type of handheld power saw) is also a high energy operation that can lead to exposures over 25 μg/m³. Due to energy applied to the material being cut from the rapid rotation of the circular blade, the dust generated can be difficult to control; available data indicate that exposures will often exceed 25 μg/m³ TWA, even when the portable cut-off saw is used with water for dust suppression. Evidence in the record indicates that, for most of the other construction operations examined, use of feasible engineering and work practice controls will still result in frequent exposures above 25 μg/m³. For other tasks in construction application groups, OSHA has insufficient data to demonstrate that engineering and work practice controls will reduce exposures to or below 25 μg/m³ most of the time (*see* Chapter IV of the FEA).

Therefore, OSHA concludes that 50 μg/m³ as an 8-hour TWA is the lowest feasible exposure limit that the record demonstrates can be applied to most general industry, maritime, and construction operations without the excessive use of respirators. OSHA also concludes that it would hugely complicate both compliance and enforcement of the rule if it were to set a PEL of 25 μg/m³ for a minority of industries or operations where it would be technologically feasible and a PEL of 50 μg/m³ for the remaining industries and operations where technological feasibility at the lower PEL is either demonstrably unattainable, doubtful or unknown. OSHA is not under a legal obligation to issue different PELs for different industries or application groups, but may exercise discretion to issue a uniform PEL if it determines that the PEL is technologically feasible for all affected industries (if not for all affected operations) and that a uniform PEL would constitute better public policy (*see* Section II, Pertinent Legal Authority (discussing the chromium (VI) decision)). In declining to lower the PEL to 25 μg/m³ for any segment of the affected industries, OSHA has made that determination here.

E. Costs of Compliance

Overview

This section assesses the costs to establishments in all affected industry sectors of reducing worker exposures to silica to an 8-hour time-weighted average (TWA) permissible exposure limit (PEL) of 50 μg/m³—or, alternatively, for employers in construction to meet the Table 1 requirements—and of complying with the standard's ancillary requirements. This cost assessment is based on OSHA's technological feasibility analysis presented in Chapter IV of the FEA; analyses of the costs of the standard conducted by OSHA's contractor, Eastern Research Group; testimony during the hearings; and the comments submitted to the docket as part of the rulemaking process.

OSHA estimates that the standard will have a total cost of $1,029.8 million per year in 2012 dollars. Of that total, $370.8 million will be borne by the general industry and maritime sectors, and $659.0 million will be borne by the construction sector. Costs originally estimated for earlier years in the PEA were adjusted to 2012 dollars using the appropriate price indices. In general, all employee and supervisor wages (loaded) were from the 2012 BLS OES (Document ID 1560); medical costs were inflated to 2012 dollars using the medical services component of the Consumer Price Index; and, unless otherwise specified, all other costs were inflated using the GDP Implicit Price Deflator (Document ID 1666).

All costs were annualized using a discount rate of 3 percent, which—along with 7 percent [26]—is one of the discount rates recommended by OMB. Annualization periods for expenditures on equipment are based on equipment life, while there is a 10-year annualization period for one-time costs. Note that the benefits of the standard, discussed in Section VII.G of this preamble and in Chapter VII of the FEA, were annualized over a 60-year period to reflect the time needed for benefits to reach steady-state values. Therefore, the time horizon of OSHA's complete analysis of this rule is 60 years. Employment and production in affected

[26] Appendix V–D of the FEA presents costs by NAICS industry and establishment size category using, as alternatives, both a 7 percent discount rate and a 0 percent discount rate. In the sensitivity analysis presented in Chapter VII of the FEA, OSHA compares the estimated cost of the rule using the 3 percent discount rate to the estimated cost using these alternative discount rates.

industries are being held constant over this time horizon for purposes of the analysis. All non-annual costs are estimated to repeat every ten years over the 60-year time horizon, including one-time costs that recur because of changes in operations over time or because of new entrants that must comply with the standard.[27] Table VII–10 shows, by affected industry in the sectors of general industry and maritime, annualized compliance costs for all establishments, all small entities (as defined by the Small Business Act and the Small Business Administration's (SBA's) implementing regulations; *see* 15 U.S.C. 632 and 13 CFR 121.201), and for all very small entities (those with fewer than 20 employees). Table VII–11 similarly shows, by affected industry in construction, annualized compliance costs for all entities, all small entities, and all very small entities. Note that the totals in these tables and all other tables in this chapter, as well as totals summarized in the text, may not precisely sum from underlying elements due to rounding.

OSHA's exposure profile, presented in Chapter III of the FEA, represents the Agency's best estimate of current exposures (*i.e.,* baseline exposures). Except for compliance with Table 1 in construction, OSHA did not attempt to determine the extent to which current exposures in compliance with the new silica PEL are the result of baseline engineering controls or the result of other circumstances leading to low exposures. This information is not needed to estimate the costs of (additional) engineering controls needed to comply with the new PEL, but it is relevant to estimate the costs of complying with Table 1 in construction.

For both construction and general industry/maritime, the estimated costs for the silica rule represent the additional costs necessary for employers to achieve full compliance with the new standard, assuming that all firms are compliant with the previous standard. Thus, the estimated costs do not include any costs necessary to achieve compliance with previous silica requirements, to the extent that some employers may not be fully complying with previously-applicable regulatory requirements. OSHA almost never assigns costs for reaching compliance with an already existing standard to a new standard addressing the same health issues. Nor are any costs associated with previously-achieved compliance with the new requirements included.

Because of the severe health hazards involved, as well as current OSHA regulation, the Agency expects that the estimated 11,640 abrasive blasters in the construction sector and the estimated 3,038 abrasive blasters in the maritime sector are currently wearing respirators as required by OSHA's abrasive blasting provisions (29 CFR 1915.154 (referencing 29 CFR 1910.134)). Furthermore, an estimated 264,761 workers, including abrasive blasters, will need to use respirators at least once during a year to achieve compliance with the new silica rule in construction, and, based on the NIOSH/BLS respirator use survey (NIOSH/BLS, 2003, Document ID 1492), an estimated 56 percent of construction employees whose exposures are high enough that they will need respirators under the new rule currently use such respirators. OSHA therefore estimates that 56 percent of affected construction employees already use respirators in compliance with the respirator requirements of the final silica rule.

Other than respiratory protection, OSHA did not assume baseline compliance with any other ancillary provision, even though some employers have reported that they currently monitor silica exposure, provide silica training, and conduct medical surveillance.

The remainder of this chapter is organized as follows. First, unit and total costs by provision are presented for general industry and maritime and for construction. Following that, the chapter concludes with a summary of the estimated costs of the rule for all affected industries.

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[27] To the extent one-time costs do not recur, OSHA's cost estimates, when expressed as an annualization over a 10-year period, will overstate the cost of the standard.

Table VII-10: Annualized Costs, by Industry, for All General Industry and Maritime Entities Affected by the Silica Standard

NAICS	Industry	All Establishments	Small Firms (SBA-Defined)	Very Small Entities (<20 Employees)
213112	Support Activities for Oil and Gas Operations	$97,927,752	$24,247,594	$11,907,226
324121	Asphalt Paving Mixture and Block Manufacturing	$513,042	$257,611	$57,921
324122	Asphalt Shingle and Coating Materials Manufacturing	$3,811,893	$1,272,241	$267,935
325510	Paint and Coating Manufacturing	$1,008,627	$572,603	$96,372
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$8,788,336	$5,059,640	$2,389,156
327120	Clay Building Material and Refractories Manufacturing	$21,252,204	$13,647,591	$1,765,486
327211	Flat Glass Manufacturing	$725,452	$129,486	$11,319
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$2,208,578	$970,207	$276,747
327213	Glass Container Manufacturing	$2,212,672	$2,113,092	$23,711
327320	Ready-Mix Concrete Manufacturing	$30,004,503	$20,250,184	$5,616,970
327331	Concrete Block and Brick Manufacturing	$7,020,737	$4,550,565	$1,383,138
327332	Concrete Pipe Manufacturing	$3,810,088	$1,900,067	$336,697
327390	Other Concrete Product Manufacturing	$20,878,235	$14,539,705	$4,568,859
327991	Cut Stone and Stone Product Manufacturing	$14,628,182	$13,106,845	$5,664,898
327992	Ground or Treated Mineral and Earth Manufacturing	$4,288,421	$2,075,935	$426,975
327993	Mineral Wool Manufacturing	$2,615,391	$990,251	$140,721
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$11,597,806	$5,872,264	$2,430,981
331110	Iron and Steel Mills and Ferroalloy Manufacturing	$646,402	$146,290	$0
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	$163,038	$83,666	$0
331221	Rolled Steel Shape Manufacturing	$51,060	$42,989	$0
331222	Steel Wire Drawing	$92,206	$67,130	$0
331314	Secondary Smelting and Alloying of Aluminum	$35,312	$19,590	$0
331420	Copper Rolling, Drawing, Extruding, and Alloying	$135,310	$68,335	$0
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$70,791	$37,734	$0
331511	Iron Foundries	$23,362,955	$12,442,276	$967,507
331512	Steel Investment Foundries	$5,450,435	$2,672,675	$124,895
331513	Steel Foundries (except Investment)	$11,118,366	$5,503,027	$559,542

Table VII-10: Annualized Costs, by Industry, for All General Industry and Maritime Entities Affected by the Silica Standard (continued)

NAICS	Industry	All Establishments	Small Firms (SBA-Defined)	Very Small Entities (<20 Employees)
331524	Aluminum Foundries (except Die-Casting)	$4,120,657	$3,130,109	$842,096
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$2,569,518	$1,693,459	$816,991
332111	Iron and Steel Forging	$154,626	$79,975	$0
332112	Nonferrous Forging	$40,101	$13,664	$0
332117	Powder Metallurgy Part Manufacturing	$52,988	$29,903	$0
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$340,536	$266,352	$0
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	$48,090	$27,196	$0
332216	Saw Blade and Handtool Manufacturing	$179,774	$120,315	$0
332323	Ornamental and Architectural Metal Work Manufacturing	$44,015	$35,067	$13,862
332439	Other Metal Container Manufacturing	$76,117	$42,327	$0
332510	Hardware Manufacturing	$171,563	$91,570	$0
332613	Spring Manufacturing	$96,006	$63,105	$0
332618	Other Fabricated Wire Product Manufacturing	$158,941	$126,762	$0
332710	Machine Shops	$1,580,507	$1,463,233	$0
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	$3,443,786	$2,755,111	$949,586
332911	Industrial Valve Manufacturing	$229,195	$100,135	$0
332912	Fluid Power Valve and Hose Fitting Manufacturing	$219,774	$88,050	$0
332913	Plumbing Fixture Fitting and Trim Manufacturing	$49,483	$29,537	$0
332919	Other Metal Valve and Pipe Fitting Manufacturing	$92,474	$48,163	$0
332991	Ball and Roller Bearing Manufacturing	$145,507	$28,037	$0
332996	Fabricated Pipe and Pipe Fitting Manufacturing	$192,491	$116,327	$0
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$460,336	$398,663	$0
333318	Other Commercial and Service Industry Machinery Manufacturing	$348,809	$220,586	$0
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$156,056	$75,552	$0
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	$116,177	$76,185	$0
333511	Industrial Mold Manufacturing	$226,974	$196,365	$0

Table VII-10: Annualized Costs, by Industry, for All General Industry and Maritime Entities Affected by the Silica Standard (continued)

NAICS	Industry	All Establishments	Small Firms (SBA-Defined)	Very Small Entities (<20 Employees)
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	$275,889	$239,261	$0
333515	Cutting Tool and Machine Tool Accessory Manufacturing	$183,291	$148,284	$0
333517	Machine Tool Manufacturing	$156,698	$120,338	$0
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	$75,852	$52,800	$0
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	$102,884	$48,595	$0
333613	Mechanical Power Transmission Equipment Manufacturing	$100,450	$43,878	$0
333911	Pump and Pumping Equipment Manufacturing	$217,882	$79,486	$0
333912	Air and Gas Compressor Manufacturing	$135,840	$61,295	$0
333991	Power-Driven Handtool Manufacturing	$56,450	$16,285	$0
333992	Welding and Soldering Equipment Manufacturing	$98,775	$48,996	$0
333993	Packaging Machinery Manufacturing	$129,107	$82,146	$0
333994	Industrial Process Furnace and Oven Manufacturing	$71,404	$52,056	$0
333995	Fluid Power Cylinder and Actuator Manufacturing	$153,238	$64,620	$0
333996	Fluid Power Pump and Motor Manufacturing	$68,340	$22,056	$0
333997	Scale and Balance Manufacturing	$24,516	$11,603	$0
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$329,237	$197,602	$0
334519	Other Measuring and Controlling Device Manufacturing	$221,763	$115,924	$0
335210	Small Electrical Appliance Manufacturing	$24,524	$17,998	$1,302
335221	Household Cooking Appliance Manufacturing	$28,748	$13,297	$0
335222	Household Refrigerator and Home Freezer Manufacturing	$26,111	$4,707	$0
335224	Household Laundry Equipment Manufacturing	$12,403	$157	$0
335228	Other Major Household Appliance Manufacturing	$26,829	$3,765	$0
336111	Automobile Manufacturing	$362,562	$20,482	$0
336112	Light Truck and Utility Vehicle Manufacturing	$324,735	$7,727	$0
336120	Heavy Duty Truck Manufacturing	$183,916	$36,819	$0
336211	Motor Vehicle Body Manufacturing	$260,377	$164,332	$0
336212	Truck Trailer Manufacturing	$180,129	$97,653	$0
336213	Motor Home Manufacturing	$45,680	$10,810	$0

Table VII-10: Annualized Costs, by Industry, for All General Industry and Maritime Entities Affected by the Silica Standard (continued)

NAICS	Industry	All Establishments	Small Firms (SBA-Defined)	Very Small Entities (<20 Employees)
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$334,051	$116,317	$0
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$315,816	$157,980	$0
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$180,676	$58,720	$0
336340	Motor Vehicle Brake System Manufacturing	$140,620	$60,248	$0
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$364,252	$129,753	$0
336370	Motor Vehicle Metal Stamping	$516,924	$310,283	$0
336390	Other Motor Vehicle Parts Manufacturing	$778,085	$366,093	$0
336611	Ship Building and Repairing	$9,586,384	$2,404,761	$110,154
336612	Boat Building	$2,566,768	$1,969,321	$156,109
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	$69,849	$23,894	$0
337110	Wood Kitchen Cabinet and Countertop Manufacturing	$204,454	$155,433	$64,773
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$215,675	$156,085	$0
339114	Dental Equipment and Supplies Manufacturing	$5,930,743	$4,331,589	$1,716,366
339116	Dental Laboratories	$6,857,347	$5,719,685	$4,641,195
339910	Jewelry and Silverware Manufacturing	$2,690,864	$2,065,825	$993,578
339950	Sign Manufacturing	$408,620	$354,823	$140,698
423840	Industrial Supplies Merchant Wholesalers	$2,292,917	$1,287,104	$528,996
444110	Home Centers	$110,386	$6,043	$1,681
482110	Rail transportation	$16,562,059	NA [a]	NA [a]
561730	Landscaping Services	$24,481,907	$18,249,100	$15,602,766
621210	Offices of Dentists	$2,592,207	$2,432,481	$2,094,401
	Totals	**$370,810,530**	**$186,093,853**	**$67,691,610**

[a] Not available. This estimate excludes NAICS 482110 (Railroad transportation) because the Census data did not include information sufficient for OSHA to identify the number of railroad establishments that are small firms and very small entities.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA (2016).

Table VII-11: Annualized Costs, by Industry, for All Construction Establishments Affected by the Silica Standard

NAICS	Industry	All Establishments	Small Firms (SBA-Defined)	Very Small Entities (<20 Employees)
236100	Residential Building Construction	$54,944,997	$49,798,948	$41,976,835
236200	Nonresidential Building Construction	$52,733,126	$34,357,970	$19,584,315
237100	Utility System Construction	$83,397,297	$30,262,348	$14,713,621
237200	Land Subdivision	$1,960,835	$966,584	$670,956
237300	Highway, Street, and Bridge Construction	$48,314,733	$21,399,925	$8,185,695
237900	Other Heavy and Civil Engineering Construction	$13,342,117	$5,415,610	$2,958,952
238100	Foundation, Structure, and Building Exterior Contractors	$139,227,106	$110,212,308	$65,772,437
238200	Building Equipment Contractors	$60,058,912	$41,087,873	$28,091,857
238300	Building Finishing Contractors	$55,340,177	$44,499,467	$32,007,884
238900	Other Specialty Trade Contractors	$101,830,889	$76,873,828	$48,852,375
221100	Electric Utilities	$3,203,249	$0	$199,861
999200	State Governments	$8,620,645	$0	$0
999300	Local Governments	$35,997,165	$0	$0
	Totals	**$658,971,248**	**$414,874,862**	**$263,014,788**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA (2016).

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1. Engineering Controls

a. General Industry and Maritime

The engineering control section in Chapter V of the FEA covers OSHA's estimates of engineering control costs for general industry and maritime sectors. Oil and natural gas fracturing operations are addressed separately because OSHA used a different methodology to estimate engineering control costs for this application group. This section will address OSHA's overall methodology, the methodology for each category of costs (such as ventilation, housekeeping, conveyors), issues specific to small entities, and issues specific to the hydraulic fracturing industry. Within each of these discussions, this section summarizes the methodology used in the PEA to estimate engineering control costs, summarizes and responds to the comments on the PEA, and summarizes the changes made to the methodology used in the PEA for the FEA. Finally, the chapter presents OSHA's final estimates of engineering control costs.

Introduction

The PEA's technological feasibility analysis identified the types of engineering controls that affected industries or sectors would need in order to control worker exposures to at

or below the proposed PEL of 50 μg/m³. Through its contractor, Eastern Research Group (ERG), OSHA generated cost estimates for those controls using product and technical literature, equipment vendors, industrial engineers, industrial hygienists, and other sources, as relevant to each item. Wherever possible, objective cost estimates from recognized technical sources were used. Specific sources for each estimate were presented with the cost estimates.

Table V–4 of the PEA provided a list of possible controls on an industry-by-industry basis and included details on control specifications and costs. The basic information for the types of controls needed was taken from the PEA's technological feasibility analysis. The following discussion explains how OSHA developed and used these estimates to prepare the aggregate costs of engineering controls presented in the PEA.

In developing engineering control cost estimates for the PEA, OSHA made a variety of estimates about the size or scope of the engineering or work practice changes necessary to reduce silica exposures in accordance with the proposed rule. In some cases, OSHA estimated that employers would need to install all new engineering controls. In other cases, though, employers were expected to only need to add additional ventilation capacity or improve maintenance for existing equipment. In these cases, the costs were based on judgments of the amount of incremental change (either additional capacity or additional maintenance work) required per year. These estimates of the size or scope of the necessary engineering or work practice changes reflected representative conditions for the affected workers based on technical literature (including National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations), judgments of knowledgeable consultants and industry observers, and site visits. A detailed list of the specific costing assumptions and information sources for each control, grouped by job category or industry sector, was shown in PEA Appendix V–A, Table V–A–1.

In order to estimate costs in a consistent manner, OSHA, in the PEA, estimated all costs on an annualized basis. For capital costs, OSHA calculated the annualized capital cost, using a three percent discount rate over the expected lifetime of the capital item. The capital costs for long-lasting capital items (such as ventilation system improvements) were annualized over ten years. OSHA estimated that, in the general industry and maritime sectors, any capital expenditure would also entail maintenance costs equal to ten percent of the value of the capital investment annually.

General Methodology

General Methodology: Per-Worker Basis and Treatment of Overexposures for Cost Calculations

PEA Estimates

OSHA, in the PEA, estimated control costs on a per-worker basis. Costs were related directly to the estimates of the number of workers needing controls (*i.e.,* workers exposed over 50 μg/m³). OSHA divided engineering control costs into two categories: (1) Those only needed by establishments with employees exposed to levels of silica that exceeded the preceding general industry PEL of 100 μg/m³; and (2) those applicable to all establishments where workers were exposed to levels of silica above the proposed PEL (whether just above 50 μg/m³ or also above 100 μg/m³). It should be noted that the maritime sector has been subject to a different preceding PEL of 250 μg/m³. The PEA estimates were presented in the PEA cost analysis tables. The overwhelming majority of the costs (90 percent of all engineering control costs and 85 percent of costs associated with meeting the preceding PEL of 100 μg/m³) were associated with the second category (controls applicable to all establishments with exposures above the proposed or preceding PEL). Because OSHA is not accounting for the costs of controls necessary to reach the preceding PEL, the PEA focused on controls that may be needed to meet the new PEL. OSHA derived per-worker costs by examining the controls needed for each job category in each industry and dividing the cost of that control by the number of workers whose exposures would be reduced by that control. OSHA then multiplied the estimated per-worker control cost by the number of workers exposed between the proposed (new) PEL of 50 μg/m³ and the preceding PEL of 100 μg/m³. The numbers of workers in this category were based on the exposure profiles for at-risk occupations developed in the technological feasibility analysis in Chapter IV of the PEA and the estimates of the number of workers employed in these occupations were developed in the industry profile in Chapter III of the PEA. The exposure profile information was determined to be the best available data for estimating the need for incremental controls on a per-worker basis.

In general, in the PEA, OSHA inferred the extent to which exposure controls were already in place from the distribution of overexposures among the affected workers. Thus, if most exposures in a facility were above the preceding PEL, OSHA broadly interpreted this as a sign of limited or no controls, and if most exposures were below the proposed (new) PEL of 50 μg/m³, this would be indicative of having adequate controls in place. OSHA calculated the costs of controls per exposed worker in each job category and assigned this cost to the total number of employees exposed between the proposed (new) PEL and the preceding PEL. For example, if a control cost $1,000 per year and covered 4 employees, the cost per employee would be $250 per year. If 100 employees in the job category were exposed between the preceding and proposed (new) PEL, then the total costs would be $250 times 100 employees or $25,000. No costs were estimated for employees currently exposed above the preceding PEL or below the proposed (new) PEL.

OSHA determined that multiple controls would be needed for almost all jobs in general industry in order reduce exposures from baseline conditions to meeting the proposed (new) PEL of 50 μg/m³. Some of these controls cover a group of workers, while others might be individualized (such as daily housekeeping by each individual worker).

Comments on the Per-Worker Basis and Proportionality of Costs

URS, speaking for the American Chemistry Council (ACC), argued that OSHA's approach underestimated the costs of controls because it based costs on controls per worker instead of controls per facility (Document ID 2307, Attachment 8, p. 4). Since OSHA did not provide a distribution of exposures by facility or provide facility-specific information, URS used data in the record to create its own models to account for facility size. URS described its approach as follows:

> URS created three statistical binomial distributions of overexposed workers, one for each of the three facility sizes, using OSHA's estimate of the percentage of over-exposed workers for that job. The result was a binomial distribution curve indicating the percentage of overexposed workers for each job category for each size-specific ''model facility.''
>
> For each binomial distribution, the peak of the distribution curve centers on the average number of overexposed workers per facility for that job description according to OSHA's estimate (Document ID 2307, Attachment 8, p. 7).

In taking this approach, URS erroneously assumed that the

distribution of overexposed workers per facility was random, as evidenced by its use of a binomial distribution to approximate overexposures per facility within each of three facility sizes (Document ID 2307, Attachment 8, p. 7). Examination of the spreadsheet URS provided shows that this approach approximately doubles the number of controls needed and, and for this reason, doubles the total cost of engineering controls (Document ID 2307, Attachment 26, Table 2A, URS Summary Worksheet).

OSHA disagrees with URS's implicit conclusion that overexposures are random across facilities. It is not reasonable to assume that controls have no relation to exposure level as this approach assumes. As will be discussed later in the context of OSHA's treatment of the preceding PEL, the data underlying the exposure profile show that establishments with low exposures are much more likely to have controls in place than those with very high exposures.

URS then assumed that if one worker in a job category is overexposed, then all controls listed by OSHA will be needed (Document ID 2307, Attachment 25, Engineering Costs). URS did not dispute that multiple controls would be needed for almost all jobs in general industry in order reduce exposures from baseline conditions to meeting the proposed (new) PEL of 50 μg/m^3. The existence of multiple controls weakens the theory suggested by URS—that all controls are needed if even one worker is exposed at levels above the PEL—because as explained above, some controls are individualized while some protect groups of workers.

The best possible approach to what engineering controls are needed might differ based on whether: (1) There are no controls for a job category in place at all and most workers are overexposed by a large margin; or (2) only some workers in a job category are overexposed by a small margin (*i.e.,* a set of controls is already in place).

In the first case, the most common approach would be to apply a relatively full set of controls, as explained in OSHA's technological feasibility analysis. This might start with enclosures and local exhaust ventilation (LEV), but, if exposures are high and the establishment is very dusty, it might also include initial cleaning or the introduction of ongoing routine housekeeping. In these situations, in which most employees are overexposed, OSHA estimated that the full set of controls listed in the technological feasibility analysis would be applied and, in these cases, there would be little difference in the results obtained using OSHA's approach and the results obtained using the approach suggested by URS.

However, the approach to controlling silica exposures that OSHA believes to be typical when establishments are faced with the second situation would be quite different, and therefore different from what URS expected. Commenters from both labor (Document ID 4204, p. 40) and industry (Document ID 1992, p. 6) pointed out that when there are controls in place or only some workers are overexposed, the first step is to examine work practices. The AFL–CIO noted that exposures can be controlled through work practices, repositioning ventilation systems, and controlling fugitive emissions (carryover from adjacent silica emitting processes) (Document ID 4204, p. 40). Implementing these types of changes can be inexpensive. The principal cost of improving work practices may only be training or retraining workers in appropriate work practices. OSHA's proportional cost approach in the PEA may therefore overestimate costs for situations in which overexposures can be corrected with work practice changes because the Agency will have included costs for engineering controls when, in fact, none will be needed. The URS approach will always include the costs of all controls for a job category in any facility where anyone in a job category is overexposed, and will thus yield even higher estimates.

As described in Chapter IV, Technological Feasibility, of the FEA, and summarized below, in situations in which there are LEV systems in place but the PEL is still not being met, employers would typically try many things short of removing the entire system and replacing it with a system with greater air flow velocities (and thus greater capacity and cost). The incremental solutions to controlling silica exposures include minor design modification of existing controls, better repair and maintenance of existing controls, adding additional LEV capacity to existing systems, improving housekeeping, modifying tools or machinery causing high levels of emissions, and reducing cross contamination.

Some worksites might require a slightly different and readily modified design. For example, an OSHA special emphasis program inspection of a facility in the Concrete Products industry discovered that installing a more powerful fan motor, installing a new filter bag for the bag-filling machine LEV, and moving hoods closer to the packing operator's position reduced respirable dust exposure by 92 percent, to 11 μg/m^3 (Document ID 0126, pp. 7–8). In an assessment of the Asphalt Roofing industry, NIOSH recommended repair and servicing of existing process enclosures and ventilation systems to eliminate leaks and poor hood capture but did not indicate that entirely new systems would need to be installed (Document ID 0889, pp. 12–13; 0891, pp. 3 and 11; 0890, p.14; 0893, p. 12).

In other cases, better equipment repair and maintenance procedures can be the key to meeting the PEL when there are already controls in place. For example, as described in Chapter IV of the FEA, in the Concrete Products industry, OSHA obtained a sample of 116 μg/m^3 for a material handler who operated a forklift to transport product between stations. The inspector noted that there were leaks in the silo bin chute and that some controls were not fully utilized. The report indicated that dust generated by various other processes in the facility was a contributing factor to the forklift operator's high level of exposure. In this case, the first course of action for the employer would be to correct the deficiencies in the existing systems. Similarly, at a site visit in the Paint and Coating industry, ERG monitored mixer operators' exposures and obtained results below the limit of detection while workers emptied 50-pound bags of powder into hoppers when dust control systems were working properly. These values are 95 percent lower than the 263 μg/m^3 obtained during another shift, at the same plant, when the dust control systems malfunctioned (Document ID 0199, p. 9).

In other cases, as pointed out by a foundry commenter, adding LEV capacity to existing systems for silica emissions not yet subject to any LEV control can be a good strategy for lowering exposures (Document ID 1992, p. 6). In one foundry, NIOSH investigators recommended installation of LEV over the coater and press areas, enclosure of the coating process, and/or repair and servicing of existing process enclosures and ventilation systems to eliminate leaks and poor hood capture (Document ID 0889, pp. 12–13; 0891, pp. 3 and 11; 0890, p. 14; 0893, p. 12).

Various combinations of improved housekeeping, initial cleaning, and switching to High-Efficiency Particulate Air (HEPA) vacuums can also help employers meet the PEL. In the Structural Clay industry, professional cleaning in a brick manufacturing facility removed ''several inches'' of dust from floors, structural surfaces and equipment (Document ID 1365, pp. 3-19–3-20; 0571). These changes alone led

to a dramatic decrease in exposures, by as much as 90 percent, to below 50 μg/m³, for materials handlers. Similar results were observed for grinding operators (Document ID 0571). In one NIOSH evaluation, operators in a grinding area where good housekeeping practices were being implemented had substantially lower exposures than operators in a grinding room where the housekeeping practices were poor. The grinding room referred to as the ''C plant'' had 2 to 3 inches of settled dust on the floor and had an exposure result of 144 μg/m³. Grinding operators at the grinding room referred to as the ''B plant,'' where dust had been cleaned up, had substantially lower exposures (24 μg/m³) (Document ID 0235, pp. 6–7).

Good housekeeping also increases the useful life of equipment. As discussed in Chapter IV of the FEA, dust clogs machines and reduces their useful life. As an example, regulating cotton dust was acknowledged to increase productivity by reducing down time. It also increased the useful life of looms (Document ID 2256, Attachment 4, p. 11). The Agency predicts that this is likely to be the case with silica controls as well. Dust being properly captured at the source can also result in cost savings in housekeeping activities because less dust needs to be cleaned up when it is captured at the source and not allowed to spread (Document ID 2256, Attachment 4, p. 11).

In specific situations, there are a variety of other controls that may be useful. As discussed in the Technological Feasibility chapter of the FEA, Simcox et al. (1999) (Document ID 1146) found that Fabricators in the Cut Stone industry had a mean exposure of 490 μg/m³, which was reduced 88 percent to 60 μg/m³ when dry grinding tools used on granite were replaced or modified to be water-fed. Similar reductions were found at other facilities when wet grinding, polishing, and cutting methods were adopted (Document ID 1365, p. 11–20; 1146, p. 579). In the technological feasibility chapter, OSHA examined the work practices of cut stone splitters and chippers and found that a combination of wetting the floor at appropriate times, modifying ventilation directly from the top of the saws, and retrofitting splitting stations with LEV reduced exposures from a mean of 117 μg/m³ to a mean of 18 μg/m³, an 85 percent reduction (Document ID 1365, p. 11–22; 0180).

Finally, in situations where there is cross contamination, employers may achieve the PEL for some workers without implementing any controls specific to that job category. As pointed out by the AFL–CIO, when this occurs, OSHA's costs may be overestimated (Document ID 4204, Attachment 1, p. 105).

These examples show that in many situations, where there are already controls in place, or where exposures are only slightly above the PEL, the PEL can be met by a variety of mechanisms short of installing an entirely new set of controls. Since the record shows that, frequently, exposures can be controlled without installing new engineering controls, OSHA's approach of estimating costs based on the proportion of the workers exposed above the PEL is much more likely to be accurate than estimates based on URS's suggestion that all controls are needed whenever one worker is exposed above the PEL.

The URS facility-based approach would require taking the costs of newly installing a full set of controls even if only one worker is exposed above the PEL. This approach assumes that (1) the existing exposure levels in a given facility have been achieved without the use of any controls; and (2) existing controls cannot be improved upon for less than the cost of installing an entirely new system of controls. These assumptions are unsupported by the URS comments and the nature of exposure control, as discussed above.

OSHA, therefore, rejects URS's approach and is maintaining its per-worker basis for calculating costs for the FEA. Based on the evidence presented in this section, the Agency concludes that OSHA's proportional approach of assigning control costs to each worker based on the cost per worker of a complete set of controls is a better approach to commonly encountered exposure situations than to assume that any reading above the PEL triggers the need for a complete set of controls.

The AFL–CIO argued that OSHA's proportional approach resulted in an over-estimation of costs because it involved adding costs for the exposed occupation wherever there was an overexposure, even when the overexposure was primarily or solely the result of cross contamination. The AFL–CIO recommended that OSHA ''identify operations which are unlikely to [generate] silica emissions, or background and bystander exposure measurements, and subtract those measured exposure levels from those operations which do emit silica'' (Document ID 4204, Attachment 1, pp. 31–32). OSHA has routinely included the elimination of cross contamination as a component of the controls needed for some job categories. As discussed in Chapter IV of the FEA, OSHA also believes that other controls will still be needed for many job categories in which cross contamination is common and as long as these additional controls are needed, overall costs will not decline as a result of controlling cross contamination. However, OSHA agrees that there may be situations in which correcting cross contamination alone would be sufficient. In this case, the commenter is right that OSHA may sometimes overestimate costs.

General Methodological Issues—Comments on Costs Associated With Exposures Over the Preceding PEL

Many commenters argued that OSHA should have attributed the costs of reaching the preceding PEL of 100 μg/m³ to this standard (Document ID 2307, Attachment 8b, p. 16; 2195, p. 33; 1819, p. 2; 2375, Attachment 2, p. 65; 2307, Attachment 1, p. 2; 2379, Attachment 2, p. 9). For example, Stuart Sessions of Environomics, commenting on behalf of the ACC, stated that of the workers currently exposed over 50 μg/m³, two-thirds are exposed over 100 μg/m³, and that OSHA erred in excluding the costs of reducing those exposures to 100 μg/m³ (Document ID 2307, Attachment C, pp. 2–3).

OSHA's preliminary initial regulatory flexibility analysis (PIRFA) for the 2003 Small Business Advocacy Review (SBAR) panel included benefits and costs associated with future compliance with existing silica requirements on the basis that the rule would help improve compliance with the existing silica rules (OSHA, 2003a and 2003b) (Document ID 1685 and 0938, respectively). Upon further consideration, OSHA determined that a more fair and accurate measure of the benefits and costs of the proposed rule was to begin the analysis with a baseline of full compliance with existing requirements; OSHA has retained this approach for the final rule. The Agency offers three reasons in support of this approach. First, the obligation to comply with the preceding silica PEL is independent of OSHA's actions in this rulemaking. The benefits and costs associated with achieving compliance with the preceding silica rules are a function of those rules and do not affect the choice of PEL. The question before the Agency was whether to adopt new rules, and its analysis focused on the benefits and costs of those new rules. Second, the Agency's longstanding policy is to assume 100 percent compliance for purposes of estimating the costs and benefits of new rules, and to assume less than full compliance with the existing OSHA rules would be inconsistent with that policy. Finally, assuming full compliance with the existing rules is in keeping with standard OSHA practice in

measuring the incremental effects of a new rule against pre-existing legal obligations. Reliance on costs that assume full compliance with both the preceding and proposed (new) OSHA rules makes it easier to compare the two regulatory schemes.

Some commenters also disagreed with the way OSHA attributed costs to employers whose workers were being exposed to silica at levels greater than the preceding PEL of 100 μg/m³ (Document ID 3251, p. 2; 3296, p. 2; 3333, p. 2; 3373, p.2; 2503, p.2; 2291, p. 16; 4209, p. 111). These commenters argued that OSHA did not attribute any costs to reaching 50 μg/m³ to employers whose employees were exposed above 100 μg/m³. They argued that OSHA instead assumed that the costs and controls necessary to reach 100 μg/m³ would also be sufficient to reach a level of 50 μg/m³, and as discussed above, that OSHA did not account for those costs because reducing exposures to the preceding PEL of 100 μg/m³ was already required before this rulemaking. The American Foundry Society (AFS) argued that OSHA reduced costs by two-thirds ''under the logic that employers must comply with the current PEL and the proposal does not add any existing obligation'' (Document ID 2379, Appendix 1, p. 10). AFS added that OSHA's underestimation of costs in this manner was particularly severe because OSHA used outdated data that showed more employees with exposures over 100 μg/m³, whereas more recent data would show fewer employees with exposures above 100 μg/m³ and more with exposures between 50 and 100 μg/m³. Had OSHA used this updated data, in AFS's estimation, the Agency would have identified more employers needing to install additional engineering controls and thus there would be additional costs that were not accounted for in the PEA (Document ID 2379, Attachment 3, pp. 9–10). ACC made a similar point, saying that as a result of OSHA's methodology, ''the exposure reduction costs for the estimated 81,000 workers now exposed above 100 μg/m³ are not taken into account by OSHA on either a full cost basis or an incremental cost basis'' (Document ID 2308, Attachment 9, pp. 2–3).

In addition URS, among others, argued that ''OSHA fails to account for the non-linear costs associated with each incremental reduction in silica concentrations,'' meaning that URS believed that it is more costly to achieve additional reductions in exposure as exposures are lowered. For example, according to URS's contention, it would be more costly to reduce exposures from 75 μg/m³ to 50 μg/m³ than from 125 μg/m³ to 100 μg/m³ (Document ID 2308—Attachment 8, p. 11; 2291, p. 16; 4209, p. 11; 2307, Attachment 2, pp. 181–182; 2379, Attachment 2, p. 9; 3487, p. 13).

OSHA has several responses to these criticisms. In response to the criticism that OSHA overestimated the number of workers with exposure levels above 100 μg/m³ as a result of using outdated data, the Agency has updated the exposure profile used to develop the final analysis of costs. This update is described previously in Chapters III and IV of the FEA. As a result of this update, OSHA found that, in the aggregate, the percentage of workers in general industry and maritime exposed to silica levels between 50 μg/m³ and 100 μg/m³ rose from 33 percent as estimated in the PEA to 42 percent. And, as the commenters noted would be the case, the percentage exposed at levels above 100 μg/m³ fell from 67 percent to 58 percent. OSHA has updated this analysis to incorporate these data and has estimated costs for these additional workers whose exposures fall between 50 μg/m³ and 100 μg/m³. The revised distribution also shows that of those workers with exposures above the new PEL, 41 percent are exposed between the new PEL and the preceding general industry PEL with an average exposure level of 70 μg/m³, 29 percent are exposed between the preceding PEL and 250 μg/m³ with an average exposure level of 156 μg/m³, and 30 percent are exposed above 250 μg/m³ with an average exposure level of 485 μg/m³. Where an industry submitted more recent exposure data or information about exposure distributions within their industry, OSHA was able to show that its final exposure distribution was roughly equivalent (*see* Chapter IV of the FEA).

The technological feasibility analysis (presented in Chapter IV of the FEA) describes the controls necessary for reducing exposures from the highest levels observed in an industry's exposure profile to the new PEL. In all application groups except two (asphalt paving products and dental laboratories), the highest observed exposures were above the preceding PEL. With the exception of hydraulic fracturing,[28] the technological feasibility analysis did not distinguish between the controls necessary to meet the preceding general industry PEL of 100 μg/m³ and those necessary to meet the new general industry PEL of 50 μg/m³. Instead, the technological feasibility analysis simply listed the controls necessary for those employers whose employees had the highest baseline exposures to significantly reduce exposures and, in most operations, meet the new PEL.

It was not necessary for OSHA to distinguish between controls necessary to achieve the preceding PEL and those necessary to achieve the new PEL in order to demonstrate the technological feasibility of achieving a PEL of 50 μg/m³. Such a distinction would have been difficult because, from a baseline of uncontrolled exposures, the controls necessary to meet the preceding and new PELs are difficult to distinguish. For example, if there are two different controls necessary to fully meet the new PEL, then it is logically possible that two different establishments may achieve an exposure level at or below the preceding PEL in different ways. One establishment may have excellent housekeeping but poorly maintained LEV. Another may have well maintained LEV but poor housekeeping. For individual cases, there is not a simple demarcation of which controls of the total set of controls are necessary to achieve the new PEL when only the exposure level and not the controls already in place are known. Nor, as discussed above, is it the case that a control, once installed, will always provide identical protection. Two otherwise equal facilities may have the same installed controls but different exposure levels because of the quality of the maintenance of the system.

For the purposes of costing engineering controls for general industry and maritime in the PEA, OSHA assigned all of the costs for meeting a PEL of 50 μg/m³—including the costs of controls necessary to meet the preceding PEL of 100 μg/m³—to all workers with exposure levels between 50 μg/m³ and 100 μg/m³. However, OSHA assigned no costs in the PEA to employees whose exposures exceeded the preceding PEL. This approach would be accurate for both those above and below the preceding PEL only if the exact same controls would be needed to control exposures in both situations and these controls would always yield an exposure level below the preceding PEL. However, as discussed in the previous section on proportionality of costs, OSHA has determined that this is not typically the case. There exist multiple kinds of controls and the actual application and operation of the control can differ. The approach applied in the PEA applied more controls than will typically be needed where exposures are below the preceding PEL and thus overestimates costs in these situations, but then assigns no costs for achieving

[28] Due to an unusually rich data set, and the great similarity of different fracturing operations, both with respect to the equipment used and the current levels of control, OSHA was able to estimate which controls are necessary to go from an uncontrolled situation to the preceding PEL and which are necessary to get from the preceding PEL to the new PEL in the hydraulic fracturing industry.

the new PEL where exposures are above the preceding PEL. In the latter situation, it can reasonably be expected that, in most cases, some costs would be incurred to meet the new PEL even after the preceding PEL is met and therefore the PEA methodology underestimated costs in those situations. Although these over- and under-estimates are partially offsetting, OSHA acknowledges that any over-estimates of cost do not necessarily offset the potential under-estimates of costs.

OSHA has therefore decided to adopt an approach to the estimation of costs different from that adopted in the PEA. In the FEA, OSHA relied on data available in the rulemaking record to both correct the overestimate of costs for those below the preceding PEL and, as many industry commenters urged, estimate the costs necessary to meet the preceding PEL as well as the new PEL for those above the preceding PEL.

To be clear, these data still do not enable OSHA to distinguish between the exact controls needed to get from uncontrolled exposures to the preceding PEL and those needed to get from the preceding PEL to the new PEL on an industry-by-industry and occupation-by-occupation basis. However, the data do enable OSHA to show that the majority of the costs of controlling silica exposures are incurred in order to reduce exposures from uncontrolled levels to the preceding PEL. OSHA will then assume that 50 percent of the costs incurred will be to implement the controls necessary to get from the uncontrolled situation to the preceding PEL and 50 percent to implement the controls necessary to go from the preceding PEL to meeting the new PEL. If, in fact, a majority of the costs are incurred in order to reduce exposures to the preceding PEL, the assumption that attributes 50 percent of costs to going from the preceding PEL to the new PEL will overestimate the true costs for establishments with exposures at the preceding PEL or between the preceding PEL and the new PEL.

In order to assess whether the majority of the costs are necessary to meet the preceding PEL, OSHA first examined what kinds of exposures are associated with the uncontrolled situations that served as the starting point for the estimates of needed controls in the technological feasibility analysis. The average level of exposure across all of general industry for employees with exposure exceeding the preceding PEL is over 300 μg/m^3. Thus, on average, across all industries the uncontrolled situation involves high levels of exposure, commonly more than 3 times the preceding PEL.[29]

In general, to reduce exposures from over 2.5 times the preceding PEL to the preceding PEL, employers would have to implement some measure or measures, and those measures would be the ones that provide the greatest reduction in silica exposures and therefore control most of the silica exposures in the facility. In most cases this will be a working LEV system or some form of worker isolation. Measures like improved housekeeping cannot reduce exposures from the levels observed in uncontrolled exposure situations to the preceding PEL. OSHA reviewed industry-by-industry and occupation-by-occupation cost estimates for engineering controls and found that, on average 63 percent of the costs were for LEV, 23 percent were for housekeeping, and 16 percent were for other controls, most commonly wet methods (based on OSHA, 2016). In many cases, where wet methods were applicable, wet methods represented the majority of the costs and there were not significant LEV costs. As a result, 79 percent of the costs of controls, on average, are attributable to either wet methods or LEV. The combination of LEV or wet methods with some improvement in housekeeping (though not the improvements necessary to meet the new PEL) will constitute the majority of costs for virtually all occupational categories. Some improvement in housekeeping will typically also be required to meet even the preceding PEL.[30] While employers can probably meet the preceding PEL with less than ideally maintained LEV systems, improvements in maintenance will not reverse the conclusion that the majority of the costs are incurred to meet the preceding PEL. This is the case because on average 63 percent of engineering control costs are necessary to reach the preceding PEL and some housekeeping costs will also be necessary, leaving a significant percentage of expenditures above 50 percent of the costs available for improved maintenance.

To confirm the findings of this cost-spreadsheet-based analysis of where the majority of the costs are incurred, OSHA reviewed industries where good data are available on controls in both uncontrolled situations and situations with exposures between the new and the preceding PEL. OSHA examined the exposures and controls in eight ferrous sand casting foundry facilities. In these eight facilities, four had relatively few workers exposed above 50 μg/m^3, and the other 4 had many exposures over 100 μg/m^3. OSHA found that those facilities with most exposures over 100 μg/m^3 generally had little or no LEV (relying instead on general ventilation), poor housekeeping, no enclosures for workers, and poor maintenance. The foundries where silica dust was better controlled generally had working LEV systems, good housekeeping that kept surfaces free of silica dust, and good maintenance practices. This indicates that LEV and some housekeeping are essential to meeting the preceding PEL. OSHA also examined data on all exposures with control descriptions. These data showed that exposures above 250 μg/m^3 occurred in uncontrolled situations or situations in which controls, though installed, were not in use. In situations where exposures were between the preceding and new PELs, most exposures showed some controls in place, normally LEV, but not all controls recommended. In some cases there were no controls in place. These generally represented situations in which exposures were much lower than the typical uncontrolled situations and such facilities would not normally need the full controls necessary to go from very high levels of exposure to the new PEL (*See* Exhibit: *Descriptions of Control,* available in Docket OSHA–2010–0034 at *www.regulations.gov*).

Based on these findings, OSHA determined that the majority of costs are incurred in order to implement controls necessary to get from an uncontrolled situation to the preceding PEL. However, OSHA developed cost estimates for engineering controls based on the conservative assumption that 50 percent of the total costs of going from an uncontrolled situation to the new PEL is incurred in order to reach the preceding PEL and the remaining 50 percent are incurred to reach the new

[29] To check that this was not the result of a very high exposures for a small number of employees or industries, OSHA examined the exposure profile presented in Table III–9 and found that in only 4 industries (with 1.1 percent of all employees exposed above the preceding PEL) were there no exposures above 250 μg/m^3.

[30] For example, in several industry sectors where workers are currently manually dumping silica-containing materials, the use of automated and ventilated dumping stations is needed to reduce exposures from over 250 μg/m^3 to below the preceding PEL. However, once these controls are installed and in use, final exposures are often below the limit of detection or less than 12 μg/m^3—well below the new PEL (*see* technological feasibility chapter for paint and coatings). However, to maintain these exposures below the new PEL, these industry sectors will need to ensure that ventilation systems are properly maintained and will need sufficient housekeeping to ensure against build-ups of dust.

PEL.[31] For example, in the cut stone industry 63 percent of those exposed above the new PEL are also above the preceding PEL and 37 percent are below the preceding PEL but above the new PEL. The total cost to the cut stone industry of going from uncontrolled exposure to the new PEL is $17.7 million. With OSHA's assumption that half of the costs of going from an uncontrolled situation to the new PEL is incurred in order to reach the preceding PEL, then the cost for those employers with employees exposed above the preceding PEL would be 63 percent of $17.5 million times 0.5, which equals $5.5 million. The cost for those below the preceding PEL would be 37 percent of $17.7 million times 0.5, which equal $3.3 million. The total cost of going from the preceding PEL to the new PEL in the cut stone industry is therefore the sum of these two calculations: $8.8 million. This will overestimate the costs of reaching the new PEL, given the majority of the costs are incurred to implement controls necessary to reach the preceding PEL.[32]

As presented in more detail below, this approach results in a total annualized cost estimate for general industry and maritime engineering controls of $225 million. Fortunately, this cost estimate is not highly sensitive to the allocation percentage chosen. Each decrement of 5 percentage points changes the engineering control costs by approximately 5.5 percent. Thus, for example, if 65 percent of the costs are necessary to go from the preceding PEL to the new PEL, then the annualized cost estimate for engineering controls would rise to $261 million per year.[33]

Accounting for Costs of Downtime

Some commenters suggested that OSHA failed to account for the downtime that installing engineering controls or performing an initial through cleaning would require (*e.g.,* Document ID 2368, p. 13 for engineering controls; Document ID 2379, Attachment 2, p. 16 for initial thorough cleaning).

Almost all firms need downtime occasionally in order to perform general maintenance, inventory, or other tasks. In the final rule, OSHA has extended the compliance date for general industry from one year to two years. This will allow almost all employers to schedule work that might require downtime to install, improve, or maintain controls that they determine are necessary to meet the new PEL or to perform the initial thorough cleaning at times when they would already need scheduled downtime for other purposes. Therefore, OSHA has determined that there will be no additional costs incurred for downtime in order for employers to install engineering controls or to perform the initial thorough cleaning.

Technological Change

One commenter, Dr. Ruth Ruttenberg, testifying for the AFL–CIO, argued that OSHA had overestimated costs by failing to consider technological change:

> Technological improvements—both engineering and scientific—are constantly occurring, especially when the pressure of a pending or existing regulation provide a strong incentive to find a way to comply at a lower cost. . . . These improvements are well-documented following the promulgation of rules for vinyl chloride, coke ovens, lead, asbestos, lock-out/tag-out, ethylene oxide, and a host of others (Document ID 2256, Attachment 4, p. 2).

Dr. Ruttenberg recognized that OSHA, in the PEA, already predicted some ''technological and cost-saving advances with silica,'' such as expanding the use of automated processes and developing more effective bag seals, but criticized OSHA for not accounting for those cost savings in its analysis:

> Technological improvements are as sure a reality—based on past experience and academic research—as overestimation of cost and underestimate of benefits are in an OSHA regulatory analysis. More than 40 years of OSHA history bear this out (Document ID 2256, Attachment 4, p. 3).

When promulgating health standards, OSHA generally takes an approach in which cost estimates and economic feasibility analyses are based on the technologies specified in the technological feasibility analysis. This is a conservative approach to satisfying OSHA's legal obligations to show economic and technological feasibility. As a result, the Agency does not account for some factors that may reduce costs, such as technological changes that reduce the costs of controls over time and improvements in production that reduce the number of employees exposed. As pointed out in the PEA, and from the examples described in the ''Total Cost Summary'' at the end of this chapter, some past experience suggests that these factors tend to result in OSHA's costs being overestimated.[34] OSHA considers the primary purpose of the cost estimate to be to provide a basis for evaluating the economic feasibility of the rule, and OSHA has determined that for this rulemaking, feasibility is most accurately demonstrated by using an approach that does not account for the potential impacts of future technological changes.

General Methodological Issues: Number of Workers Covered by a Control PEA Estimates

The cost calculations in the PEA included estimates of the number of workers whose exposures are controlled by each engineering control. Because working arrangements vary within occupations and across facilities of different sizes, there are no definitive data on how many workers are likely to be covered by a given set of controls. In many small facilities, especially those that might operate only one shift per day, some controls will limit exposures for only a single worker. Also, small facilities might have only one worker in certain affected job categories. More commonly, however, and especially in the principal production operations, several workers are likely to derive exposure reductions from each engineering control.

The PEA relied on case-specific judgments of the number of workers whose exposures are controlled by each engineering control (see Table 3–3 in ERG, 2007b, Document ID 1608). The majority of controls were estimated to benefit four workers, based on the judgment that there is often multi-shift work and that many work stations are shared by at least two workers per shift. The costs of some types of equipment that protect multiple employees, such as HEPA vacuums, were spread over larger groups of employees (*e.g.,* six to eight workers). In the PEA, the average number of workers affected represented

[31] This approach was not applied to the two industries, dental laboratories and asphalt paving materials, where the exposure profile showed that there were no exposures above the preceding PEL.

[32] OSHA also notes that this approach shows rising incremental costs of control, which is consistent with some comments. This is because 50 percent of the costs are estimated to be incurred to go from levels of over 250 μg/m^3 to 100 μg/m^3 and equal costs are estimated to be incurred to go from 100 μg/m^3 to 50 μg/m^3.

[33] A value of 100 percent would be totally implausible as it would imply that all establishments currently far above the preceding PEL could achieve that PEL without cost. Put another way, this would be equivalent to saying that, if OSHA had decided to adopt the alternative PEL of 100 μg/m^3 (*i.e.,* the same as the preceding general industry PEL), as some employer groups recommended, any employers currently above that PEL—regardless of how far above the PEL they were—would be able to meet a PEL of 100 μg/m^3 without implementing any new engineering controls.

[34] On the other hand, there is supplemental evidence from Harrington et al. (2000) [Harrington, Winston, Richard D. Morgenstern and Peter Nelson. ''On the Accuracy of Regulatory Cost Estimates.'' Journal of Policy Analysis and Management, 19(2), 297–322, 2000] that OSHA does not systematically overestimate costs on a per-unit basis, and that the reason for overestimation of costs at the aggregate level has been a combination of difficulty with establishing baseline conditions and noncompliance. Nevertheless, several examples of OSHA's overestimation of costs reported in the article are due to technological improvements.

an average across all establishments, large and small.

Comments and Responses

Some commenters questioned OSHA's estimate of the number of workers whose exposures could be controlled per newly added or enhanced control. OSHA's PEA most commonly estimated that four workers would have their exposures reduced for each new or enhanced engineering control. Dr. Ronald Bird, testifying for the Chamber of Commerce, argued that OSHA's estimates were simply arbitrary assumptions (Document ID 2368, p. 14). Stuart Sessions, testifying for the ACC, argued that the use of a single standard crew size of four led OSHA to underestimate costs and economic impacts for smaller establishments, at which, he argued, ''there are virtually never as many as four overexposed workers in any job category, and it is simply impossible that one application of a package of controls in this situation could protect as many as 4 overexposed workers on average'' (Document ID 4231, Attachment 1, p. 6).

The approach OSHA used was intended to represent the average number of employees affected by a given set of controls. Larger establishments may have more than four workers whose exposures are reduced by a single control, and smaller establishments may have fewer than four. However, OSHA agrees that this approach may result in an underestimate of costs for the smallest establishments. Because it is particularly important to consider the costs to the smallest establishments, OSHA has reduced the number of employees whose exposures are reduced per control by half for establishments with fewer than twenty employees, so that in those small establishments a given control is assumed to reduce exposures for two workers instead of four as assumed in the PEA. Because larger establishments may have greater numbers of employees whose exposures are reduced per control, this change may result in an overall overestimation of costs. (In the PEA, the overestimation of costs for larger facilities was partially offset by the underestimation of costs for smaller establishments. This is no longer the case in the FEA.) OSHA nevertheless believes the revised approach used in the FEA is better than the approach used in the PEA for purposes of capturing economic impacts on smaller establishments, even though it may result in aggregate costs being overestimated.

Variability

Some commenters argued that both OSHA's technological feasibility and cost analyses were flawed because OSHA neglected to address the day-to-day variability of exposure measurements. By failing to address the issue of variability, these commenters argued, OSHA grossly underestimated the costs of engineering controls. These commenters reported that silica exposures would have to be controlled to levels considerably lower than the proposed (new) PEL in order to account for the variation in exposures across jobs and from day to day (*e.g.*, Document ID 2307, Attachment 2, p. 202; 2308, Attachment 7, p. 2; 2308, Attachment 8, p. 6; 2379, Attachment 4, p. 1; 2291, p. 11; 2195, pp. 26–27; 2503, p. 2; 2222, Attachment 1, p. 1). For example, in response to a written question about the activities in which employers were able to achieve the proposed (new) PEL ''most of the time,'' AFS objected to the premise of the question, noting that ''[s]everal foundries have received citations for exposures above the current PEL on operations or tasks for which the proposed PEL is achieved most of the time'' (Document ID 2379, Appendix 1, p. 18). AFS argued that OSHA's non-compliance model of enforcement requires employers to reduce average exposures to half the PEL in order to have confidence that exposures will never exceed the PEL (Document ID 2379, Appendix 2, p. 29). The Asphalt Roofing Manufacturing Association (ARMA) made a similar point and said that the majority of asphalt roofing plants operated by its members have some exposures over the PEL of 50 μg/m^3, even if it's a ''relatively small incidence'' (Document ID 2291, p. 11).

Both AFS and ARMA offered estimates of the magnitude of this variability by measuring the statistical variance of exposures. AFS stated that to assure 84 percent confidence in compliance with the preceding PEL, the mean exposures in some specific jobs in specific foundries would need to be below half that PEL, and that the ''mean level necessary to achieve the 95 percent confidence of compliance could not be determined but is significantly below one half the PEL'' (Document ID 2379, Appendix 1, p. 23).

ARMA examined the distribution of silica exposures in over 1,300 samples from 57 asphalt roofing facilities. These data showed that even though the median exposures for all jobs were below the new action level of 25 μg/m^3, a total of 9 percent of all samples were above the new PEL of 50 μg/m^3 (Document ID 2291, p. 5, Table 1). ARMA also provided an estimate of the ''lowest strictly achievable level'' (meaning a level not to be exceeded more than 5 percent of the time) which varied by job classification from 67 to 310 μg/m^3 (Document ID 2291, p. 9, Table 2).

One serious problem with the ARMA analysis is that the discussions of variability and the estimates of mathematical variance are based on results either from different facilities with potentially different levels of controls or from all job categories within one facility. The key issue for assessing the importance of variability is the variance within a given job category in a specific establishment with specific controls. The methodology employed is such that even if individual job categories or individual facilities had no variance, pooling data across facilities would create variance.

ARMA estimated that sufficiently controlling variation would require investment in capture vents, duct work, and dust collection systems costing up to $2.1 million each in initial costs per manufacturing line (Document ID 2291, p. 12). AFS did not provide a cost estimate solely for sufficiently controlling variation.

The AFL–CIO disagreed with industry's arguments and instead argued that the best way to reduce variability was not simply to add additional engineering controls because, as explained earlier in the discussion of URS's comments on the per-worker cost basis, overexposures are not random:

> The worker-to-worker variation is explainable and controllable: Workers use different methods, they may take different positions relative to ventilation systems, they may use different work practices, and they may be subject to fugitive emissions (carryover from adjacent silica emitting processes). These differences in conditions can be observed by the industrial hygienist collecting the air sample, compared to exposure levels, and changed. Day-to-day variation for the same worker is caused by variation in materials, ventilation systems, production rate, and adjacent sources showing such variation. Sometimes these variations can be large, based on breakdowns of ventilation, process upsets and blowouts (Document ID 4204, p. 40).

OSHA's enforcement policies are discussed in Chapter IV of the FEA and in this preamble. Variability of exposures is potentially a cost issue when there are technologically feasible controls that have costs not otherwise accounted for that could further reduce environmental variability. If it is not technologically feasible to reduce variability then there will be no further costs. For example, if an employer has

installed all feasible controls, there are no additional costs for engineering controls because there are no additional controls to purchase, regardless of variability. On the other hand, an employer who has a median exposure level of 80 percent of the PEL with frequent excursions above and who could feasibly reduce variability would be required to do so.

As noted above, those (AFS, ARMA) who argued that OSHA had underestimated costs by failing to account for exposure variability, in general, assumed that the best approach to reducing variability would be to increase the levels of LEV to reduce the average exposure level to half of the PEL or less, without examining the origin of the variability.

OSHA agrees with the AFL–CIO that variability in exposure is likely controllable by examining the origins of the variability. One origin is poor work practices. To improve work practices, employers could observe work practices when monitoring takes place; determine which work practices are associated with high exposures; and modify those work practices found to lead to high exposures. Variability can also be the result of a failure of controls not functioning properly, either resulting from sudden failures or from gradual deterioration of performance over time. The latter can be prevented by good maintenance.

Both in its cost assessment for the proposal and in the modifications made for this final rule, OSHA has taken account of the costs necessary to reduce unusual and exceptionally high exposure levels and thus reduce some sources of variation. As discussed in the cost of ancillary provisions, OSHA has estimated costs for exposure monitoring that include the time for observation of the worker. OSHA has also estimated costs for training to assure good work practices, and has increased the estimated length of training in general industry to ensure that the time is sufficient for training on work practices. In this section, OSHA has costed LEV, LEV maintenance, and the need for replacement LEV to assure that the LEV will function properly. OSHA has therefore already accounted for a variety of costs associated with steps that can be taken to reduce variability in exposures.

Substitution of Low- or Non-Silica Inputs

PEA Estimate

For several industries, employers might lower silica exposures by substituting low- or non-silica inputs for existing inputs. While this option can be an extremely effective method for controlling silica exposures in many industries, OSHA did not cost this option in the PEA. OSHA determined that there were often complicating factors that restricted the potential for broad substitution of non-silica-containing inputs for silica-containing inputs throughout the affected industries. It is possible that the same product quality cannot be maintained without using silica. Some products made with substitute ingredients were judged to be inferior in quality and potentially not viable in the market. In addition, a substitute silica ingredient might introduce adverse health risks of its own. Further, in several instances, the availability of reasonably inexpensive alternative non-silica ingredients was well known but the alternative was not selected as a control option by most firms. In light of these concerns, OSHA decided not to include the option of non-silica substitutes in estimating the cost of the proposed rule.

Comments and Responses on Substitution

Some commenters complained that OSHA's analysis did not account for the costs of substitution (Document ID 2264, Attachment 1, p. 27; 2379, Attachment 2, p. 6; 3485, p. 25; 3487, p. 17).

OSHA considered the comments on the issue but has decided to adhere to the approach taken in the PEA. OSHA did not take account of the costs of substituting other substances for silica, because, while such substitution might have substantial benefits and avoid the need for engineering controls, OSHA determined that, in most situations, substitution is not the least costly method of achieving the proposed or new PEL (Document ID 2379, Attachment 2, p. 6). As a result, OSHA's final cost analyses do not account for the possibility that firms would choose to substitute for substances other than silica. To the extent that substitutes are the least costly solution in some situations, OSHA has overestimated the costs.

Cost of Air Quality Permit Notification

The Agency received comments suggesting that foundries and other manufacturing plants would be required by the Environmental Protection Agency (EPA), or other federal or state environmental authorities, to incur an administrative cost to ensure their systems are compliant with relevant EPA regulations. Commenters expressed concern that the permitting process itself could be a major undertaking, made worse by difficult compliance deadlines. Given that the final rule provides extra time for planning and permitting, OSHA has examined the potential impacts of the new rule and finds that the commenters are overstating the potential for such costs. The argument for significant permitting costs was typically combined (*e.g.*, Document ID 2379, Appendix 3) with an argument that the Agency underestimated the amount of ventilation required to comply with the final rule; comments on ventilation requirements are dealt with in great detail elsewhere in this chapter.

Upon investigation, while OSHA agrees that it would be appropriate to recognize an administrative burden with respect to the interfacing environmental regulations, the Agency believes that many of the commenters' concerns were overstated. First, many control methods needed to comply with the final rule will not require alterations to existing ventilation systems. As discussed earlier in Chapter V of the FEA, work practices, housekeeping and maintenance are important components in controlling exposures; in many cases existing ventilation, as designed and permitted with the environmental authority, is adequate, but needs to be maintained better. In addition, most establishments, particularly smaller ones, will continue to have particulate emissions levels that fall below the level of EPA permit requirements. In the case of large facilities that do not, the changes will be on a sufficiently small scale that they will not require elaborate repermitting, but will only require minor incremental costs for notifying the environmental authorities, or in some cases, submitting a ''minor'' permit (*see http://www2.epa.gov/nsr* and *http://www2.epa.gov/title-v-operating-permits*). Taking into account the preceding silica PEL and the estimate that baghouses will capture 99 percent of silica emissions (Document ID 3641, p. VII–19), OSHA concludes that it is unlikely that facilities will encounter a need for significant air permit modifications.

The Agency recognizes, however, that there will be minor incremental costs for notifying environmental authorities. While many establishments in the United States may have no requirement to do so, the Agency has conservatively assumed that all establishments with twenty or more employees in most industries will need to dedicate a certain amount of time to preparing a one-time notification to environmental authorities to ensure that their air permits accurately reflect current operating conditions. OSHA has determined that small establishments

would generally lack the large scale industrial facilities requiring permits, and that the few that might require such permits would be balanced out by the likely inclusion of medium establishments that do not actually require permits for their emissions. The industries excluded were those that generally lack large scale industrial facilities, or that do not produce a concentrated, as opposed to diverse or unconsolidated, emission source. The excluded industries were hydraulic fracturing, shipyards, dental equipment and labs, jewelry, railroads, and landscaping.

To allow for adequate administrative time for creating and submitting the notification, at those facilities that could potentially incur costs, OSHA allocated 20 hours to establishments with 20 to 499 employees and 40 hours to establishments with 500 or more employees. A manager's loaded hourly wage rate of $74.97 was applied to estimate the cost to employers (BLS, OES, 2012, Document ID 1560). The costs per establishment were estimated at approximately $1,500 per medium establishment and $3,000 per large establishment. Because both new permit applications and permit modifications are minor administrative chores, OSHA's cost estimates are sufficient to cover either case.

Costs for Specific Engineering Controls

Ventilation Costs

PEA Estimates

In the PEA, OSHA determined that at many workstations, employers needed to improve ventilation to reduce silica exposures. The cost of ventilation enhancements estimated in the PEA generally reflected the expense of ductwork and other equipment for the immediate workstation or individual location and, potentially, the cost of incremental capacity system-wide enhancements and increased operating costs for the heating, ventilation, and air conditioning (HVAC) system for the facility.

In considering the specific ventilation enhancements for given job categories the PEA estimated the type of LEV and the approximate quantity in cubic feet per minute (cfm) of air flow required to reduce worker exposures.

To develop generally applicable ventilation cost estimates for the PEA, a set of workstation-specific and facility-wide ventilation estimates were defined using suggested ventilation approaches described in the American Conference of Governmental Industrial Hygienists (ACGIH) Industrial Ventilation Manual, 24th edition (Document ID 1607). With the assistance of industrial hygienists and plant ventilation engineering specialists, workstation estimates of cfm were derived from the ACGIH Ventilation Manual, and where not covered in that source, from expert judgements for the purpose of costing LEV enhancements (Document ID 1608, p. 29).

Over a wide range of circumstances, ventilation enhancement costs, which included a cost factor for HEPA filters and baghouses, where needed, varied from roughly $9 per cfm to approximately $18 per cfm (Document ID 1608, p. 29). Because of a lack of detailed data to estimate the specific ventilation installation costs for a given facility, an estimate of the likely average capital cost per cfm was used and applied to all ventilation enhancements. Based on discussions with ventilation specialists, $12.83 per cfm was judged to be a reasonable overall estimate of the likely capital costs of ventilation enhancements (Document ID 3983, p. 1).

OSHA applied the per-cfm capital cost estimate to estimated cfm requirements for each workstation. By using the unit value of $12.83 per cfm, the cost estimates for each ventilation enhancement included both the cost of the LEV enhancement at the workstation and the contribution of the enhancement to the overall facility ventilation system requirements. That is, each ventilation enhancement at a workstation was expected to generate costs to the building's general ventilation system either by requiring increased capacity to make up for the air removed by the LEV system or to filter the air before returning it to the workplace.

For operating costs, engineering consultants analyzed the costs of heating and cooling system operation for 12 geographically (and therefore, climatologically) diverse U.S. cities. The analysis, presented in Table 3–2 in the ERG report (Document ID 1608, p. 30), showed the heating and cooling British Thermal Unit (BTU) requirements for 60-hours-a-week operation (12 hours a day, Monday through Friday) or for a continuous 24-hour-a-day, year-round operation, with and without recirculation of plant air. Facilities that recirculate air have much lower ventilation system operating costs because they do not need to heat or cool outside air to comfortable inside temperatures.

In the PEA, ventilation operating costs were based on a weighted average of the costs of four operating scenarios: (1) No recirculated air, continuous operation; (2) no recirculated air, operating 60 hours per week; (3) recirculated HEPA filtered air, continuous operation; and (4) recirculated HEPA filtered air, operating 60 hours per week. These scenarios were chosen to reflect the various types of operating system characteristics likely to be found among affected facilities. The weights (representing the share of total facilities falling into each category) and operating costs per cfm for each of these scenarios are shown below in Table VII–11–1:

Table V-11-1: Ventilation Operating Cost Averaging Assumptions in the PEA		
Type of system	**Average Cost per CFM**	**Share of Total**
No recirculated air, continuous operation	$15.55	5.0%
No recirculated air, operating 60 hours per week	$5.78	15.0%
Recirculated HEPA filtered air, continuous operation	$1.40	20.0%
Recirculated HEPA filtered air, operating 60 hours per week (cost proportional to the number of hours operated)	$0.50	60.0%
Weighted average operating cost per CFM	**$2.22**	

Source: Document ID 1781, Workbook #6 - GI Unit Costs_Active, Vent op costs.

The national average annual operating cost per cfm was estimated to be $2.22. This estimate was a weighted average of the operating costs for facilities that recirculate air and those that require make-up air. The operating costs for HEPA-filter recirculated air were estimated at $0.50 per cfm for facilities operating 60 hours per week and $1.40 per cfm for those continuously operating 24 hours per day. The operating costs for facilities that do not recirculate air were $5.78 per cfm for those operating 60 hours per week and $15.55 per cfm for those operating continuously. In generating these estimates, it was judged that 80 percent of facilities would recirculate airflow and 20 percent would not, and that 75 percent within each group operate for 12 hours per day on weekdays, with the remainder operating continuously, year-round, for 24 hours a day.

OSHA also added a maintenance factor to the operating cost estimates, which was 10 percent of the capital cost investments of $12.83 per cfm for ventilation systems. As a result, the total annual costs per cfm, excluding annualized capital costs, were estimated to be $3.50 (weighted average operating costs of $2.22 plus annual maintenance costs of 10 percent of $12.83).

Underlying the cost results was the assumption that, over the course of the proposed one-year compliance period for engineering controls, employers would schedule installation of ventilation to minimize disruption of production, just as they would with any modification to their plants.

Comments and Responses on Local Exhaust Ventilation Issues: Need for a Complete New System

Local exhaust ventilation represents one of the major costs associated with engineering controls in both the PEA and in the FEA. Commenters raised issues both about OSHA's PEA estimates of the unit costs of LEV and about the adequacy of OSHA's estimates of the volume of LEV that would be needed to adequately control silica exposures.

URS, testifying on behalf of ACC, argued that any firm that would be utilizing LEV to meet a PEL of 50 μg/m^3 would need to remove any existing LEV and install an entirely new LEV system. Thus, in URS's estimation, there would be no incremental addition of LEV. In a discussion of the URS approach during OSHA's informal public hearings, OSHA asked the URS representative to confirm that his organization commented that when a majority of workers are exposed over the PEL, the existing controls must be replaced instead of enhanced:

> MR. BURT: I want to be sure I understand what that's saying. Let's say you encountered a situation in which there were four workers. Two were exposed at 35, two at 60. You would scrap all of the controls and start over again. That's what it seems to be saying.
> [. . .]
> MR. WAGGENER: [Y]es, that they would need to be replaced with a more adequate system (Document ID 3582, Tr. 2109–2110).

OSHA's examination of the spreadsheets URS provided documenting its independently developed cost estimates shows that, in all cases where any employee in an establishment was exposed above 50 μg/m^3, URS assumed that the employer would need to install a complete new LEV system and included the costs for installing and operating this entirely new system (Document ID 2308, Attachment 8, pp. 13–14).

John Burke from OSCO Industries took a different approach to the question that better illustrates the options that OSHA believed to be available when it developed the PEA estimates:

> A single large dust collector is probably already handling the exhausting of the entire sand conditioning system. Most likely all the pick-up points referenced in the economic analysis already have suction being applied and yet there is still an overexposure. What do you do and how much is that going to cost? If the sand system operator is overexposed then you could first evaluate work practices controls. If work practice controls are unsuccessful and additional suction is needed, that suction is going to be very expensive! If your environmental operating permit allows it you may be able to tweak the performance of the dust collector. There may be some things you can

do to tweak the capacity of your existing dust collector to bring it up to exactly its permitted air volume or you might have to enlarge your dust collector (Document ID 1992, p. 6).

OSHA agrees with Mr. Burke. As discussed above, there are usually a wide variety of ways to improve existing controls before removing and reinstalling an LEV system. As a result, OSHA finds the URS approach unrealistic and likely to significantly overestimate costs.

Comments and Responses on the Volume of Controls Needed

One commenter, URS, questioned OSHA's estimates of the volume of additional LEV that would be needed to comply with the standard. URS, testifying for ACC, reported that OSHA's estimates in the PEA were too low as compared to the recommendations in Table 6–2 of the ACGIH Ventilation Manual (28th Edition). They criticized OSHA's estimates saying that OSHA routinely underestimated required capture velocities by at least a factor of two for particles with high (conveyor loading, crushing) or very high (grinding, abrasive blasting, tumbling) energies of dispersion (Document ID 2308, Attachment 8, pp. 12 and 14). URS said that ''the capture velocities for LEV systems in OSHA's models were often based on the minimum recommended velocity,'' that OSHA's estimated additional LEV was too low because ''the ACGIH capture velocity values used by OSHA were first developed and published many years ago'' and were not sufficient to control dust to the levels OSHA is now proposing, and that ''the velocity values used in OSHA's cost model are most likely undersized by a factor of 2 or more'' (Document ID 2308, pp. 11–12). Other than its own supposition, URS did not identify an alternative source for OSHA to use as the basis for estimates of ventilation capacity necessary to control silica exposures.

In response to these comments, and in order to determine whether ACGIH recommendations had changed between the 24th edition (which OSHA used to develop estimates in the PEA) and the more recent 28th edition, OSHA checked its estimated volumes against those in the more recent ACGIH Ventilation Manual (Chapter 13 in the 28th edition (Document ID 3883)). In the 24th edition of the Manual, ACGIH provided a single recommendation for ventilation capacity rather than a range. In the PEA, OSHA adopted this recommendation and did not choose a value from within a range of values. The 28th edition of the Manual provides more flexibility in system design and specification and incorporates a recommended range. However, OSHA determined that the ventilation capacity estimates did not change between the 24th edition of the Manual and the 28th edition. In most cases, OSHA's estimated volumes were identical to those recommended by ACGIH. The exceptions were situations in which ACGIH provided no recommendation (in which case OSHA relied on recommendations of industrial hygienists), and situations in which the technological feasibility analysis recommended additional volumes of LEV capacity above what employers were typically using. In the latter situations, OSHA estimated that an additional 25 percent of the ACGIH specification would be necessary to adequately control silica exposures (*See* Exhibit: *Comparison of OSHA CFM Volumes to ACGIH Values*, available in Docket OSHA–2010–0034 at *www.regulations.gov*).

URS argued that silica was different from other substances LEV might be applied to in ways that would call for higher volumes of ventilation (Document ID 2308, Attachment 8, p. 14). However, in all cases involving silica (such as shake-out stations), the ACGIH Manual recommended the volumes used by OSHA and criticized by URS.

OSHA's estimates of the ventilation capacity necessary to control silica exposures relied on a detailed set of recommendations provided by ACGIH while URS simply asserted that these values are ''most likely undersized by a factor of 2 or more'' without providing additional evidence to support this (Document ID 2308, Attachment 8, p. 12). Based on these findings, OSHA has determined that the ACGIH recommendations constitute the best available evidence and has maintained the estimates of ventilation capacity from the PEA for the FEA.

Comments Providing Alternative Ventilation System Cost Estimates

Other commenters provided much higher costs than OSHA's estimates but without providing any background to allow OSHA to put those costs in context. It is difficult for OSHA to evaluate a cost estimate without information on the size of the facility, the estimated volume of air, and the exposure levels before and after the LEV was installed.

The Interlocking Concrete Pavement Institute (ICPI) commented that OSHA underestimated compliance costs because ''[o]ne ICP manufacturer reported that it could cost $150,000 to acquire and install highly efficient vacuum and water dust-control systems'' and other manufacturers reported similarly high costs (Document ID 2246, p. 11). At the public hearings, OSHA sought clarification on the assumptions underlying the ICPI cost estimate, and the ICPI representative stated that $150,000 was a mid-range estimate. The representative also confirmed that this was the cost of an entirely new system:

MR. BLICKSILVER: [D]oes this actually represent the incremental cost associated with complying with OSHA's proposed rule? . . . Or is this an overall cost for dust control in these manufacturing plants?

MR. SMITH: The latter (Document ID 3589, Tr. 4407–4409).

In a follow-up verbal exchange, OSHA requested that ICPI analyze its survey data to produce median values for the range of cost estimates and submit their analysis as a post-hearing comment (Document ID 3589, Tr. 4409). However, no ICPI comments appeared in the record following the Institute's testimony at the hearings.

Similarly, OSHA asked Mr. Tom Slavin, testifying for AFS, for additional information from AFS on the many cost estimates for individual foundries that it had included in its comments:

MR. BURT: You provide many examples of cost to specific foundries of specific activities. I would like to suggest that those can be most useful if we have data on the size of the firm in question, the type of foundry if that's appropriate, and what they were trying to accomplish with this effort.

Were they at 400 and trying to get to 100, at 100 trying to get lower? Something that puts it in context would again make these many, many helpful quotes much more useful.

Size is just critical, just because of the fact that when we don't know whether we're talking about 20 or 200 people in a foundry really affects what you want to do with those cost estimates. And that one's relatively simple, size of firm, type of foundry if you have it, what they were trying to do with that effort (Document ID 3584, Tr. 2773–2774).

Later in the exchange, OSHA requested information on ''the components of [AFS's estimated cost per cfm of additional ventilation] that would be capital cost, installation cost, and then any other operating costs you have'' (Document ID 3584, Tr. 2784). OSHA received no response to this request.

Unfortunately, it is almost impossible for OSHA to make use of commenters' estimates of costs or volume of LEV systems without information on the size of the facility and on what the resulting system accomplished in terms of reducing exposure levels. OSHA consistently requested this kind of

information, but did not receive it. As shown in the discussion of alternative estimates of costs by small entity representatives during the SBAR Panel (discussed below), even estimates that appear higher than OSHA's average costs can be consistent with those costs when the full context for the estimates is examined.

Comments and Responses on Unit Cost per CFM

Many commenters thought that OSHA's unit costs for ventilation were too low. With respect to the annualized value of the capital costs plus operating and maintenance costs of $5.33 that OSHA used in the PEA, AFS stated:

> The PEA uses an annual cost factor of $5.33 for ventilation, including ducting and bag house operation [...] is far below foundry experience. A group of foundry ventilation managers and ventilation experts estimated the annual cost per CFM at $20 for exhaust alone and another $6–10 for makeup air critical to achieving the lower PEL. The cost to meet the new U.S. Environmental Protection Agency (EPA) dust loading criteria increases the exhaust annual cost to $25 per CFM. Any new installation would be expected to design to the new criteria even if not yet required to do so for that specific jurisdiction (Document ID 2379, Appendix 3, p. 9).

URS, commenting on behalf of ACC, estimated the annualized cost of LEV to be $27 per cfm, and increased OSHA's original estimate of capital costs from $12.83 to $22 per cfm for the purpose of URS's cost estimate (Document ID 2308, Attachment 8, pp. 13–14).

Many other commenters from industry suggested unit costs for additional LEV. For example, AFS provided independent estimates of annualized costs of $20 to $25 per cfm and URS estimated $22 to $27 capital costs per cfm (Document ID 2379, Appendix 1, p. 45; 2308, Attachment 8, p. 14; 2379, Appendix 2, p. 13; 2503, p. 2; 2119, Attachment 3, p. 4; 2248, p. 8; 3490, p. 3; 3584, Tr. 2779).

OSHA agrees that there can be a wide range of both capital and operating costs associated with LEV. Capital costs will vary according to such factors as the exact nature of the ventilation (including the design of the slot, hood, or bagging station), the volume of materials to be handled by the ventilation, and the length of the ductwork necessary. OSHA also would like to clarify that, as shown in OSHA's spreadsheets (OSHA, 2016), where there are major structural changes associated with a control, such as automation, a new bagging station, or conveyor closure, these costs are estimated over and above the basic capital costs of LEV. Annual operating costs vary according to climate, hours of operation, and the extent to which air is recirculated. To examine these possible costs, OSHA reviewed the thoroughly documented LEV costs presented in its Final Economic Analysis for the Occupational Exposure to Hexavalent Chromium Standard (Document ID 3641). In that FEA, OSHA's estimates of the capital costs for LEV (updated to 2012 dollars) averaged more than $20 per cfm when major work station changes, such as automated bag slitting stations, were included in the cost of LEV. Ordinary additional LEV without major workstation changes was estimated to have an average capital cost of $9 per cfm in 2012 dollars. Operating costs in that rulemaking were estimated to be somewhat higher than estimated here, but combined annualized costs (capital plus operating costs) were approximately the same (*See* Exhibit: *Analysis of LEV Costs from Hex Chrome*, available in Docket OSHA–2010–0034 at *www.regulations.gov*).

OSHA agrees that the capital costs of some kinds of LEV that involve significant workstation modifications or even automation can exceed $20 per cfm, but finds an average of $13.34 (in 2012 dollars) per cfm in capital costs to be reasonable given that some kinds of LEV installation can cost as little as $3 to $5 per cfm. OSHA also finds the operating cost estimates used in the FEA to be a reasonable average across a very wide variety of circumstances.

Housekeeping and Dust Suppression Costs

PEA Costs

For a number of occupations, the technological feasibility analysis in the PEA indicated that improved housekeeping practices were needed to reduce silica exposures. The degree of incremental housekeeping depended upon how dusty the operations were and the appropriate equipment for addressing the dust problem. The incremental costs for most such occupations reflected labor associated with additional housekeeping efforts. Because incremental housekeeping labor was required on virtually every work shift by most of the affected occupations, the costs of housekeeping in the PEA were significant. The PEA also estimated that employers would need to purchase HEPA vacuums and to incur the ongoing costs of HEPA vacuum filters. The time needed for such housekeeping varied from five to twenty minutes per affected worker per day. Appendix V–A in the PEA provided detailed specifications on the application of housekeeping and other dust-suppression controls in each occupational category and the sources of OSHA's unit cost data for such controls.

For some indoor dust suppression tasks, it was assumed that dust suppression mixes—often sawdust-based with oil or other material that adheres to dust and allows it to be swept up without becoming airborne—were spread over the areas to be swept. For these products, estimates were made of usage rates and the incremental times necessary to employ them in housekeeping tasks.

For outdoor dust suppression, the PEA determined that workers must often spray water over storage piles and raw material receiving areas. The methods by which water is provided for these tasks can vary widely, from water trucks to available hoses. It was judged that most facilities would make hoses available for spraying and that spraying requires a materials-handling worker to devote part of the workday to lightly spray the area for dust control.

The PEA did not include any costs for thorough cleaning designed to remove accumulated dust, either as a one-time cost or as an annual cost.

Comments and Responses on Costs of Routine Housekeeping and Initial Cleaning

Commenters had a number of issues with respect to how OSHA treated the costs of housekeeping, including the time and equipment needed for vacuuming, the need for professional floor to ceiling cleaning, and the costs of the ban on dry sweeping.

Comments and Responses on Costs of Routine Housekeeping

With respect to the use of HEPA vacuums, AFS commented that due to the volume of sand involved, foundries often use vacuum systems that cost $45,000 instead of the $3,500 estimated by OSHA in the PEA (Document ID 4229, Attachment 1, p. 23). Several commenters reported that HEPA semi-mobile central vacuum systems cost more than $40,000 to purchase and cost approximately $4,000 per year to maintain, and that sweeping compound costs approximately $4,000 per year (Document ID 2384, p. 7; 2114, Attachment 1, p. 4). Several others noted that acquiring HEPA vacuums and employee time for vacuuming would be expensive (Document ID 2301, Attachment 1, p. 74; 3300, pp. 4–5; 2114, Attachment 1, p. 4).

OSHA's costs are for improved housekeeping, beyond the necessary tasks related to dealing with the large volumes of sand used in foundries. For this final rule, OSHA estimates the costs

of additional housekeeping as those necessary for overexposed workers to spend 10 minutes vacuuming their immediate work areas with a 15-gallon HEPA vacuum. It is possible that a large firm may find a dust handling system or a semi-mobile central vacuum system less expensive than having individual workers equipped with smaller capacity HEPA vacuums spend additional time performing housekeeping on each shift.

With respect to the shipbuilding sector, OSHA found that it had not accounted for the costs of HEPA vacuums for abrasive blasting helpers. OSHA has added costs for the vacuums, but not for the time spent performing housekeeping as the vacuums replace dry sweeping.

As to the possible costs of the ban on dry sweeping, OSHA has modified this prohibition in ways that should avoid significant costs in situations where dry sweeping is the only effective method of housekeeping.

Comments and Responses on Costs of Initial Cleaning

URS, testifying for ACC, questioned OSHA's omission of ''professional cleaning'' from its cost models for some industries, noting that professional cleaning was identified in the PEA as necessary for some industries to achieve the PEL (Document ID 2308, Attachment 8, p. 12). URS also provided estimates of the cost of professional cleaning:

> Based on communications with several industries, URS estimates that a thorough annual professional cleaning will cost about $1.00 per square foot of the facility process operations area.
>
> . . . A professional cleaning can take several days to accomplish [. . .] For square footage, URS assumed 20,000 square feet for very small facilities, 50,000 square feet for small facilities, and 200,000 square feet for large facilities (Document ID 2308, Attachment 8, p. 24).

Initial thorough facility cleaning and rigorous housekeeping are supplemental controls and work practices addressed in the technological feasibility analysis for the following application groups: Concrete Products, Pottery, Structural Clay, Mineral Processing, Iron Foundries, Nonferrous Sand Foundries, and Captive Foundries. OSHA failed to include the costs of a thorough initial cleaning in the PEA, but has developed estimates of these costs for the FEA in response to the URS comment. The final standard sets the performance objective of achieving the PEL using engineering controls, work practices, and where necessary, respiratory protection, and, with respect to facility cleaning and housekeeping, the rule does not mandate that firms hire outside specialists. To estimate the final costs for initial thorough facility cleaning, OSHA first developed an analysis of average production floor space in square feet for two plant sizes based on data on plant floor space and employment for individual facilities reported in various NIOSH control technology and exposure assessment field studies (OSHA examined Document ID 215; 216; 268; 1373; 1383; 3786; 3996; and 4114. The analysis is in Exhibit: *Analysis of Plant Floor Space*, available in Docket OSHA–2010–0034 at *www.regulations.gov*).

For the purpose of estimating cleaning costs, OSHA characterized establishments with fewer than twenty employees as very small establishments, and characterized establishments with twenty or more employees as larger establishments.

OSHA determined, based on a review of the data in the NIOSH field studies, that production floor space averages 725 square feet per employee (*See* Exhibit: *Analysis of Plant Floor Space*).

For very small establishments with fewer than 20 employees, OSHA used an average of 7 employees per establishment. For larger establishments, OSHA used an average of 80 employees. (These estimates of the number of employees are based on OSHA (2016), which shows that the average number of employees for establishments with fewer than 20 employees is 7 employees and that the average number of employees for establishments with more than 20 employees is 80 employees.) Based on these parameters, OSHA's floor space model found that the typical floor space for very small establishments is 5,075 square feet and for larger establishments is 58,000 square feet.

ERG spoke with a representative of an upper-Midwestern firm specializing in the industrial cleaning of foundries and related facilities (Document ID 3817, p. 2). According to that representative, cleaning costs depend on numerous factors, such as the distance to the facility that needs to be cleaned, the size and number of machines and pieces of equipment present, the types of required cleaning activities, and the presence of confined spaces. The representative described one of his company's clients as a sand-casting foundry that produces 42,000 tons of gray and ductile iron castings per year in a 210,000 square foot facility. According to the representative, a crew of two technicians cleans the facility every 2 to 3 weeks at a cost of $2,200 to $3,500 per cleaning, which requires one day, or roughly $0.01 to $0.02 per square foot in 2014 dollars.

For the FEA, OSHA is estimating, based on data from the ERG field interviews, that it will take 4 to 5 days to perform a one-time initial cleaning (remove all visible silica dust) and that if the same facility is cleaned every 2 to 3 weeks it will take 1 day to clean it. At a cost of $0.02 per day per square foot, and using a cleaning duration of 5 days, OSHA calculated a cost of $0.15 per square foot in 2012 dollars for an initial thorough cleaning. This value is derived from inflating the 2003 estimate of $0.10 per square foot ($0.02 per day per square foot over 5 days) to 2012 dollars, which raised the cost to $0.12 per square foot. OSHA also allowed for an additional allotment of 25 percent of the estimated cost of $0.12 per square foot (in 2012 dollars) to ensure that the cleaning was sufficiently thorough to achieve compliance, increasing the total from $0.12 to $0.15. OSHA judges that this is a reasonable average for the range of facilities to be covered, especially given that some annual cleaning is probably already occurring at most facilities and therefore the full cost of cleaning would not be attributable to this rule. The costs here are applied to represent an incremental cleaning beyond that employed for normal business purposes.

As discussed earlier in this chapter, URS, an engineering consultant to ACC, estimated that a thorough annual professional cleaning will cost about $1.00 per square foot of a facility's process operations area. URS provided no specific reference for that unit estimate other than that it communicated with industry representatives (Document ID 2308, Attachment 8, p. 24). The data OSHA used to develop its cost estimates are based on interviews with a company that provides housekeeping services rather than companies that may or may not have purchased such services. OSHA's estimated costs for a thorough initial cleaning are over five times the costs of a thorough cleaning where there is just few weeks' worth of accumulated dust. Greater accumulations during an initial cleaning do not mean that the initial cleaning will cost 50 times the cost of a more basic/regular cleaning, as much of the cost of the initial cleaning will be due to the time spent going over the entire facility with the appropriate cleaning devices—a cost that is fixed by area and not by accumulation. OSHA therefore rejects the URS unit estimate of $1.00 per square foot as not representative of a typical cost for initial thorough facility cleaning, particularly for firms that choose to use in-house resources. Nonetheless, OSHA

acknowledges that unique circumstances may create higher unit costs than the value OSHA is using in the FEA. OSHA also acknowledges that the cost of cleaning per square foot probably declines as facility size increases (Document ID 4231, p. 4). The paucity of data on square footage for the affected facilities, however, did not allow for further modeling of cleaning costs.

For this final analysis of costs for initial thorough facility cleaning, OSHA estimated that an upfront, one-time, extensive servicing (using vacuum and wash equipment) to rid the production area of respirable crystalline silica during plant turnaround or other downtime would cost $0.15 per square foot (including the additional allowance to ensure a sufficiently thorough cleaning) or $0.02 when annualized at 3 percent for 10 years, and OSHA applied that unit cost along with the average production floor space discussed above in OSHA's cost model (725 square feet per employee) to derive final costs for facility cleaning by application group. For the seven affected application groups, OSHA estimates that annualized initial thorough facility cleaning costs will range from just under $45,000 for Nonferrous Sand Foundries to $488,000 for Concrete Products. Across all seven affected application groups, OSHA estimates that annualized costs for initial thorough facility cleaning will total $2.8 million.

Conveyor Covers

The technological feasibility analysis in the PEA recommended reducing silica exposures by enclosing process equipment, such as conveyors, particularly where silica-containing materials were transferred (and notable quantities of dust can become airborne), or where dust is generated, such as in sawing or grinding operations. For the PEA, OSHA estimated the capital costs of conveyor covers as $20.73 (updated to 21012 dollars) per linear foot, based on Landola (2003, Document ID 0745) (as summarized in footnote a in Table V–3 of the PEA). OSHA estimated that each work crew of four affected workers would require 100 linear feet of conveyors. OSHA, based on ERG's estimates, calculated maintenance costs as 10 percent of capital costs. Based on the technological feasibility analysis, OSHA also included the cost of LEV on the vents of the conveyors for the structural clay, foundry, asphalt roofing, and mineral processing application groups, but not for the glass and mineral wool application groups.

URS commented that OSHA underestimated the length of conveyors by using 100 linear feet in its estimate, and suggested that the estimate of 200 feet that it used as the basis for its estimates was still an underestimation for some foundries (Document ID 2307, Attachment 26, Control Basis and Control Changes tabs). URS maintained OSHA's estimate of $20.73 per linear foot in its own calculations. However, it appears that URS did not understand that OSHA estimated 100 linear feet of conveyors for every 4 workers, not 100 linear feet of conveyors for an entire affected establishment. Further, the URS comment indicated that 100 linear feet was an underestimate for ''medium and large foundries.'' But because OSHA's estimate of 100 linear feet is for every four workers, OSHA actually estimated much longer conveyor lengths for larger facilities with more workers. OSHA has determined that its estimate of 100 linear feet for every four workers at a cost of $20.73 per linear foot is a reasonable approach for estimating the costs of conveyor covers.

Selected Control Options That Are Not Costed

Consistent with ERG's cost model, in the PEA OSHA chose not to estimate costs for some control options mentioned in the accompanying technological feasibility analysis in Chapter IV of the PEA. In these cases, OSHA judged that other control options for a specific at-risk occupation were sufficient to meet the PEL. AFS identified several control options for which OSHA did not estimate costs:

- Substitution of non-silica sand (V–A–51)
- Pneumatic sand handling systems (V–A–51)
- Didion drum to clean scrap for furnace operators (V–A–52)
- Non-silica cores and core coatings (V–A–52)
- Professional cleaning costs and associated downtime (V–A–52)
- Physical isolation of pouring areas (V–A–52)
- Modify ventilation system to reduce airflow from other areas (V–A–52)
- Automation of a knockout process (V–A–53)
- Automated abrasive blast pre-cleaning of castings for finishing operators (V–A–54)
- Wet methods (V–A–54)
- Low silica refractory (V–A–55) (Document ID 2379, p. 16)

Just because a control is mentioned in the technological feasibility analysis does not mean that OSHA has determined that its use is required—only that it represents a technologically feasible method for controlling exposures. The Agency developed cost estimates based on the lowest cost combination of controls that allows employers to move from an uncontrolled situation to meeting the new PEL. OSHA did not include the costs for possible controls that were either more expensive or were not necessary to achieve the PEL. OSHA (2016) describes in detail which controls were considered necessary to achieve the PEL. OSHA continues in the FEA to exclude costs for these kinds of more expensive possible controls.

Railroads

In its preliminary estimates, OSHA inadvertently applied the preceding general industry PEL of 100 μg/m^3 in its analysis of the railroad industry. Silica exposures among railroad employees, however, result from ballast dumping, which is track work that is generally subject to OSHA's construction standard and covered by the preceding construction PEL of 250 μg/m^3 (*see* discussion of railroads in Chapter III, Industry Profile). As a result, OSHA has changed its conclusion that there would be no incremental costs for railroads to meet the new PEL. OSHA has reassigned all costs previously assigned to meeting the preceding PEL to being incremental costs of meeting the new PEL. Although the railroad activities affected by the new silica rule will typically constitute construction work, OSHA has categorized all compliance costs for railroads with general industry costs under NAICS 482110 because the railroad industry is predominantly engaged in non-construction work and its NAICS code is not typically classified as a construction code.

Costs of Engineering Controls for Hydraulic Fracturing in the PEA

Both in the PEA and in the FEA, OSHA presented the methods of estimating the costs of controlling silica exposures during hydraulic fracturing separately from the engineering control costs for all other portions of general industry because there are some fundamental differences in the methodology OSHA used, and thus in the comments OSHA received on that methodology. In the PEA, OSHA began its analysis of hydraulic fracturing in the standard way of examining the set of engineering controls available to control employee exposures to silica. Unlike the way OSHA handled the rest of general industry, however, for hydraulic fracturing OSHA identified precisely which controls were necessary to go from current levels of exposure to the preceding general industry PEL of 100 μg/m^3 and then what further

controls would be necessary to go from the preceding general industry PEL of 100 μg/m³ to the new PEL of 50 μg/m³. OSHA took a different approach for this sector because the data available for this industry, as a result of an extensive set of site visits, were adequate to make this type of determination. OSHA determined that a combination of wet methods, partial enclosure, and LEV controls would be sufficient to meet a PEL of 100 μg/m³ for hydraulic fracturing. OSHA then determined that LEV controls at thief hatches and operator enclosures would be sufficient to reduce exposures during hydraulic fracturing from 100 μg/m³ to 50 μg/m³. The costs of these additional engineering controls were shown in Tables A–14, A–15, and A–16 for large, medium, and small fleets, respectively, in the PEA (the full derivation of the results in these tables can be found in ERG, 2013, Document ID 1712).

As discussed in the Industry Profile section of the FEA (Chapter III), the basic unit for analysis for this industry is the fleet rather than the establishment. Rather than allocating costs according to the proportion of workers above a given exposure level, as was done for the rest of general industry, for hydraulic fracturing the controls applied per fleet were judged to reduce the exposures of all workers associated with the fleet.

Public Comments on OSHA's Preliminary Cost Estimates for Engineering Controls in Hydraulic Fracturing

General Methodology

Though there were extensive comments on OSHA's estimates of engineering control costs for hydraulic fracturing, no commenter objected to the differences in methodology compared to OSHA's treatment of the other general industry sectors (as outlined above). Halliburton Energy Services, Inc. commented that OSHA's analysis ''lacks data'' (Document ID 4211, p. 5). As discussed in Chapter IV Technological Feasibility, OSHA agrees that there is limited experience with many possible controls. For this reason, OSHA has allowed this industry an extended compliance deadline of five years before they have to meet the new PEL with engineering controls. However, OSHA does not agree that this adds significant uncertainty to the costs analysis. The costs of the controls OSHA has examined, and especially those needed to go from the preceding general industry PEL to the new PEL can readily be ascertained. It is possible that the cost of some controls that have not yet been tested and that OSHA has not costed could be much lower than the costs OSHA estimated in the PEA and in the FEA.

Compliance Rate

In the joint comments submitted by the American Petroleum Institute and the Independent Petroleum Association of America (API/IPAA or ''the Associations''), the Associations disagreed with OSHA's estimated current compliance rate for the use of engineering controls. In the PEA, OSHA estimated a compliance rate of ten percent for engineering controls in this industry. In their comments the Associations said that ''ERG assumed that 10% of all hydraulic fracturing firms already utilize: (1) Baghouse controls; (2) caps on fill ports; (3) dust curtains; (4) wetting methods; and (5) conveyor skirting systems'' (Document ID 2301, p. 40, fn. 148).

While OSHA used a compliance rate of ten percent for all of these controls, it is not meant to represent that all prescribed controls are used in ten percent of firms. OSHA's compliance rates take into account that some well sites, as documented in Chapter IV of the FEA, were observed to be using a variety of controls that reduce dust levels, and as a result, those firms will not need to implement as many additional controls in order to achieve the new PEL. Further, as noted in Chapter IV of the FEA, the industry is constantly installing additional controls to reduce silica exposures. Thus the Agency sees no reason to change its estimate of current compliance. In any case, removing the assumption would make only a ten percent difference to the cost estimates, which would not be a change of large enough magnitude to threaten OSHA's conclusion that compliance with the final rule is economically feasible for the hydraulic fracturing industry.

Maintenance Costs

In the PEA, OSHA estimated that the life of most capital equipment would be ten years, and that maintenance and operating costs would range from ten to thirty percent of capital costs per year (ten percent being most common).

API/IPAA argued that the hostile, sandy environment of the well site shortens the useful life of equipment and increases maintenance costs. The Associations estimated that the useful life of equipment ranges from 5 years to 7.5 years and that annual operating and maintenance costs range from 10 percent to 25 percent of capital costs. While OSHA agrees that the oilfield environment is challenging and dusty, there is no evidence in the record that these environments are more challenging than other industrial settings where equipment lives of 10 years and operating and maintenance costs of 10 to 30 percent have been used as reasonable estimates.

Cost of Specific Controls

Dust Booths

In the PEA, OSHA estimated that there would need to be one dust booth for each sand moving machine, and that this would result in one dust booth for small fleets, three for medium fleets, and five for large fleets. In critiquing OSHA's cost analysis for hydraulic fracturing, API/IPAA disagreed with OSHA's estimates that only sand mover operators would need to utilize dust control booths in order to achieve the new PEL (Document ID 2301, p. 69). API/IPAA suggested that instead there would need to be one booth per affected worker and that only one worker could utilize a given booth. In the Associations' estimate this would mean that there would need to be 3, 8 and 12 booths for small, medium, and large fleets, respectively (Document ID 2301, Attachment 4, Dust Booths, row 9).

As discussed in the technological feasibility chapter of the FEA, OSHA agrees that workers other than sand mover operators will need to use dust booths. However, OSHA does not agree that a booth can only accommodate a single person. These booths are places of refuge and are not assigned to specific individuals. The technological feasibility chapter in the FEA determined that dust booths can accommodate more than one person per booth. Because OSHA agrees that more employees than sand mover operators will need booths, OSHA has raised its estimates of booths needed by size class from 1, 4, and 5 booths to 3, 6, and 8 booths. While this estimate of the number of booths is lower than that recommended by API/IPAA, OSHA finds that these booths can accommodate 2 persons per booth and thus can accommodate more workers than API/IPAA suggested.

In the PEA, OSHA estimated the transportation costs for booths as $37.25 per booth. API/IPAA disagreed. The Associations argued that a cost of $513 for a small fleet, which would only have one booth, would be more appropriate (Document ID 2301, p. 69). Most of the difference between API/IPAA's cost estimate for deploying dust control booths and OSHA's estimate is attributable to the fact that the Associations presented their cost per fleet and OSHA presented its cost per

booth. API/IPAA applied their estimate of the number of booths necessary at these worksites when deriving their estimate and they estimated about six times as many booths being necessary as OSHA did. However, after further examination of this cost, OSHA determined that the standard per-mile shipping rate that it used to estimate transportation costs in the PEA was applied incorrectly. This resulted in an estimate of transportation costs for booths in the PEA that was too low. OSHA has determined that the cost to transport dust booths presented by the Associations more completely captured the costs associated with transporting these booths. For the FEA, OSHA has accepted the Associations' per-fleet transportation cost of $513 for each booth and applied the cost to the Agency's estimate of the number of booths necessary to control silica exposures on well sites.

Water Misting

In the PEA, OSHA estimated that water misting system would be needed to control residual emissions from some releases from sand moving systems. These water misting systems were estimated to cost $60,000 per fleet to purchase and an additional 20 percent of the purchase cost for installation. API/IPAA incorrectly assumed that these water misting systems were intended to control all dust emission from truck traffic and other sources (Document ID 2301, pp. 69–70). This was not the case—dust suppression for truck and other traffic was costed at a much higher rate separately from water misting.

OSHA's cost estimates for misting systems were based on conversations with a mining dust control specialist who indicated the price and efficacy of available water misting systems (Document ID 1571). While API/IPAA disagreed with OSHA's costs, they did not offer any data to show an alternative cost, instead simply carrying OSHA's estimate for water misting systems forward in their analysis to arrive at their cost estimate (Document ID 2301, Attachment 3, Water Misting, cells K:O6 and J8). OSHA has determined that the equipment that formed the basis for its cost estimates in the PEA may not be durable enough to stand up to the wear from frequent loading, unloading, and transportation. Therefore, the Agency, based on its own judgement, has increased the estimated cost of a water misting system by 33 percent in order to account for the need for a more durable system. Based on this, OSHA's final cost analysis for hydraulic fracturing includes costs of $79,800 per fleet to purchase the equipment plus installation costs of $15,960 for installation (20 percent of the purchase price) for water misting equipment to control residual dust emissions from sand moving systems.

Costs of Transportation

In developing the costs for hydraulic fracturing firms to comply with this rule in the PEA, it was determined that the baghouse controls that are commercially available are integrated into sandmover units and therefore should not present any logistical difficulties for transportation purposes. However, in examining the costs to transport, assemble, and disassemble the control equipment, API/IPAA noted potential difficulties in adding baghouse controls to sandmovers, which are often nearly at weight limits for road movement (Document ID 2301, p. 71).

OSHA's determination about integrated units has not changed since the PEA. The existence of integrated units is further discussed in Chapter IV of the FEA, Technological Feasibility. OSHA notes that sandmover units are not the heaviest items transported by hydraulic fracturing firms, so the additional weight associated with baghouse controls would be insignificant in this context. These firms are highly experienced in moving the heavy, bulky equipment needed on well sites and including additional controls on this equipment is not expected to create a situation that exceeds the capabilities of these firms.

Containerized Systems

Commenting on OSHA's analysis of the cost of controls for hydraulic fracturing, API/IPAA expressed concern that OSHA was considering requiring the use of containerized systems. The Associations stated that these systems would be economically infeasible for small fleets and raised questions about whether these systems would be sufficient to allow fleets using them to achieve the PEL (Document ID 4222, p. 7). Neither in the PEA nor the FEA has OSHA's cost analysis reflected the use of containerized systems, nor does OSHA require their use. Instead, containerized systems represent a possible technological change that could potentially reduce the costs of silica control. OSHA has in no way quantitatively tried to estimate the effects of this possible reduction.

Conveyor Skirting

In the PEA, OSHA found that conveyor skirting systems with appropriate LEV would be needed to meet the new PEL, and included the cost of such controls in the incremental costs associated with the new PEL. As discussed in Chapter IV, Technological Feasibility, in the FEA, however, OSHA now finds that these conveyor skirting systems will be needed to meet the preceding PEL, but not to further lower exposures to the new PEL, so OSHA is not including costs for these controls as incremental costs associated with achieving the new PEL. As a result, the FEA does not include costs for conveyor skirting systems and LEV.

Dust Suppression—Control of Dust Generated From Traffic

On the other hand, dust suppression to control silica emissions generated by truck traffic, estimated in the PEA as necessary only to meet the preceding PEL, has now been determined to be necessary to meet the new PEL (*see* Chapter IV, Technological Feasibility in the FEA). As a result, in the FEA OSHA added the costs of dust suppression to control silica dust generated by truck traffic to the estimated incremental costs of meeting the new PEL. OSHA estimates that dust suppression is more expensive in the aggregate than conveyor skirting systems with appropriate LEV.

OSHA made two additional changes to the costs of dust suppression from the PEA to the FEA. First, OSHA accepted the unit costs for dust suppression application provided by API/IPAA (Document ID 2301, Attachment 3, Dust Suppression). This unit cost is somewhat lower than the original estimate that OSHA adopted in the PEA (Document ID 1712). This seems reasonable to OSHA based on the costs of the most commonly used dust suppression materials. Second, OSHA has determined that these controls will be utilized to reduce exposures for ancillary support workers and remote/intermittent workers, 50 percent of whom work in situations that currently have exposures below the new PEL (as shown in the exposure profile in the section on hydraulic fracturing in Chapter IV, of the FEA, technological feasibility). As a result, instead of assigning dust suppression costs for all wells (as in the PEA), OSHA determined in the FEA that dust suppression costs would be incurred by 50 percent of wells. This aligns with a view that, in many cases, natural conditions (silica content of soils, dustiness, wetness and/or climate) are such that dust suppression is not needed.

Small Business Considerations

Small Business Regulatory Enforcement Fairness Act (SBREFA) Comments on Compliance

Costs in General Industry and Maritime

Before publishing the NPRM, OSHA received comment on the accuracy of its unit costs through the Small Business Advocacy Review (SBAR) Panel process.

The Small Entity Representatives (SERs) who participated in the 2003 SBAR Panel process on OSHA's draft standards for silica provided many comments on the estimated compliance costs OSHA presented in the Preliminary Initial Regulatory Flexibility Analysis (PIRFA) for general industry and maritime (Document ID 0938).

In response to the SERs' comments, OSHA carefully reviewed its cost estimates and evaluated the alternative estimates and methodologies suggested by the SERs. OSHA updated all unit costs presented in the PIRFA to reflect the most recent cost data available and inflated all costs to 2009 dollars prior to publication of the proposed rule. However, the Agency generally determined that the control cost estimates in the PIRFA were based on sound methods and reliable data sources.

For the PEA, OSHA reviewed the SERs' cost estimates for small entities in the foundry and structural clay industries. Given that those SERs did not report their own sizes, the Agency could not compare their estimates to the estimates in the PEA. OSHA concluded that the compliance costs reported by the SERs in general industry that did provide size data were not incompatible with OSHA's own estimates of the costs of engineering controls to comply with the PEL. As discussed above, for the FEA, OSHA has halved the number of workers assumed to be covered by each control for most controls in establishments with fewer than twenty employees, which results in a doubling of the engineering control costs for these establishments.

Comments and Responses on Costs for Small Establishments

Stuart Sessions, testifying on behalf of ACC, argued that OSHA had underestimated costs to small establishments for two reasons: (1) Small establishments may have higher exposures and therefore many need to spend more money installing controls to reduce those exposures; and (2) costs to small establishments may involve diseconomies of scale—whereby smaller facilities would have to pay more per unit to procure and install systems—that OSHA had not accounted for (Document ID 4231, Attachment 1, pp. 2–4).

With respect to the issue about small establishments having higher exposures—the commenter simply asserted that this is the case without providing any evidence to support the claim. Mr. Sessions speculated that smaller businesses have a ''lesser ability to afford compliance expenditures and lesser ability to devote management attention to compliance responsibilities'' (Document ID 4231, Attachment 1, p. 2). While it is possible that very small establishments may not have the same controls already in place as large establishments, as asserted by the commenter, this does not necessarily mean that very small establishments will have higher exposures. Small and very small establishments typically only have one shift per day, so fewer shifts are being worked where there is a potential for exposure. They also may spend more time on activities not involving silica exposures. For example, a small art foundry that produces one or two castings a week will simply spend proportionally less time on activities that lead to silica exposure than a large production foundry.

With respect to the issue of diseconomies of scale, OSHA has taken this phenomenon into account in its cost estimates in the FEA. First, in order to provide a conservative estimate of costs for the purposes of determining the impacts on very small employers, OSHA has revised what Mr. Sessions called ''the most inappropriate of OSHA's assumptions'' (Document ID 4231, Attachment 1, p. 6). In the PEA, OSHA estimated that a single control would reduce the exposures of four workers. For the FEA, OSHA has revised its estimates so that the number of workers whose exposures are reduced by a control are half that used in the PEA for establishments with fewer than 20 employees—reducing the number of workers covered by a control from four to two. OSHA made this adjustment even though there are ways in which small establishments may have lower costs per cfm than larger establishments. For capital costs, a major element of cost per cfm is the length of ductwork. Within the same industry, the length of ductwork will be much shorter in smaller establishments. For operating costs per cfm, length of operating time is a key element of costs.

OSHA has continued to estimate that the exposures of four employees whose exposures would be reduced per control for establishments with more than twenty employees (even though it is likely that more than four workers have their exposures reduced per control in the largest establishments). This effectively means that very large establishments with hundreds of employees have been modeled as if their costs were equivalent to that of several 20–40 person establishments combined. Far from neglecting diseconomies of scale, in an effort to be conservative and adequately account for the challenges faced by smaller establishments, OSHA has instead neglected to account for economies of scale in larger establishments.

Mr. Sessions calculated some higher overall costs for smaller establishments (Document ID 4231, Attachment 1, pp. 6–10). However, these costs are critically dependent on the assumptions already addressed and rejected by OSHA, such as that exposures are random and that any exposures require that all possible controls be installed to control those exposures.

Final Control Costs

Unit Control Costs

Methodology

For the FEA, OSHA used unit costs developed in the PEA for specific respirable crystalline silica control measures from product and technical literature, equipment vendors, industrial engineers, industrial hygienists, and other sources, as relevant to each item. Some PEA estimates were modified for the FEA based on comments in the record, and all costs were updated to 2012 dollars. Specific sources for each estimate are presented with the cost estimates. Wherever possible, objective cost estimates from recognized technical sources were used. Table V–4 in the FEA provides details on control specifications and data sources underlying OSHA's unit cost estimates.

Summary of Control Costs for General Industry and Maritime

Table V–5 in the FEA summarizes the estimated number of at-risk workers and the annualized silica control costs for each application group. Control costs in general industry and maritime for firms to achieve the PEL of 50 $\mu g/m^3$ level are expected to total $238.1 million annually. As shown, application group-level costs exceed $15.0 million annually for concrete products, hydraulic fracturing, iron foundries, railroads, and structural clay.

Table V–6 in the FEA shows aggregate annual control costs in general industry and maritime by NAICS industry. These costs reflect the disaggregation of

application group costs among the industries that comprise each group (*see* Table III–1 in Chapter III of the FEA on the profile of affected industries.)

b. Control Costs in Construction

In both the PEA and the FEA, OSHA determined that employers, in order to minimize exposure monitoring costs, would select appropriate controls from Table 1. The final estimate for control costs, however, includes Table 1 control costs for a larger number of employees than in the PEA. For the purpose of estimating control costs in the PEA, OSHA examined all of the employers with employees engaged in Table 1 tasks but judged that only a subset of those employers (those with workers exposed above the proposed silica PEL) would require additional engineering controls. For this final rule, OSHA has judged, for costing purposes, that *all* of the construction employers with employees performing any task covered in Table 1 will adopt the engineering controls for that task as specified in Table 1. Thus, in the FEA, OSHA took the more conservative approach—which may result in an overestimate of costs—of identifying the cost of controls for all employers with employees engaged in Table 1 tasks, not just the subset of employers with employees exposed above the PEL. However, as discussed in Chapter III of the FEA, OSHA did adjust control costs to reflect the 44 percent of workers in construction currently exposed at or below the PEL who are estimated to be in baseline compliance with the Table 1 requirements.

OSHA is also likely overestimating the cost of controls for another reason. If the employer is able to demonstrate by objective data, or other appropriate means, that worker exposures would be below the action level under any foreseeable conditions, the employer would be excluded from the scope of the final rule. These employers would not require additional controls. OSHA did not have sufficient data to identify this group of employers and did not try to reduce the costs to reflect this group, so OSHA's estimate of costs is therefore overestimated by an amount equal to the costs for those employers engaged in covered construction tasks but excluded from the scope of the rule.

A few tasks involving potentially hazardous levels of silica exposure are not covered in Table 1. Employers would have to engage in exposure monitoring for these tasks pursuant to paragraph (d) and use whatever feasible controls are necessary to meet the PEL specified in paragraph (d)(1). For example, tunnel boring and abrasive blasting are not covered by Table 1 and are therefore addressed separately in this cost analysis. Although several commenters identified various other activities that they believed were not covered by Table 1 that could result in crystalline silica exposure over the PEL (Document ID 2319, pp. 19–21; 2296, pp. 8–9), some of these activities were simply detailed particularized descriptions of included activities. For example, overhead drilling is addressed in the FEA, Chapter IV–5.4 Hole Drillers Using Handheld or Stand-Mounted Drills, and the demolition of concrete and masonry structures is addressed in the FEA, Chapter IV–5.3 Heavy Equipment Operators. For the remainder, the available exposure data did not indicate that these activities resulted in a serious risk of exposure to respirable crystalline silica (*see* FEA, Chapter III Industry Profile, Construction, Public Comments on the Preliminary Profile of Construction and Summary and Explanation, Scope and Application); furthermore, these other activities could be addressed using the controls identified in the FEA. Because OSHA did not have sufficient data to identify a significant number of silica exposures above the PEL of 50 μg/m^3 for these activities, the Agency did not include costs for controlling silica exposures during these activities. Nevertheless, to the extent that employers find it necessary to implement controls for any activity that OSHA did not explicitly include in this analysis, the FEA shows that those controls are clearly economically feasible.

The control costs for the construction standard are therefore based almost entirely on the tasks and controls specified in Table 1. Most of the remainder of this section is devoted to explaining the manner in which OSHA estimated the costs of applying appropriate engineering controls to construction activities as required by Table 1 of the final standard. These costs are generated by the application of known dust-reducing technology, such as the application of wet methods or ventilation systems, as detailed in the technological feasibility analysis in Chapter IV of the FEA. These costs are discussed first, and, following that, the control costs for tasks not specified in Table 1 are separately estimated.

OSHA revised Table 1 between the PEA and the FEA. The entries included in the table have been modified with some tasks being added and some being removed.[35] In addition, the methods of controlling exposures that Table 1 requires for certain tasks have changed in response to comments and additional analysis. Excluding changes to respirator requirements, which are addressed elsewhere in this preamble, significant and substantive revisions to Table 1 that have the potential to impact control costs include:

- New entries on Table 1—
  - Handheld power saws for cutting fiber-cement board (with blade diameter of 8 inches or less)
  - Rig-mounted core saws and drills
  - Dowel drilling rigs for concrete
  - Small drivable milling machines (less than half-lane)
  - Large drivable milling machines (half-lane and larger for cuts of any depth on asphalt only and for cuts of four inches in depth or less on any other substrate)
  - Heavy equipment and utility vehicles used to abrade or fracture silica-containing materials (*e.g.,* hoe-ramming, rock ripping) or used during demolition activities involving silica-containing materials.
  - Heavy equipment and utility vehicles for tasks such as grading and excavating but not including: Demolishing, abrading, or fracturing silica-containing materials
- Removed entry for drywall finishing from Table 1
- Revised entries on Table 1—
  - Drivable saw entry revised to permit outdoor use only.
  - Portable walk-behind or drivable masonry saws divided into two entries—walk-behind saws and drivable saws.
  - Handheld drills entry revised to include stand-mounted drills and overhead drilling.
  - Combined entries for vehicle-mounted drilling rigs for rock and vehicle-mounted drilling rigs for concrete.
  - Milling divided into three tasks—walk-behind milling machines and floor grinders; small drivable milling machines (less than half-lane); and large drivable milling machines (half-lane and larger with cuts of any depth on asphalt only and for cuts of four inches in depth or less on any other substrate).
  - Heavy equipment used during earthmoving divided into two tasks—(1) heavy equipment and utility vehicles used to abrade or fracture silica-containing materials (*e.g.,* hoe-ramming, rock ripping) or used during demolition activities involving silica-containing materials, and (2) use of heavy equipment and utility vehicles for tasks such as grading and excavating but not including: Demolishing, abrading, or fracturing silica-containing materials.

[35] Additionally, the nomenclature changed from ''Operation'' in the NPRM to ''Equipment/Task'' in the final rule.

○ Revised crushing machines entry to require equipment designed to deliver water spray or mist for dust suppression and a ventilated booth or remote control station.

In addition to the new and revised tasks in Table 1, some of the controls and specifications required by Table 1 were revised for this final rule, including removal of ''Notes/Additional Specifications'' from individual Table 1 entries and addition of substantive paragraphs after the table. Those revisions include:

• Revised or newly required controls/specifications for Table 1 tasks—

○ Revised requirement to operate and maintain tools/machine/equipment in accordance with manufacturer's instructions to minimize dust emissions.

○ Revised specifications for dust collectors to require they provide at least 25 cubic feet per minute (cfm) of air flow per inch of blade/wheel diameter (for some, but not all entries that include a dust collection system as a control method).

○ Revised specification for dust collectors to require they provide the air flow recommended by the tool manufacturer, or greater, and have a filter with 99 percent or greater efficiency and a filter-cleaning mechanism (for some, but not all entries that include a dust collection system as a control method). The entries for handheld grinders for mortar removal (*i.e.,* tuckpointing) and handheld grinders for uses other than mortar removal require a cyclonic pre-separator or filter-cleaning mechanism.

○ Revised requirement for tasks indoors or in enclosed areas to provide a means of exhaust as needed to minimize the accumulation of visible airborne dust (paragraph (c)(2)(i)).

○ Added requirement for wet methods to apply water at flow rates sufficient to minimize release of visible dust (paragraph (c)(2)(ii)).

○ Revised specifications for enclosed cabs to require that cabs: (1) Are maintained as free as practicable from settled dust; (2) have door seals and closing mechanisms that work properly; (3) have gaskets and seals that are in good condition and working properly; (4) are under positive pressure maintained through continuous delivery of fresh air; (4) have intake air that is filtered through a filter that is 95% efficient in the 0.3–10.0 μm range (*e.g.,* MERV–16 or better); and (5) have heating and cooling capabilities (paragraph (c)(2)(iii)).

○ Added requirement to operate handheld grinders outdoors only for uses other than mortar removal, unless certain additional controls are implemented.

○ Added wet methods option for use of heavy equipment and utility vehicles for tasks such as grading and excavating but not including: Demolishing, abrading, or fracturing silica-containing materials.

○ Added requirement to use wet methods when employees outside of the cab are engaged in tasks with heavy equipment used to abrade or fracture silica-containing materials (*e.g.,* hoe-ramming, rock ripping) or used during demolition activities involving silica-containing materials.

• Removed controls/specifications for Table 1 tasks—

○ Removed requirements to change water frequently to avoid silt build-up in water.

○ Removed requirements to prevent wet slurry from accumulating and drying.

○ Removed requirements to operate equipment such that no visible dust is emitted from the process.

○ Removed local exhaust dust collection system option and requirement to ensure that saw blade is not excessively worn from the entry for handheld power saws.

○ Removed requirement to eliminate blowing or dry sweeping drilling debris from working surface from the entry for handheld and stand-mounted drills (including impact and rotary hammer drills).

○ Removed additional specifications for dust collection systems for vehicle-mounted drilling rigs for concrete (*e.g.,* use smooth ducts and maintain duct transport velocity at 4,000 feet per minute; provide duct clean-out points; install pressure gauges across dust collection filters; activate LEV before drilling begins and deactivate after drill bit stops rotating).

○ Removed requirements to operate grinder for tuckpointing flush against the working surface and to perform the work against the natural rotation of the blade.

○ Removed dust collection system option and requirement to use an enclosed cab from crushing machines.

These and other changes to Table 1 are discussed in detail in Section XV: Summary and Explanation of this preamble. While Table 1 has changed with regard to the tasks included and the control methods required, OSHA's methodology used to estimate the costs of controls for the construction industry has remained basically the same as that explained in detail in the PEA, with steps added (and explained in the following discussion) to address cost issues raised during the comment period and the updates and revisions to Table 1. OSHA summarizes the methodology in the following discussion, but the PEA includes additional details about the methodology not repeated in the FEA.

OSHA adopted the control cost methodology developed by ERG (2007a, Document ID 1709) for the PEA and subsequently for the FEA. In order to provide some guidance on that cost methodology, OSHA itemizes below the three major steps, with sub-tasks, used to estimate control costs in construction, with two additional steps added for the FEA to estimate the number of affected workers by industry and equipment category [36] (numbered Step 3) and to estimate control costs for self-employed persons (numbered Step 5)—tables referenced below are in Chapter V of the FEA:

• Step 1: Baseline daily costs, relative costs of controls, and labor share of value

○ Use RSMeans (2008, Document ID 1331) estimates to estimate the baseline daily cost for every representative job associated with each silica equipment category (Table V–30) and unit labor and equipment costs (Table V–31).

○ Use vendors' equipment prices and RSMeans estimates to estimate the unit cost of silica controls (Table V–32), and estimate the productivity impact for every silica control and representative job, to be added to the cost of the control applied to a particular job (Table V–33).[37]

○ Use the costs from Tables V–32 and V–33 to calculate the incremental productivity impact, labor cost, and equipment cost for each representative job when controls are in place (Table V–34).

○ Using Tables V–30 and V–34, calculate the percentage incremental cost of implementing silica controls for each representative job (Table V–35).

○ Calculate the weighted average incremental cost (in percentage terms) and labor share of total costs for each silica job category (outdoors and indoors estimated separately) using the assumed distribution of associated representative jobs (Tables V–36a and V–36b).

• Step 2: Total value of activities performed in all Table 1 silica equipment categories

○ Match BLS Occupational Employment Statistics OES

[36] The term ''equipment category'' as used here matches the broad headings used in the Technological Feasibility analysis. Later on in this section, OSHA identifies which Table 1 tasks are included in each equipment category.

[37] This latter sub-step was performed in the PEA, but it was inadvertently omitted in the text summary.

occupational classifications for key and secondary workers with the labor requirements for each equipment category (Table V–37) and estimate the full-time-equivalent (FTE) number of employees by key and secondary occupations working on each silica task (Tables V–38a and V–38b).

○ Based on the distribution of occupational employment by industry from OES, distribute the full-time-equivalent employment totals for each equipment category by NAICS construction industry (Table V–39).

• Step 3: Total affected employment by industry and equipment category

○ Disaggregate construction industries into four distinct subsectors based on commonality of construction work (Table V–40a) and then estimate the percentage of affected workers by occupation, equipment category, and construction subsector (Table V–40b).

○ Use the percentage of affected workers by occupation, equipment category, and construction subsector (Table V–40b) to obtain total affected employment by occupation (Table V–41) and total affected employment by industry and task (Table V–42).

• Step 4: Aggregate silica control costs (not including self-employed persons)

○ Using the FTE employment totals for each task by NAICS construction industry (Table V–39) and the mean hourly wage data from OES, adjusted for fringe benefits, calculate the annual labor value of each Table 1 silica activity by NAICS construction industry (Table V–43).

○ Using the labor share of value calculated for each activity performed in a silica-related equipment category (Table V–43), estimate the total value of each Table 1 equipment/task category by industry (Table V–44).

○ Estimate the distribution of silica work by equipment type, duration of activity, and location of activity (Table V–45).

○ Multiply the total value of Table 1 construction activities requiring controls (Table V–44) by the percentage incremental cost associated with the controls required for each activity that uses equipment in each equipment category (Tables V–36a and V–36b) and weighted by the percentage of tasks performed outdoors and indoors/within an enclosed space (Table V–45), to calculate the total control costs, adjusted for baseline compliance, by Table 1 equipment category and industry (Table V–46).

○ Calculate engineering control costs for silica-generating construction activities not covered in Table 1 (Tables V–47a and V–47b).

○ Combine the control costs for Table 1 construction activities (Table V–46) and the control costs for construction activities not covered in Table 1 (Tables V–47a and V–47b) to calculate the total control costs by equipment category and construction industry (Table V–48).

• Step 5: Adjust aggregate silica control costs to include self-employed persons

○ Use data from the BLS Current Population Survey to estimate the ratio of the number of self-employed persons to the number of employees by occupation (Table V–49) and then redo the estimation after restricting self-employed persons to just those occupations covered by OSHA that potentially involve exposure to hazardous levels of respirable crystalline silica (Table V–50).

○ Multiply the FTE rate for each occupation (from Tables V–38a and V–38b) by the number of self-employed workers and employees in that occupation (from Table V–50) to obtain the ratio of FTE self-employed persons to FTE employees and then reduce that ratio to reflect only self-employed persons working on a multi-employer worksite where the work of the self-employed person cannot be isolated in time or space (Table V–51).

○ Increase the earlier estimate of control costs by equipment category and industry (Table V–48) by the adjusted FTE ratio of self-employed workers (Table V–40) to calculate total control costs by equipment category and industry with self-employed persons included (Table V–52).

Baseline Costs of Representative Jobs

Baseline Job Safety Practices

OSHA's cost estimates address the extent to which current construction practices incorporate silica dust control measures. Thus, OSHA's baseline reflects such safety measures as are currently employed. To the limited extent that silica dust control measures are already being employed, OSHA has reduced the estimates of the incremental costs of silica control measures to comply with the new PEL. As discussed in Chapter III of the FEA and summarized in Tables III–A–1 and III–A–2, OSHA estimates that 44 percent of workers with exposures currently below the new PEL are using the controls required in Table 1.

Representative Jobs

Unlike the situation with the general industry/maritime standard, OSHA does not have extensive data identifying the number of employees engaged in Table 1 tasks or the duration of their exposure to respirable crystalline silica during those tasks. Therefore, ERG developed a model based on ''representative jobs'' for the purposes of identifying the control costs necessary to comply with Table 1. Using RSMeans *Heavy Construction Cost Data* (RSMeans, 2008, Document ID 1331), which is a data source frequently used in the construction industry to develop construction bids, ERG (2007a, Document ID 1709) defined representative jobs for each silica-generating activity described in the feasibility analysis. These activities and jobs are directly related to the silica-related construction activities described in the technological feasibility chapter of the FEA. ERG (2007a, Document ID 1709) specified each job in terms of the type of work being performed (*e.g.,* concrete demolition), the makeup of the crew necessary to do the work, and the requisite equipment. For example, for the impact drilling activity, ERG defined three representative jobs for various types of demolition work. For each job, ERG derived crew composition and equipment requirement data from the RSMeans (2008,Document ID 1331) guide and then calculated the per-day baseline cost from the labor rates, equipment charges, material costs, and overhead and profit markups presented in the cost estimating guide.

Table V–30 of the FEA shows the specifications for each representative job and the associated daily labor, equipment, and material costs. Table V–31 of the FEA provides a summary of the labor rates and equipment charges used to estimate the daily cost of each representative construction job in Table V–30 of the FEA. Note that the data on hourly wages with overhead and profit in Table V–31 of the FEA, obtained from RSMeans (2008, Document ID 1331), are employed here to be consistent with other RSMeans cost parameters to estimate the baseline costs of representative jobs. The RSMeans estimates are published for the purpose of helping contractors formulate job bids, so ERG relied on that data as an indicator of the amount of labor and time that would be required for each of the representative jobs in the cost model developed for this analysis. These RSMeans estimates are later used only to determine two ratios: The labor share of the costs of representative construction jobs and the percentage increase in the cost of each representative job due to the addition of controls to comply with the final rule. Everywhere else in the cost chapter, when the actual wages were important to the calculations and are expressed as

fixed amounts and not just ratios, OSHA used 2012 BLS wage data, which include fringe benefits but not overhead and profit.

SBREFA Panel Comments on Cost Methodology for Construction

Prior to the publication of the PEA, one SBREFA commenter criticized the methodology for estimating engineering control costs on the grounds that while RSMeans estimates were used to establish the marginal costs of new controls (as a percentage of baseline costs), average wage rates (including fringe benefits) from the BLS *Occupational Employment Statistics Survey,* 2000, were used to calculate the value of at-risk tasks without providing a justification for not using RSMeans wage data (Document ID 0968, p. 13). Since BLS wage rates are significantly lower than the RSMeans rates used by ERG in earlier parts of the analysis, the commenter argued that this would significantly lower the base to which the marginal cost factors are applied to estimate compliance costs (*Id.*). This SBREFA commenter further argued that the RSMeans estimates are likely to be on the high end of estimated wages because they only cover unionized labor and are therefore likely to lead to high estimates of impacts. The commenter then recommended that more appropriate indexed labor wage costs be computed and used consistently throughout the analysis (Document ID 0968, p. 14).

First, the commenter's concern is misplaced because the choice of the RSMeans estimates source does not skew the results in the manner suggested by the commenter; nor does it even have a significant impact on the cost analysis. The RSMeans estimates were used only to develop the ratio of costs for the representative jobs to the total labor cost and then to determine the incremental compliance costs as a percentage of the total and the share (percentage) of estimate value with controls accounted for by labor. Because the RSMeans estimates are organized by project cost to assist contractors in bid planning, that data set is the logical choice for this purpose over BLS data, which provides wage data but does not provide comparable costs for projects. Dividing project labor value by the labor share of project value yields an estimate of total project value.

The absolute level of the RSMeans wage and equipment cost levels do not directly affect the resultant aggregate compliance costs. While lower wage rates would lower the baseline costs of the representative jobs, it does not follow that control costs as a percent of baseline costs would also be lower. In fact, if lower wage rates are combined with the same equipment costs, the equipment part of incremental control costs would be a higher percentage of total baseline costs. Only the labor share (percentage) of baseline costs, along with the incremental compliance costs as a percent of baseline costs, are taken from the analysis of representative costs and used in the subsequent estimation of aggregate costs. The absolute levels of the wage rates and equipment costs taken from RSMeans do not directly enter the aggregate cost analysis.

Second, OSHA notes that the BLS wage data, on which the aggregate compliance costs are based, are obtained from a statistically valid, national survey of employment and compensation levels and are the best available data characterizing national averages of wages by detailed occupation. For some of the reasons the commenter noted, OSHA believes that the BLS wage estimate provides a more accurate reflection of average wages.

Another set of SBREFA commenters criticized OSHA's cost estimation methodology, arguing that fundamental errors resulted in serious underestimates of the costs of engineering controls. The commenters asserted without any significant explanation that the task-by-task incremental cost estimates (shown in Table V–23 of the PIRFA, Document ID 1720, p. 749) should have been multiplied by two factors: (1) ''The ratio of the RSMeans labor rate to the BLS wage and benefits rate,'' and (2) the inverse of the ''percentage in key occupations working on task'' from Table V–26 (also in the PIRFA, Document ID 1720, p. 766). Under this approach, the commenters argued that ''the cost of PEL controls for brickmasons, blockmasons, cement masons and concrete finishers performing grinding and tuckpointing would be approximately seventy-two (72.0) times the ERG estimate, and . . . the cost of PEL controls for drywall finishing (at the 50 μg/m^3 PEL) would be approximately 7.2 times the ERG estimate'' (Document ID 0004).

The rationalization for these calculations was not provided, and OSHA found these conclusions without merit. The incremental control costs shown in Table V–34 of the FEA were based on RSMeans estimates for labor and equipment costs. As shown in Table V–34, these cost estimates, after adjustments for productivity impacts, are used to calculate the percentage increase in baseline costs associated with each control. The RSMeans-based cost estimates shown in Table V–34 are also used to estimate the share of total baseline task/project costs accounted for by labor requirements. The averages of the percentage increase due to incremental control costs and the labor share (percentage) of total baseline costs are shown in Table V–37 of the FEA. These two percentages are used to extrapolate the aggregate control costs associated with each task. This extrapolation was based on (1) the full-time-equivalent employment in key and secondary occupations associated with each task, and (2) the value of the labor time as measured by the BLS occupational wage statistics, adjusted for fringe benefits.

OSHA provided similar responses in the PEA and requested comment on its responses to the SBREFA comments, but received none (*see* PEA, p. V–131).

The same set of SBREFA commenters further argued that OSHA's analysis contained five more ''fundamental errors'' (Document ID 0004). First, the commenters asserted that OSHA's calculations understate the actual cost because they are based on old data (1999 or 2000 data from RSMeans rather than RSMeans 2003 data). OSHA used the most recent available data at the time the initial preliminary analysis was completed and subsequently updated those data for the PEA (and the FEA) using RSMeans estimates from 2008 (Document ID 1331). However, as noted previously, the RSMeans estimates do not directly determine the absolute level of aggregate compliance costs, but rather the labor share (percentage) of project costs and incremental compliance costs as a percentage of baseline costs. This aspect of the analysis received no further comment and has been retained for the FEA.

Second, the commenters asserted that there is no information to ''suggest much less substantiate the premise that the exposure monitoring data in Tables 3–1 and 3–2 [in the ERG (2007a) report, Document ID 1709)] (even if they were properly collected and analyzed) are in any way representative of current workplace exposures across the country'' (Document ID 0004). In response, OSHA points out that the profiles used to estimate the numbers of workers exposed in excess of each PEL option were, in fact, based on the extensively documented technological feasibility analysis with many of the data points in the exposure profiles being taken from the findings of OSHA inspections (and based on ERG, 2007a, Document ID 1709). OSHA is tasked with using the best available evidence to develop the analyses, and the data in the exposure profile represent the best available evidence on current workplace

exposures to respirable crystalline silica. More importantly, for estimating the cost of controls, Table 1 in the final rule is intended to be the default option for protecting workers performing covered tasks, regardless of actual exposure level. The FEA reflects this, while recognizing that a sizable minority of workers with exposures below the PEL have limited their exposures by using such controls currently.

Third, the commenters claimed that there is ''is no information to suggest much less substantiate the premise that the exposure monitoring data in Tables 3–1 and 3–2 (even if they were representative of current workplace exposures) are in any way representative of the non-existent, theoretical jobs artificially created by the FTE [full-time equivalent] analysis so as to justify their use as the foundation for Table 4–12'' (Document ID 0004). However, OSHA notes that the representative jobs on which the cost analysis is based were designed to correspond directly to the tasks assessed in the technological feasibility analysis. Furthermore, Table 4–12 in ERG (2007a, Document ID 1709) was derived directly from Table 3–2 and is independent of the ''FTE analysis.''

Fourth, the commenters argued that a more logical and appropriate methodology would assume that all FTEs were exposed above the PEL in the absence of controls, and the commenter could find ''no justification, and substantial support to the contrary, for an approach that artificially condenses actual exposures into far more highly concentrated exposures (by condensing all at-risk task hours into FTEs) and then [assumes] that, despite the impact of this change, the grab bag of exposure monitoring described in ERG Tables 3–1, 3–2 and 4–12 represents these FTEs'' (Document ID 0004). The commenters asserted that the effect in ERG (2007a, Document ID 1709) of ''first multiplying total project costs by the FTE percentage (from Table 4–8) and then by the 'Percentage of Workers Requiring Controls' from Table 4–12 (and then by the average 'Total Incremental Costs as % of Baseline Costs' by job category from Table 4–7) results in an unjustified double discounting of exposed workers in the incremental cost calculation'' (Document ID 0004).

OSHA disagrees. The Agency notes that ERG (2007a, Document ID 1709) used the exposure profiles from the industry profile to estimate the number of full-time equivalent workers that are exposed above the PEL. In other words, this exposure profile is applicable if all exposed workers worked full time only at the specified silica-generating tasks. The *actual* number exposed above the PEL is represented by the adjusted FTE numbers (*see* Table 4–22 in ERG, 2007a, Document ID 1709). The adjusted FTE estimate takes into account that most workers, irrespective of occupation, spend some time working on jobs where no silica contamination is present. The control costs (as opposed to some program costs) are independent of the number of workers associated with these worker-days. OSHA noted in the PEA that the thrust of the comment about ''double discounting'' was unclear, but the commenters did not respond with clarification. Nothing is ''discounted'' in the estimation of aggregate control costs.

Finally, the SBREFA commenters argued that the ''application of the FTE analysis to the additional equipment costs is based on the wholly unfounded assumption, contrary to actual experience, that this additional equipment could be used with perfect efficiency (*i.e.,* never idle) so that it is only at a particular site during the time the at-risk tasks are being performed'' (Document ID 0004). In response, OSHA notes that its analysis does in fact assume some efficiency with respect to the use of additional equipment required for controls. However, many of the equipment costs are based on monthly equipment rental rates provided by RSMeans that already embody some degree of idleness over the course of a year (*see* ERG, 2007a, Table 4–3, Document ID 1709). In other cases, daily equipment costs were directly estimated based on equipment purchase costs, annualization factors, and assumed operating and maintenance costs.[38] OSHA did receive further comment on the issue following the publication of the PEA (Document ID 4217, pp. 84–88), and, in response, the Agency developed prorated ownership costs (equivalent to twice the rental rates) for control equipment for tradespersons performing tasks involving short-term, intermittent silica work.

Public Comment on Engineering Control Costs in Construction

Having already incorporated comments from small business in the SBREFA panel process, the Agency produced revised estimates for the PEA in support of the proposed silica rule. In the PEA, OSHA requested comments from rulemaking participants on the Agency's preliminary estimate of control costs in construction. Below are comments representative of the prominent issues that raised concerns.

The most broad-based critique of the construction cost analysis came from the Construction Industry Safety Coalition (CISC), and its consultant Environomics (Document IDs 2319, 2320, and 4217). Several of their arguments regarding underestimation of costs related to an undercount of the affected construction population (for example, they believed OSHA should have accounted for the cost to control silica exposures for plumbers). OSHA agrees in part that there were some occupations—plumbers, plumber helpers, electricians, electrician helpers, roofers, roofer helpers, terrazzo workers and finishers, and sheet metal workers—that likely have exposure and should be included in this analysis, as they do perform some activities covered by Table 1. These are discussed in FEA Chapter III, Industry Profile.

Owning Versus Renting Engineering Controls in Construction

OSHA also received comments regarding the availability of control equipment. In its post-hearing brief, CISC commented:

> In the Agency's cost analysis, it has also made the entirely impractical assumption that controls (*e.g.,* wet methods, LEV) for the tools that construction workers use in performing tasks that generate respirable silica need to be available only during the exact duration while a dusty task is performed. The CISC estimates costs instead to provide control equipment on an ''always available'' basis to workers who engage in dusty tasks. Control equipment must be available whenever a worker may need to perform an at-risk task, and not for only the very limited duration when the at-risk task is actually being performed. Costs for the engineering controls required to meet the reduced PEL in the proposed rule will be far higher than OSHA estimates (Document ID 4217, p. 29).

While OSHA agrees that CISC's argument has merit, during hearing testimony CISC's representative acknowledged that its estimates did not initially take into account the economic life of a control. This is reflected in the following conversation between CISC's Stuart Sessions and OSHA's Robert Stone:

> MR. STONE: So returning to the methodology for costing, you pretty much used our numbers and you used our, presumably, like you mentioned the dust shroud that has a one-year life and, therefore,

[38] These were originally translated to daily costs on the assumption of full-time usage (240 days per year). However, in response to this comment, this rate was adjusted downward, assuming instead that equipment would be used 150 days per year (30 weeks), on average; OSHA applied this downward adjustment to equipment usage in the PEA and the effect of this change in equipment usage was to increase the daily cost of control equipment.

after one year, you take the cost again the second year, is that right? And the third year, and so on? Okay. I think this is perhaps a problem with the way you've done your analysis. We used basically FTEs, full-time equivalents. You're using three percent of the time let's say for plumbers, as an example, you're applying it to three crews, all right? At the end of one year, you're having them buy another dust shroud. And my view . . . they will have used nine percent of the economic life of the dust shroud. Now, you can argue I'd make an adjustment because we estimate 150-[day construction work-year] use of it, for full-time use. This would suggest, though, that after one year, you will have used one-sixth of the life of that dust shroud and an employer is not going to throw it out. It's still functional. He'll use it for the next five years. He'll use it for six years. Any views on that?

* * *

MR. SESSIONS: Yes. That's a good point, and I hadn't thought about that.

MR. STONE: Okay, thank you. A related point is actually the same issue. It would be operating in maintenance costs. You're—it's going to be one-sixth of our original estimate, but I don't think you've made that adjustment.

MR. SESSIONS: Correct. (Document ID 3580, Tr. 1501–1502).

After the hearing discussion, CISC revised its methodology, noting:

After additional thought and discussion about this issue with several construction tradespeople, we . . . concluded that useful life is a function of both how often the tool and controls are used, but also how long they sit in the construction worker's truck and get bounced around going from job site to job site (even when they are not used), and how often they are taken out of the truck and returned to the truck (even when they are only set up then taken down at the job site but not actually used). Thus useful life will increase if a tool sits idle for some percentage of the time when it is available, but useful life will not increase to the same proportional extent as the decrease in usage. We assumed in the example in workbook Tab # X2B that using the tool and equipment 1/4 as often will double its useful life (Document ID 4217, p 89).

OSHA agrees with this updated methodology and has adopted CISC's approach—essentially assuming one-half of the usage life over which to amortize the purchased control equipment—for jobs that typically involve intermittent short-term exposure. The jobs for which the Agency assumed a half-life of the control equipment were: (1) Hole drillers using hand-held or stand-mounted drills—for electricians, plumbers, carpenters, and their helpers, and for sheet metal workers; and (2) handheld power saws for carpenters and their helpers. Note that OSHA's adoption of this updated approach resolves CISC's criticism that OSHA had not accounted for productivity decreases from controls not being available when the worker needs to use them for short-term or intermittent silica jobs.

For all other construction jobs (*i.e.,* those not itemized above involving intermittent short-term exposure), OSHA did not adopt CISC's approach but instead (as in the PEA) used the market-derived rental rate for control equipment without either doubling the rental rate to take into account ''down-time'' or requiring purchase of the control equipment. There are several reasons OSHA retained its PEA approach for these jobs in the final rule:

- In most cases, an employer's own/rent decision for control equipment will be determined by the own/rent decision for the construction equipment (including construction tools) to which the control equipment will be applied. If the employer rents/owns the construction equipment, the employer will rent/own the control equipment. The major exception would be if a particular piece of control equipment could be applied to many types of construction equipment. An example might be a dust collector. In that situation, the employer might find it economic to rent the construction equipment and own the control equipment. But, in that case, the purchased control equipment will not be sitting idle.
- Construction equipment is sufficiently expensive that employers, as a general matter, will not find it economically efficient to have it sitting idle. That is why employers so frequently rent construction equipment. Of course, employers that do only one type of construction job all year (or those that are sufficiently large that they work on that particular type of construction job all year) will find it economic to own the construction equipment—as well as the control equipment—but then the control equipment will not be sitting idle.
- In light of permit requirements and other job-planning requirements, in almost all cases, the employer will have advance knowledge of the details of the construction job (as opposed to, sometimes, repair work in general industry). This knowledge would include the construction equipment—and controls—required to perform the job. In fact, employers will often schedule construction jobs precisely to avoid having construction equipment sitting idle. In other words, the typical employer—and certainly the competent employer—won't come to the job site unprepared, needing to leave the job site to obtain rental equipment or controls.
- The construction sector is a significant component of the U.S. economy. There is a large, competitive construction equipment/control rental market in place to serve it. In most places, employers should be able to obtain needed construction equipment/controls in a timely manner under terms similar to those estimated here.

For the aforementioned reasons, OSHA believes that the ownership-versus-rental cost issue, except in the case of construction jobs that involve intermittent short-term exposure, is somewhat of a red herring. The difference in amortized cost should be negligible, given that employers will choose to own or rent based on whichever is the lower-cost alternative. In fact, because rental costs are typically somewhat higher than amortized ownership costs, OSHA may have overestimated compliance costs for those employers who purchase control equipment.

Self-Employed Persons

CISC, and its contractor Environomics, claimed in their comments that OSHA had omitted the costs of compliance by sole proprietors (typically self-employed persons) (Document ID 4217, p. 80). The inclusion of such costs and the circumstances under which they would arise are discussed in Chapter III of the FEA. In the FEA OSHA has accounted for costs associated with controlling employee exposures from sole proprietor activities. The actual self-employment data and the estimated effect on employer costs are presented at the end of this section on engineering control costs in construction.

Full Cost vs. Incremental Cost

Prior to the PEA, a participant in the SBREFA process noted that while OSHA established the total incremental cost for each silica control method (summarized for the final rule in Table V–35 of the FEA), the cost estimates were based on the application of a single control method. The commenter argued that there may be cases where two or more control methods would have to be applied concurrently to meet the exposure limits (Document ID 0968, p. 14). In response, OSHA noted in the PEA that for each task, specified control options correspond to the control methods described in the technological feasibility analysis in Chapter IV (of the PEA). These methods reflected the choices laid out in Table 1 of the proposed rule; they were also presented in Table V–25 in the PEA along with OSHA's calculation of the weighted average proportion of project costs attributable to labor and the incremental

control costs as a percentage of baseline project cost.

Throughout the comment period, CISC reiterated its pre-PEA objections to OSHA's methodology of estimating incremental costs instead of the ''full'' compliance costs, which CISC defined as including the costs for employers to meet their existing duty to comply with OSHA's old PEL (CISC claims employers of ''nearly 60,000 workers'' were not in compliance with OSHA's preceding standard and would have OSHA attribute the costs of compliance with the preceding standard to the costs of this rule) (Document ID 4217, p. 33):

In our view, OSHA has made two errors in the approach it has taken:

• First, the ''full'' compliance costs for reducing worker exposures from their current levels to below the proposed new PEL are the conceptually correct costs to estimate when assessing economic feasibility, not the ''incremental'' costs for reducing exposures to below the proposed new PEL from a starting point assuming compliance with the current PEL. In practice, employers will face the full costs, not the lesser incremental costs, and the economic feasibility assessment should consider whether employers can afford these full costs, not the hypothetical and lower incremental costs.

• Second, OSHA has made a conceptual error in the Agency's methodology for estimating compliance costs * * * Insofar as OSHA omits all costs for [employees with exposures >250 μg/m^3]—failing to estimate the costs to reduce their exposures all the way down below 50 μg/m^3 instead of only to below 250 μg/m^3—OSHA estimates costs that fall short of the incremental costs of the Proposed Standard that the Agency aims to estimate. (Document ID 4217, pp. 96–97)

Both arguments are now largely moot because in the FEA almost all of the construction engineering control costs are based on compliance with Table 1 and encompass all employees engaged in the Table 1 tasks, regardless of their current level of exposure. OSHA has included the full incremental—and full total—costs for all employers in construction who have workers who are performing tasks listed on Table 1, even those workers with exposures currently above 250 μg/m^3.

CISC's arguments for the construction sector are now only relevant to the very few tasks not covered by Table 1, such as tunnel boring. OSHA therefore addresses CISC's arguments in the context of those few tasks.

The first argument is that employers who are not in compliance with the preceding PEL of 250 μg/m^3 will have to incur costs to achieve that PEL in addition to the costs they will incur to reach the new PEL of 50 μg/m^3. As laid out in the PEA, OSHA rejects this position, as this is inappropriate for estimating economic feasibility among firms making a good faith effort to comply with the existing silica rule. Employers who had a legal obligation to comply with OSHA's preceding PEL but failed to do so are not excused from their previous obligation by the new rule; nor can the fulfillment of a pre-existing duty be fairly re-characterized as a new duty resulting from a new rule. But this issue is not limited to construction, and a more complete discussion is presented in the general industry engineering control cost section in the FEA.

The second argument can be dismissed on similar grounds. CISC's argument appears to assume that employers will incur different costs for different controls necessary to reduce exposures from above 250 μg/m^3 down to 250 μg/m^3, and from 250 μg/m^3 down to 50 μg/m^3. In many cases, however, the same controls needed to bring exposures below 250 μg/m^3 will also bring exposures to 50 μg/m^3 or below, so there would be no cost associated with the new rule. To the extent that separate controls are required to reduce exposures down from 250 μg/m^3 to 50 μg/m^3, OSHA does account for the costs for those controls.

General Comments on Cost Methodology

James Hardie Building Products commissioned Peter Soyka of Soyka & Company LLC to perform an evaluation of the PEA. While Mr. Soyka's comments cover many aspects of the analysis and overlap with those of other commenters, some were relatively unique.

In one place, Mr. Soyka questions the entire method of analyzing jobs from the level of workers and their tasks. He expressed concern about both what he termed the failure to capture the cost to the establishment, as well as the need for workers to have controls available (Document ID 2322, Attachment G, p. 165). OSHA did not, however, ignore other costs for establishments. Elements of these costs are dealt with at the establishment level for some ancillary provisions of the standard, and are discussed later in this chapter. The second element, regarding the availability of controls for certain occupations, mirrors concerns raised by Environomics and CISC, and has been dealt with above.

Elsewhere in his comments, Mr. Soyka states that ''OSHA should develop revised unit costs that consider the full array of elements that affect what a business charges its customers for a unit of time expended.'' Such unit costs,'' he submitted, ''would include direct labor, fringe benefits, overhead, SG&A, and a reasonable allowance for profit (*e.g.,* the typical cost of capital found in a specific industry or overall)'' (Document ID 2322, Attachment G, p. 182). The approach put forward in the PEA and in the FEA incorporates fringe labor costs. OSHA has provided a sensitivity analysis of the effects of including other cost elements in the sensitivity analysis section of the FEA. As noted elsewhere, for the FEA the Agency recognizes that the labor productivity effect of adopting certain controls is accompanied by a loss of productivity in equipment under certain circumstances; that additional cost has been incorporated in the FEA. The National Association of Home Builders (NAHB) faulted the costing of engineering controls in the PEA on several grounds, including several very similar to those raised by Mr. Soyka and addressed earlier. NAHB also stated that OSHA has not considered the ''unique nature of construction, in that sites are not fixed in nature, and that equipment may need to be moved between several sites in a single day'' or the ''compliance costs for cleanup of the jobsites'' (Document ID 2296, p. 38). Both are addressed in the FEA as opportunity costs or housekeeping costs.

Other Aspects of Unit Costs

Following publication of the NPRM, a representative of petrochemical employers, the American Fuel and Petrochemical Manufacturers, raised concerns about retrofitting and clean-up costs that it claimed were improperly omitted from OSHA's analysis of engineering controls in construction:

> OSHA claims ''[t]he estimated costs for the proposed silica standard rule include the additional costs necessary for employers to achieve full compliance.''[ ] Yet it fails to consider the additional costs of retrofitting existing equipment to comply with Table 1 in Section 1926.1053 (Table 1). In addition to acquiring new engineering controls not previously implemented, many employers will have to modify pre-existing equipment to come into compliance (*e.g.,* outfitting the cab of a heavy equipment bulldozer with air conditioning and positive pressure). Table V–3, found in OSHA's complete PEA, begins to address these costs by enumerating the capital and operating costs for the engineering controls required by Table 1. But it does not account for the ancillary costs of

retrofitting those controls, including the cost of retrofitting the equipment itself as well as the lost time the facility may absorb in doing so.

OSHA also fails to account for the clean-up costs associated with the natural by-products from Table 1's required engineering controls. For example, many of the engineering controls require the use of wet methods or water delivery systems. [ ] Employers will incur costs from removing (from the clean-up process itself and lost time) excess water to prevent ice or mold from developing. Yet these costs go unaccounted for in the PEA (Document ID 2350, pp. 6–7).

In the FEA, the Agency does not include any specific cost for retrofitting equipment. The record indicates that almost universally employers either already have equipment with the required controls available for use (*e.g.,* wet method for saw), or the equipment allows for the easy addition of a control (*e.g.,* shroud for HVAC). Furthermore, most equipment is portable and/or handheld and is relatively inexpensive with a useful life of two years or less. As a result, it would simply not make economic sense to retrofit the equipment when it would be less expensive to replace it. In addition, most other types of relevant construction equipment—heavier and drivable—generally have a useful life of ten years or less; control-ready equipment of this type has been on the market for years and is typically already in use. Thus, OSHA did not estimate any retrofitting costs. While some employers might still retain pieces of earth-moving equipment that do not have a cab that complies with Table 1, equipment with a cab is the industry standard for both purchase and rental. As discussed in this chapter in the context of productivity, the implication is that the market has shifted to heavy equipment with cabs even in the absence of a silica standard. In addition, in final Table 1 OSHA has reduced the number of tasks that require equipment with enclosed cabs to just a single task: Heavy equipment and utility vehicles used to abrade or fracture silica-containing materials or used during demolition activities involving silica-containing materials. For the odd piece of old, cab-less heavy equipment which does not conform to the requirements of Table 1, individual employers have the choice of renting the required equipment to perform that single task, or simply using the cab-less equipment only on non-silica tasks (thereby ceding the one silica-abrading construction task to employers that have more up-to-date equipment). In short, the requirement to use a cab when performing Table 1 tasks is not a requirement to retrofit all existing equipment that might conceivably be used for a Table 1 task.

Regarding the question of clean-up costs, the commenter treats the issue as if there were no clean-up costs associated with generating silica currently. As discussed in the Environmental Impact Analysis (Section XIV of this preamble) and in the discussion of productivity impacts later in this section, there was substantial comment to the record indicating that in many, if not most, situations, the controls associated with reducing silica exposure will lead to a net decrease in the amount of time required for cleanup after a job. While OSHA is not attempting to quantify any potential cost savings, the record likewise does not support attributing additional costs to cleanup.

Specific Industry/Equipment Category Cost Comments

Crushing Machines

William Turley, executive director of the Construction & Demolition Recycling Association (CDRA), broadly described the impacts he anticipated for his industry.

Recyclers who crush materials for reentry into the economic mainstream as aggregate products would appear to have to do all of the following:

- Purchase and install climate-controlled enclosures or cabs for all crusher operators;
- Install crusher baghouses for particulate emission reduction;
- Enclose conveyor belts—a measure unprecedented in our industry;
- Install effectively designed and maintained water spraying equipment;
- Impose full-shift use of respirators for all quality control hand pickers working on processing lines;
- Establish and implement emission testing protocols and procedures to ensure compliance with the PEL;
- Implement medical surveillance programs for all employees engaged in material crushing activities; and
- Achieve a ''no visible emissions'' standard, which frankly is both unattainable and utterly unreasonable.

To the best of our knowledge, no recycler in the United States has a system even resembling the above. The cost of such systems will unquestionably threaten the economic viability of construction & demolition debris recyclers across the Country. It must also be pointed out that the industry has an exceptionally diverse composition of larger operators with higher economic margins and small operations with limited capabilities to capitalize the type of equipment called for in this rulemaking (Document ID 2220, pp. 2–3).

The final silica rule does not require all the above steps. OSHA expects that crushing machines will be used for construction/demolition activities, as discussed in detail in the Summary and Explanation of the standard. As such, OSHA anticipates that employers engaged in the recycling operation would follow Table 1 and would not need to conduct exposure monitoring.

For crushing machines, OSHA removed the ''no visible emissions'' requirement and the requirement for enclosed cabs, both of which had been in the proposed Table 1. Employers are now required to use a spray system and comply with manufacturer instructions. Also, there is no requirement to enclose conveyor belts or install crusher baghouses. Instead, employees must use a remote control station or ventilated booth that provides fresh, climate-controlled air to the operator. For the FEA, OSHA added the cost of a ventilated booth for the use of crushing machines in construction/demolition activities. Most crushing machines are already equipped with movable controls that will allow operation of the machine from inside the booth, so no additional equipment modifications will be required for most machines. Crushers available for purchase or rental are also typically equipped with a water spray system, so OSHA has not assessed any incremental cost for sprayers.

Homebuilding—Roofing

The National Roofing Contractors Association (NRCA) objected to OSHA's preliminary cost estimates for controls used to limit silica exposure in roofing operations, claiming that OSHA's preliminary estimate of an average of $550 per year for firms that employ 20 workers or fewer (covering the majority of roofing contractors) had significantly underestimated the cost of specialized saws that would be required for roofing equipment. In support of the argument that OSHA had underestimated costs, NRCA identified costs for retrofitting portable saws with integrated dust collection systems along with specialized vacuums equipped with HEPA filters (Document ID 2214 p. 4).

The task of cutting most roofing materials would fall under ''Handheld power saws (any blade diameter)'' in Table 1, and the final version of Table 1 does not allow for the dust collection methods described, so the majority of costs quoted by NAHB are not relevant. Instead, the final version of Table 1 requires that the employer use wet methods. Second, the estimate of $550 a year in costs to very small employers was an estimated average across all affected establishments with fewer than 20 employees, not just roofing operations in homebuilding. Questions of small business impact or economic

feasibility for the roofing industry are dealt with Chapter VI of the FEA.

The comments submitted by consultant Peter Soyka on behalf of James Hardie Building Products (''Hardie'') presented a table of typical devices with engineering controls involved in fiber cement cutting and an un-sourced range of costs for the retail prices of those types of devices and their controls (Document ID 2322, p. 13).

Hardie's inclusion of a table of retail prices for the purchase of equipment with controls suggests there may have been a misunderstanding of the nature of OSHA's cost methodology—it is not based on purchasing entirely new pieces of equipment, but making sure the equipment has the controls necessary to comply with Table 1. To the extent commenters submitted estimates addressing the latter question, OSHA has taken them into consideration in its final estimates.

Asphalt Milling

Fann Contracting, Inc. acknowledged that the availability of equipment with built-in controls is rising. However, the commenter suggested that OSHA's preliminary assessment of the design specifications and costs for the engineering controls identified in Table 1 of the proposed rule had under-counted the amount of milling machines and other paving-related equipment that the commenter believed would still require additional retrofits to enclosed cabs (sealing cracks, adding air conditioning, upgrading to HEPA filters, etc.) to satisfy the requirements in Table 1 (Document ID 2116, pp. 6–7).

Table 1 in the final rule does not require a cab for milling machines or any of the equipment identified by the commenter for paving purposes, so the commenter's concerns are not relevant. Table 1 only requires cabs for ''(xvii) Heavy equipment and utility vehicles used to abrade or fracture silica-containing materials (*e.g.,* hoe-ramming, rock ripping) or used during demolition activities involving silica-containing materials,'' and specifies it as an option for ''(ix) Vehicle-mounted drilling rigs for rock and concrete.'' Table 1 requires employers to use wet methods to control dust emissions from milling machines. These costs have been accounted for in the cost analysis.

Drywall Finishing

A SBREFA commenter raised questions about the availability of silica-free joint compound for drywall finishing (Document ID 0004). In the PEA, OSHA relied on NIOSH studies showing that silica-free joint compounds had become readily available in recent years (*see* ERG, 2007a, Section 3.2) (Document ID 1709). The cost model for the PEA assumed that 20 percent of drywall finishing jobs would continue to use conventional joint compound. Based on additional information, OSHA has determined that all commercially available joint compounds have no, or very low amounts of, silica and do not pose a risk to workers from respirable crystalline silica (Document ID 2296, pp. 32, 36; 1335, p. iii) and has therefore not included drywall finishing in Table 1 or taken any costs for this task (*see* Section XV. Summary and Explanation of the Standards, Specified Exposure Control Methods for more information).

Number of Days Controls Are Used Annually

Whether equipment, and the relevant controls, are rented or purchased, the effective annual cost of the equipment is based on the assumed number of days per year that it would be used. In the PEA, OSHA had estimated rental of the equipment for 150 days during each 365-day period. Based on comments received from industry representatives during the 2003 SBAR Panel process (Docket ID 0968), this estimate had been reduced from an average of 250 days in the Preliminary Initial Regulatory Flexibility Analysis (PIRFA). This reduced workday estimate presumably reflected winter weather slowdown in many parts of the country, as well as general weather conditions (such as rain) that can interfere with many construction processes, and resulted in ⅔ higher daily rental rates for control equipment.

However, Environomics, in developing its own cost estimates, assumed that control equipment would be used for 250 days a year, without an articulated rationale for departing from the estimate provided during the SBAR Panel process (Document ID 4023, Attachment 2, X2B-Hole Drilling Unit Costs, Cell P:Q44). More importantly, Environomics selectively and inconsistently applied 250 days only to the frequency of usage but not to the daily rate (which OSHA had based on 150 days of usage). To see why it is a problem to apply a different number of days to the same daily rate, consider a piece of control equipment, with a one-year life, known to cost $1,500. Using a 150-day construction work-year, OSHA would estimate a daily rate for the control equipment of $10 ($1,500/150 days in the construction work-year). The annual cost for that control would be $1,500 ($10 multiplied by 150 days). Using the same example, Environomics would keep OSHA's daily rate of $10 (amortized over 150 days) but apply it to a 250-day calendar to arrive at an annual cost of $2,500—where the one-year cost of the equipment was known to be $1,500. In short, the selective 250-day methodology Environomics used results in an overestimation of costs by 67 percent.

Accordingly, OSHA has decided to retain the 150-day construction work year based on the best available evidence, and the Agency has consistently applied that work-year throughout the cost analysis developed in the FEA for construction. (General industry and maritime work is typically less affected by weather, so a separate work-year number of days is used for those calculations).

Unit Control Costs

In developing the cost estimates in the FEA, OSHA defined silica dust control measures for each representative job (*see* ERG (2007a, Document ID 1709). Generally, these controls involve either a water-spray approach (wet method) or a dust collection system to capture and suppress the release of respirable silica dust. Wet-method controls require a water source (*e.g.,* tank) and hoses. The size of the tank varies with the nature of the job and ranges from a portable water tank (unspecified capacity) costing $15.50 a day to a 10,000 gallon water tank with an engine-driven discharge, costing $168.38 a day.[39] Depending on the type of tool being used, dust collection methods entail vacuum equipment, including a vacuum unit and hoses, and either a dust shroud or an extractor. The capacity of the vacuum depends on the type and size of tool being used. Some equipment, such as concrete floor grinders, comes equipped with a dust collection system and a port for a vacuum hose. The estimates of control costs for those jobs using dust collection methods also include the cost for HEPA filters.

The unit costs for most control equipment are based on price information collected from manufacturers and vendors. In some cases, control equipment costs were based on data from RSMeans (2008) on equipment rental charges (Document ID 1331). Table V–32 of the FEA shows the general unit control equipment costs and the assumptions that OSHA used to estimate the costs for specific types of jobs.

For each job identified as needing engineering controls, OSHA estimated

[39] *See* Chapter X in the FEA for a discussion on the environmental impacts resulting from the use of wet methods for controlling exposure to silica.

the annual cost of the appropriate controls and translated this cost to a daily charge, based on an assumed use of 150 days per year (30 weeks), as explained earlier. The only exceptions were engineering controls expected to be used for short-term, intermittent work. For these controls, consistent with the CISC methodology that OSHA adopted, carpenters and other occupational groups were estimated to purchase this control equipment, and for costing purposes, OSHA amortized the equipment over its ''half-life''—that is, over 75 days rather than 150 days (effectively doubling the daily capital costs of the equipment). Accordingly, Table V–32 of the FEA shows separate daily cost estimates, for regular and for infrequent use, for a dust extraction kit and for a 10–15 gallon vacuum with a HEPA filter.

Incremental Labor Costs and Productivity Impacts in Construction

In addition to incremental equipment costs, OSHA estimated in the PEA the incremental labor costs generated by implementing silica dust controls. These labor costs were generated by: (1) The extra time needed for workers to set up the control equipment; (2) potential reductions in productivity stemming from use of the controls; (3) additional time to service vacuum dust control equipment; and (4) additional housekeeping time associated with or generated by the need to reduce exposures. All additional labor costs related to the use of controls were subsumed into a single additional labor productivity impact estimate for each of the representative job categories. Except where otherwise noted, the productivity impact described is negative, meaning that the addition of the control is expected to reduce productivity. To develop estimates of the labor productivity impacts of the dust control equipment that would be required as a result of the proposed standard, ERG interviewed equipment dealers, construction contractors, industry safety personnel, and researchers working on construction health topics.

In part, because most silica dust controls are not yet the norm in construction, knowledge about the impact of dust controls on productivity was uneven and quite limited. More precisely, few individuals that ERG interviewed were in any position to compare productivity with and without controls and the literature on this topic appears deficient in this regard. Overall, telephone contacts produced a variety of opinions on labor productivity effects, but very few quantitative estimates. Of all the sources contacted, equipment rental agencies and construction firms estimated the largest (negative) productivity impacts. Some equipment vendors suggested that there are positive productivity effects from control equipment due to improved worker comfort (from the reduction in dust levels). Others suggested that the use of dust collection equipment reduces or eliminates the need to clean up dust after job completion. Comments to the record, discussed below, closely mirrored this preliminary information.

The estimation of labor productivity effects is also complicated by the job- and site-specific factors that influence silica dust exposures and requirements for silica dust control. Potential exposures vary widely with hard-to-predict characteristics of some specific work tasks (*e.g.,* characteristics of materials being drilled), environmental factors (*e.g.,* wet or dry conditions, soil conditions, wind conditions), work locations (*e.g.,* varying dust control and dust cleanup requirements for inside or outside jobs), and other factors. Generalizations about productivity impacts, therefore, are hampered by the range of silica dust control requirements and work circumstances.

After considering the existing evidence OSHA concluded that labor productivity impacts are often likely to occur and accounted for them in the PEA analysis. In the PEA, depending on the general likelihood of productivity impacts for each activity, OSHA used a productivity impact ranging from zero to negative five percent of output. After considering the many comments advocating for both increasing and decreasing the productivity impact estimates, OSHA has concluded that the estimates in the PEA were approximately correct and has retained the PEA estimates for the FEA. The comments and factors influencing each selection are described in the following discussion.

SBREFA Panel Comments on Productivity Impacts

In response to the SBREFA Panel, the Reform OSHA Coalition commented on the estimates of the impact of exposure control equipment on productivity during construction operations. This SBREFA commenter noted that the estimates of the productivity impact of using additional control measures were based on interviews with dealers, contractors, and researchers working on construction health topics and expressed its opinion that it was not clear how this ''purely qualitative analysis [was translated] into productivity [impact] rates . . . . '' (Document ID 0968, p. 14). The commenter indicated that engineering control compliance costs would be sensitive to the ultimate choice of productivity impact measures (Id.).

OSHA responded to these comments in the PEA as part of the discussion of the basis for OSHA's productivity estimates. OSHA summarizes the responses to SBREFA comments here for the convenience of the reader. As described in the PEA, ERG's research revealed little substantive, quantitative evidence about the magnitude of the productivity impacts of the controls, and in some cases, the direction of the impacts (positive or negative) appeared to depend on the specific nature of the job. OSHA's estimates in the preliminary analysis reflected ERG's best professional judgment about the likely magnitude of these impacts. Some of the estimates may be conservative because under some scenarios for certain tasks the productivity impacts could be significantly smaller than those shown in Table V–23 of the PEA. In some scenarios the productivity impact may even be positive.

The same commenter also expressed a concern that even though ''silica is not now considered a hazardous waste,'' OSHA had not analyzed the impact of the proposed rule on disposal of ''[silica-]contaminated'' wastes such as ''filters of dust control vacuums and contaminated water discharge'' (Document ID 0968, p. 28). The commenter asserted that disposal issues are ''acute on the construction site where a means to readily dispose of such material or water is not available'' (Id.). The comment was somewhat puzzling because the comment was premised on the fact that there is not currently any ''hazardous'' classification for such waste that would trigger special disposal duties, and the commenter did not explain why any additional costs would be incurred beyond normal disposal practices. OSHA did not identify any new areas of cost in its Environmental Impacts analysis presented in the FEA, and finds no evidence that employers will be required to incur additional environmental costs as a result of this rule, other than some potential permit-modification notification costs addressed in the discussion of engineering control costs for general industry in the FEA. The incremental disposal costs resulting from dust collected in vacuums, discarded filters, and other sources in construction are therefore likely to be de minimis. An analysis of wet methods for dust controls suggests that in most cases the amount of slurry discharge is not

sufficient to cause a runoff to storm drains or surface water.[40]

Public Comment on Productivity Impacts in Construction

OSHA invited comment on the productivity impacts—positive and negative—resulting from the introduction of controls to limit exposure to silica. In the discussion below, OSHA reviews comments supporting both negative productivity impacts and positive productivity impacts. The comments supporting negative productivity impacts include assertions that OSHA underestimated the negative productivity impact of complying with the silica rule, failed to include a productivity impact on equipment, and failed to include a fixed productivity impact. OSHA considered those comments before concluding that it will generally retain the approach it used in the PEA, with the exception of selectively adding additional costs for productivity impacts on equipment in response to a point raised by CISC. OSHA will also explain separately why it is not calculating any productivity impact for two specific activities: (1) Use of cabs for earthmoving equipment, and (2) drywall installation.

Public Comments Suggesting That OSHA Underestimated the Productivity Impacts Associated With Engineering Controls

The Interlocking Concrete Pavement Institute reported that ''converting from in-place paver cutting to wet cutting and/or vacuum systems could induce a 50 percent productivity penalty,'' but did not otherwise substantiate that claim beyond noting that it was a survey response from one of its members (Document ID 2246, Attachment 1, p. 3).

Mr. Soyka, in the comments prepared for Hardie, critiqued OSHA's estimates of the productivity impact on construction operations as ''far too small'' and urged OSHA to adjust productivity-loss estimates based on empirical data ''if available'' (Document ID 2322, Appendix G, pp. 14–15 and 21–22). However, the commenter did not clearly identify any such empirical data in the comments. The only labor-based engineering control cost alternative offered by the commenter that resembled ''empirical data'' is the addition of a seven-hour penalty per job that was ''based on a JHI time-motion study'' apparently conducted exclusively in a single industry (new home construction) and comprised of data from just the JHI study (Document ID 2322, Appendix G, Attachment A, p. A–8). OSHA could not determine whether it would actually supply new ''empirical evidence'' that would warrant a change from the preliminary estimate because the study was not submitted into the record. The commenter cites ''James Hardie Building Products, Inc., undated, pg. 15,'' which appears to align with an entry in the list of references to an undated ''James Hardie Labor Efficiency Manual,'' but that manual was not submitted into the record.

Mr. Soyka recommended that OSHA use time-motion studies to derive the estimated productivity impacts.

> [. . . F]ew [of the productivity penalties estimated by OSHA] are supported by actual data (*e.g.,* time-motion studies). OSHA should apply a more conservative approach that considers how work flow and task completion are likely to be affected by newly required changes to existing practices as well as entirely new activities (Document ID 2322, Appendix G).

In addition, Mr. Soyka developed an alternative cost model that included additional productivity impacts that OSHA did not include. In this model Mr. Soyka ''assumed that wherever possible, company owners in the residential construction industry will outsource their compliance obligations to specific subcontractors . . . providing the products and services that might generate significant amounts of silica dust'' (Document ID 2322, Appendix G, p. 26). In this scenario, Mr. Soyka determined that the employer would require ''the subcontractor to relocate its work location outside the house(s) being constructed to a distance sufficient to ensure that silica dust concentrations remained minimal inside and around the house(s)'' and that ''relocating the materials and work giving rise to silica dust generation [. . .] would add substantially to the time required to complete the associated tasks'' (Document ID 2322, Appendix G, p. 30). He accounted for this additional time by increasing the productivity impact on the specialty subcontractors to seven hours per job, ''based upon time-motion studies conducted by James Hardie (James Hardie Building Products, Inc., undated, pg. 15)'' (Document ID 2322, Appendix G, p. 31).

Mr. Soyka's model also included a productivity impact for ''wearing respirators to account for fatigue and adverse impacts on employee-to-employee communication'' (Document ID 2322, Appendix G, p. 32).

OSHA fundamentally disagrees with the Mr. Soyka's assumptions. Mr. Soyka's assumption that all silica-generating tasks need to be removed from the homebuilding site results from a misunderstanding of OSHA's statement that ''[i]n response to the proposed rule, many employers are likely to assign work so that fewer construction workers perform tasks involving silica exposure; correspondingly, construction work involving silica exposure will tend to become a full-time job for some construction workers'' (FR, 2013, at 56357) (Document ID 2322, Appendix G, p. 25). OSHA did not mean that silica-generating tasks will be subcontracted out and that subcontractors will be forced to perform these tasks off-site. Rather, the Agency was acknowledging that construction employers would likely consolidate the responsibilities for performing silica-generating tasks to as few workers as possible in order to limit exposures to peripheral workers.

As mentioned previously, the ''time-motion studies'' performed by James Hardie, compiled in an unpublished reference, were not provided for public inspection. Moreover, the description of how those data were used in developing the model suggests that Mr. Soyka's relevant assumptions are not based on time-motion studies of how long it actually takes to perform specific tasks with controls added. Rather, it appears that Mr. Soyka assumed inflated times to perform the tasks, based on a misunderstanding of what the proposed rule required; in any case, it is not descriptive of the requirements for the final rule. Mr. Soyka's suggested approach contrasts with the estimates provided by CISC/Environomics, which accepted the limitations of the analytical exercise and agreed with most of the estimates in the PEA regarding the ''variable'' productivity effect.

Moreover, it should be noted that aside from weighing the possible competing forces on productivity in the course of a shift (*e.g.,* more time for set up vs. less time required for clean-up), there is also a short-run/long-run phenomenon over a longer period as the standard comes into use. There may be a short learning curve until workers determine the most efficient way to perform a job when controls are introduced (Document ID 3581, p. 1700); in some cases the effect may be relatively larger until the method of performing a job is reconceptualized. Mr. Sokya criticizes OSHA for not recognizing ''the dynamic nature of construction'' (Document ID 2322, Appendix G, p. 19), but one obvious aspect of the dynamic nature of construction is that employers will be constantly adapting to changing circumstances and trying to find ways to

[40] For a more detailed discussion of this issue, *see* Chapter X of the FEA.

perform the job in the most cost-effective manner. In short, the Agency believes that a time-motion study of a particular task is neither necessary to determine approximately what the effect will be in the short-run, nor would it allow OSHA to determine what the long-run cost of integrating the controls will be.

CISC and its consultant Environomics, as well as some other commenters, questioned OSHA's productivity-loss estimates associated with the required controls. CISC/Environomics claimed that overall OSHA ''underestimated productivity losses associated with performing tasks using the prescribed controls by an amount roughly equal to the average equipment intensity of about 42 percent'' (Document ID 2320, p. 29). CISC/Environomics reported that this underestimation came largely from OSHA failing to account for what they termed ''fixed productivity impacts'' and for productivity impacts to equipment. Both of these concerns are discussed below.

In its post-hearing brief, CISC/Environomics presented the results from a questionnaire and interviews conducted with employers and knowledgeable tradespeople; the results included a finding that ''the variable penalty percentages [. . .] were the same as or slightly larger than those that OSHA had estimated'' (Document ID 4217, p. 92). CISC/Environomics did not submit the questionnaire or the answers received, nor the details of the interviews, to the record so OSHA could not fully evaluate the findings or compare them to its own findings. Based on the available summary information it appears that, while CISC and OSHA's estimates for variable productivity costs were nearly identical, it is not clear that CISC's estimates took current compliance into account. CISC stated that its members felt that ''something greater than zero variable productivity penalty should be estimated for masons using portable saws controlled with wet methods [. . .] and for heavy equipment operations using enclosed cabs and HEPA filters'' (Document ID 4217, pp. 92–93). OSHA acknowledges that there would be a productivity impact to comply with the requirements of the silica rule relative to using no controls for those activities. However, as shown in Chapter III of the FEA, Industry Profile, OSHA has found high levels of baseline compliance with the provisions of the rule for those activities. As is standard in OSHA's costing methodology, only costs above and beyond those incurred under current standards are attributable to the final rule.

In addition, CISC argued that OSHA should take higher productivity impacts because ''in some fraction of these instances [(where controls would be required)], the controls are hellaciously difficult to use'' (Document ID 3580, Tr. 1321). The testimony goes on to give examples of such difficulties such as when ''building houses where the utilities are not yet in and the water is not yet in,'' when working in places where power is not readily available such as in parking garages or on scaffolding, and when doing work that requires wet methods outdoors in extremely cold temperatures (Document ID 3580, Tr. 1321–1322). A different commenter, the National Utility Contractors Association, similarly criticized OSHA's estimates for excluding additional water-transportation costs: ''there is not always a water supply available which would require trucking large volumes of water to the job site which adds additional costs.'' (Document ID 3729, p.3)

Given the fact that the majority of the silica-generating equipment requiring controls under this standard—such as tuckpointing grinders and concrete drilling equipment—require electricity, OSHA does not find merit in applying any productivity impact simply because the controls for those tools may also need electricity. If the employer can find a way to power the equipment, it can also power the controls when necessary. Similarly, employers must commonly transport water to worksites without it for cleanup and sanitation purposes, and OSHA's technological feasibility analysis explains why the amount of water required to generate the spray mist is not typically very significant. Although it seems plausible that wet methods would occasionally be used outdoors by some employers in weather cold enough to freeze the water mist used to control the silica dust, this is far from a common construction occurrence. Moreover, it is not entirely clear from the record that freezing mist would decrease productivity. OSHA's estimates of productivity impacts is intended to represent an average across all situations, and the tiny fraction of time wet methods will need to be used outdoors in extremely cold weather should not skew the average productivity impact.

CISC/Environomics stated that there should also be a productivity impact on equipment rental or use as well as for the additional labor to operate that equipment longer. Environomics reported that a complete cost estimate of productivity loss would include not only the additional labor time required, but also the cost of having to rent equipment for a longer period of time.

> . . . Simply put, a productivity penalty for labor will translate to a productivity penalty for equipment. For example, if due to a labor productivity loss, the labor time required to complete a job increases from eight hours to eight hours and 15 minutes, the equipment time required for job completion will also increase to eight hours and 15 minutes. Additional equipment rental costs will be incurred for the additional 15 minutes, or equipment owned by the employer will be delayed for use on another job by 15 minutes (Document ID 2320, p. 29).

This concern was reiterated both in its hearing testimony (Document ID 3580, Tr.1323) and in its post-hearing brief where Environomics stated that ''OSHA's analysis should add an equipment component to the costs associated with whatever productivity penalty is incurred in performing a construction task using the Table 1 controls'' (Document ID 4217, p. 91). OSHA agrees, in part, and recognizes that there can be a productivity impact for equipment (as well as for labor) for many tasks when there is a cost created by having to extend the rental time of the equipment.

In the PEA, OSHA had estimated the labor productivity impacts associated with engineering controls to reduce silica exposure. For the FEA, the Agency has added a parallel cost for the equipment portion of the cost for a number of equipment categories. These are itemized in Table V–34 of the FEA. For example, for Task 15 (Demolition of concrete slabs, mesh-reinforcing, up to 3″deep), there is estimated to be a 2 percent labor increase related to maintaining wet methods for dust suppression. In the original Means estimates, it was estimated that approximately 70 percent of the costs of the task were labor-related, divided between an operator and a laborer. This 2 percent additional cost is estimated to amount to $9.39 in added labor cost for an equipment operator and $7.84 for a laborer, or a total labor productivity cost per job of $17.23. For the FEA, OSHA is adding an additional cost item of $7.58 to reflect an opportunity cost, in the form of a prospective extended equipment rental cost, raising the total incremental estimated cost to $24.81 per task. As with the other construction engineering control costs, this additional cost item is task-specific.

While OSHA judged that equipment productivity can be impacted negatively by the new rule for many tasks, there are two general categories for which the Agency determined that there would be

no impact on equipment productivity. The first broad category is short-term, intermittent work in which the equipment and control are often idle. An example would be a plumber drilling holes in concrete. The equipment and control are sufficiently inexpensive (relatively speaking) that the construction employer or trade contractor (or possibly even the tradesperson) would typically own rather than rent the equipment and control. As discussed elsewhere in the FEA, OSHA determined that certain tradespersons, such as plumbers, electricians, and their helpers, are more likely to purchase their equipment, rather than renting it. OSHA estimated the cost of purchasing control equipment at twice the rental cost.

The second category of tasks for which the Agency did not assess any equipment productivity impact is the group of tasks in which there is not a fixed ratio of labor to capital (capital in this case including rental costs). For example, as explained in the following unit cost discussion, Task 10 (as detailed in Table V–34 of the FEA) involves performing earthmoving as a heavy equipment operation task. In this case, while extra time by a laborer would be required to tend to the application of wet methods, such application would be done simultaneously with actually performing the earth-moving task. Thus, while wet methods for Task 10 would require an added labor cost (itemized as a ''productivity'' cost), it would not actually slow down the operation so as to require the longer period of use of the equipment that would impose an equipment impact.

CISC/Environomics also argued that part of the productivity effect was fixed and would therefore need to be accounted for separately. This fixed component, CISC/Environomics reported, would be ''typically involving activities such as initial set-up and final take-down and clean-up of the control equipment, [which] often occur at the beginning and end of a job or work shift'' (Document ID 4217, p. 90, *see also* 2320, p. 28; 3580, Tr. 1320). This would mean that shorter jobs would have a relatively larger percentage loss in productivity.

Other commenters did not agree that there would be costs related to set up. During the hearings, Deven Johnson, of the Operative Plasterers' and Cement Masons' International Association, testified that the concrete grinding ''tools that are on the market today come integral with the capture device[. . .] The hose is attached to the grinder already. The electrical cord is attached to the motor already. [. . .] You simply plug it in and start using it [. . .] there's no setup time'' and that for ''a walk-behind concrete diamond-bladed saw for cutting slabs, the setup time is, make sure there's gas in it and . . . hook a water hose up to it and turn the water on'' (Document ID 3581, Tr. p. 1699). During the hearing, Manafort Brothers described a wheel-based machine used to suppress dust during demolition operations, which was simply wheeled onto the worksite and hooked up to a water supply and electrical source (Document ID 3583, Tr. 2430), and the Building Trades Construction Department (BCTD) of the AFL–CIO submitted an extensive list of available tools that included the controls required by the rule that would require little or no set up (Document ID 4073, Attachment 4a).

Based on the evidence in the record, OSHA determined that any time needed to set up the engineering controls required by this rule is adequately accounted for in the productivity impacts the Agency has included, particularly in light of the fact that OSHA is not making any adjustment to account for productivity improvements that are likely to result from this rule (see the discussion of comments identifying productivity improvements later in this section). Environomics' inclusion of both a ''fixed'' productivity impact as well as a ''variable'' productivity impact, without recognizing offsetting productivity benefits identified by other commenters', results ins a significant overestimate of the productivity impact.

Public Comments Suggesting That OSHA had Overestimated the Productivity Impacts Associated With Engineering Controls

BCTD strongly disagreed with CISC's estimates about productivity decreases resulting from the rule, stating in their post-hearing brief:

> [a]ll that [CISC] offered to support these significant increases [in the productivity impact] is an explanation of how its approach to calculating productivity differs from OSHA's and a few examples, such as:
>
> So in the case of the carpenters with the dust extraction equipment on the drill and the HEPA vacuum, the carpenter takes a little bit longer to do his hole-drilling task because he's got to attach the equipment to the drill. He's got to attach the hose to the HEPA vacuum. He's got to walk over before he drills and he's got to turn on the HEPA vacuum. Then after he drills, he's got to turn off the HEPA vacuum. He's got to periodically empty the HEPA vacuum. He's got to worry about the vacuum hose from the drill to the vacuum getting kinked and all that sort of thing. So the job takes a little bit longer. Tr:1317–18.
>
> CISC offered no evidence that its analytical approach is more accurate than OSHA's. Moreover, this description of how its hypothetical carpenter would deploy control technology assumes the employer would select the most cumbersome and inefficient technique available, rather than taking advantage of the range of more suitable and less costly tools that are readily available on the market. See, e.g., Ex. 4073, Att.7a (ROI: hand-held drill with integrated dust collection) (Document ID 4223, pp. 55–56).

BCTD also took exception to the fact that ''CISC acknowledged that 'there may be a productivity net gain in terms of cleanup from using a control,' Tr:1319 (Sessions), [but did] not appear to have taken potential gains into consideration when estimating its lost productivity cost'' (Document ID 4223 pp. 55).

Dr. Ruth Ruttenberg highlighted the various areas where the PEA may have overestimated the negative productivity effect of engineering controls in construction. She stated that the assumption of a negative impact on productivity

> . . . is yet another example of OSHA erring on the side of being conservative in cost estimates. Despite the fact that some who were interviewed suggested there could be a positive impact on productivity, OSHA's PEA assessed anywhere from 0 percent to a 5 percent penalty in productivity loss as a result of OSHA compliance with the proposed silica rule. (PEA, p. V–123–124) The impact of an assumption of lost productivity can be profound, and OSHA acknowledges this: ''. . . the magnitude of the productivity impacts can substantially change the estimate of the overall cost increase associated with controls'' (PEA, p. V–131).
>
> Despite the fact that OSHA leaves likely productivity increases out of its calculations, it does point to opportunities to increase productivity with dust control. [. . .]
>
> Limiting dust increases visibility for workers. (PEA, p. V–126) Vacuum systems speed up drilling because continuous removal of drill cuttings from the hole, reduce the need for workers to periodically stop and clean. (PEA, p. V–128) And the list goes on. OSHA's cost estimates are conservative, and high, when it comes to productivity impact (Document ID 2256–A4, p. 7).

Productivity Improvements

In addition to comment that the productivity loss due to this rule would be minimal, OSHA also received considerable comment to the record that the controls would improve productivity in a number of ways the Agency had not factored in—for example by reducing clean-up time by capturing dust at the source, improving worker comfort and morale, and encouraging innovation.

Productivity Improvements—Reduced Clean-Up Time

Testimony at the public hearings by the International Union of Bricklayers and Allied Craftworkers on the experience by union members with engineering controls suggested that use of controls may boost productivity by reducing the amount of dust that needs to be cleaned up during a given shift. The following is a hearing dialogue between Chris Trahan of BCTD, and Sean Barrett of the International Union of Bricklayers and Allied Craftworkers:

MS. TRAHAN: [. . .] In your experience is there any productivity gains or benefits that you can describe?

MR. BARRETT: I can. These machines, when running correctly, when [. . .] the vacs are regulated, the filters are running good. You can run that machine until 3 o'clock in the afternoon, shut it off, and go home. [. . .] If [the machine is] not [running correctly], you constantly got to keep going back and cleaning up what you already did. You're losing productivity. And over the course of [. . .] a month you're talking 40 man-hours. You're talking a—paying a guy for a week. It's—that's not the case at all [if dust controls are functioning]. You would actually increase productivity by having the right equipment there and not have people have to keep coming back or jimmy-rig little things to try to get by. Just do it the way it was designed, and you'll get a lot farther. . . . (Document ID 3585, Tr. 3055–3057).

Deven Johnson of the Operative Plasterers' and Cement Masons' International Association elaborated on the potential time savings of some of the new engineering controls:

other things that collecting the dust from these operations on the front end does, it saves time on cleanup. Some of the industry people have said that it's prohibitive to do that because it takes more time to collect the dust. That's also not true. If you're collecting the dust as it's generated and it's going into a HEPA-filtered container, it's not being blown all over the job site, you don't need anybody else to clean it up (Document ID 3581, Tr. 1594).

Walter Jones of the Laborer's Health and Safety Fund testified that, for some tasks, reducing or eliminating the need to clean up after a job can dramatically increase productivity, in this case by one-third:

We had the Bricklayers here a few days ago and they were talking about their ability to work till 3:00, because they did not have to clean up. Instead, when they use non-dust controlling or capturing devices, they would have to stop right after lunch in order to begin cleaning up. So we're looking at adding a few more hours to the workday. So to me, in my mind, they're way more productive (Document ID 3589, Tr. 4246).

Joel Guth, President of iQ Power Tools and a mason contractor, testified that he had been able to document the savings in clean-up time.

In certain industries we've been able to measure the time savings from cleaning up the silica dust [. . .] It saves them one to two to three hours a day in cleanup time because they don't have to wash down the house or wash the windows or wash the bushes where they're inherently dry cutting (Document ID 3585, Tr. 2981).

Scott Schneider, CIH, Director of Occupational Safety and Health. Laborer's Health and Safety Fund of North America, discussed how engineering controls contribute to a more productive workplace:

When you control the dust and you don't have—you're not breathing it into your lungs, but you're also not spraying it all over the construction site, all over the sidewalk, and you have to clean it up, there's a lot of other costs involved in not controlling. So I think we're going to realize those benefits by implementing the standard (Document ID 3589, Tr. 4277).

Productivity Improvements—Improved Worker Comfort

OSHA also heard a good deal of testimony suggesting that productivity will be improved through the use of engineering controls due to improving the working conditions for workers.

Mr. James Schultz of Wisconsin Coalition of Occupational Safety and Health described the physiological and practical benefits of introducing or enhancing engineering controls:

I think if you would work in the work environment that was less dust or hopefully dust free, it would definitely increase the amount of productivity just because so much of the time you're spending wiping the dust off your brow because it's falling into your eyes or something like that. Even if you have the respirator, it still interferes with your vision and things like that. So a cleaner environment would definitely be more productive just because [. . .], you spend less time trying to think about how you can protect yourself from this hazard, and I know myself, after working in the place for many years, I've started to have breathing problems and so if you can eliminate those breathing problems, if you can breathe freely, you're also going to be much more productive because you're not going to stop because you have [to] wheeze or go stand outside to get some fresh air for awhile or those types of things (Document ID 3586, Tr. 3253–3254).

Deven Johnson, mentioned previously, testified about the human effect of controlling silica as well:

Another thing is, an individual who is working in an environment where [. . .] he or she is constantly bombarded with concrete dust all day long, your productivity drops as you get more and more miserable as the day goes on. Commonsense would dictate, if you're not blasting me in the face with dust and sand and silica for eight hours a day, that I'm going to feel physically better and I'm not going to be as tired and exhausted and pissed off as I normally would be at the end of the day. Your productivity goes up[. . .]. (Document ID 3581, Tr. 1594–1595).

Mr. Javier Garcia Hernandez, from National Council for Occupational Safety and Health/Equality State Policy Center/Laborsafe, testified on the cognitive factors that affect productivity, and why engineering controls should aid productivity:

. . . as a construction worker, I highly believe that we're more productive when we are protected[. . . .]. We spend less energy focusing on how to protect ourselves. Just imagine you're working in a roomful of dust and you're just trying to either close your eyes or cover your mouth so the less you breathe. So you're constantly thinking about how to breathe less dust but if you have the respirator or the wet, the controlled area, whether it is water or respiratory protection, you're much more productive because our mind is less occupied in how to protect ourselves and we spend that time that we would have spent protecting ourselves working (Document ID 3586, Tr. 3248–49).

Todd Ward, a bricklayer, testified that workers have some awareness of the hazards of dry cutting blocks and that

. . . when [workers] on the job [are] dry cutting they know—it affects morale as well when they know [. . .] they have some safeguards and they're protecting their lungs. So there is an increased productivity when you have a good morale then on the job (Document ID 3585, Tr. 3057).

Productivity Improvements—Innovation

OSHA received comments on the fact that OSHA standards often lead to innovation.

The Laborers' Health and Safety Fund of North America pointed out that ''[j]ust about every OSHA standard has had a look-back that has shown [that] industry has innovated to meet the new standard'' and continued, saying that ''[w]e believe a new OSHA standard with a lower PEL will spur innovation in the construction industry to meet the challenge'' (Document ID 3589, pp. 4183–4184).

Charles Gordon observed that ''reality is that the new technology will increase productivity faster, so that the actual costs will be much less than predicted'' (Document ID 3855, Tr. 3815).

Conclusions Regarding Productivity Impacts

In summary, while some commenters have asserted that OSHA has underestimated the productivity penalties of using engineering controls in construction, other evidence in the record suggests that the aggregate net

productivity effect of implementing engineering controls could either be neutral, or possibly positive. In the absence of detailed quantitative data on these various potentially offsetting effects, OSHA has conservatively chosen to retain its percentage estimates from the PEA, while adding some additional productivity impacts that will increase not only labor costs but also equipment costs.

There is one exception: OSHA has removed the productivity impact that it had included in the PEA for drywall installers. As explained in the unit cost discussion, the Agency has determined from the record that there is no economic reason why drywall installers would now use silica-based drywall installation—the U.S. market has shifted entirely to a silica-free compound (Document ID 2287, p. 38; 2296, Attachment 1, p. 30; 1335, pp. 3–4, 7, 10). Therefore, there is no longer a logical basis for a assigning a productivity loss to workers performing this task.

Table VII–12 summarizes the labor productivity estimates. As discussed previously, while empirical quantitative data are quite limited on productivity, it is possible to gauge the relative productivity impacts across the principal control options. For example, OSHA judged that there are no productivity impacts for certain controls, such as mobile crushing machines. On the other hand, OSHA found that the controls required for tuckpointers and grinders may result in additional time being spent setting up and maintaining controls over the course of a workday. In Table V–34 of the FEA, productivity impacts, or ''lost production time,'' are shown by task and are factors in OSHA's estimate of incremental cost per day.

As discussed, OSHA has retained most of its original estimates of the productivity effects from the PEA. In some cases, however, Table 1, which forms the basis for the equipment categories listed in Table VII–12, was changed from the PEA in response to comment. (see Methods of Compliance in this preamble for further discussion on the changes to Table 1). In other cases, OSHA received clarification on the manner of exposure and added elements to Table VII–12, but did not adjust the productivity impact. For example, OSHA received very specific comments on tasks involving portable masonry saws used to cut fiber cement materials (*e.g.*, ''Hardie board''), and this is reflected in specific descriptions in Table 1 and in Table VII–12, but the estimated productivity impact for ''masonry cutting using portable saws'' remains the same. Similarly, the Table 1 task that included ''heavy equipment operations'' in the proposed rule has been broken out into two groups: (1) Heavy equipment operators and ground crew laborers used for activities such as grading and excavating that will not involve demolition or other uses that will abrade or fracture silica-containing materials; and (2) heavy equipment operators and ground crew laborers involved in demolition or the abrading or fracturing of silica-containing materials. These two categories are now estimated to have productivity impacts of two and three percent, respectively.

Table VII-12: Productivity Impact Estimates for Construction Equipment Categories Affected by OSHA's Final Silica Standard

Productivity Impact	Source/Rationale for Productivity Impacts	Equipment Categories Affected
None	Dust control is well-integrated into equipment; control set-up can be accomplished with little or no additional effort or as part of substantial set-up effort (In some cases, dust control can improve worker comfort and might enhance productivity)	Rock and Concrete Drillers; Mobile Crushing Machine Operators and Tenders
2% (approx. 10 minutes/day)	(1) Dust control requires incremental set-up time, or (2) Incremental maintenance, or (3) Additional clean-up (Controls have little impact on job performance)	Millers Using Portable or Mobile Machines; Hole Drilling Using Handheld or Stand-mounted Drills; Masonry Cutters Using Stationary Saws; Masonry and Concrete Cutters Using Portable Saws; Heavy Equipment Operators and Ground Crew Laborers (grading and excavating)
3% (approx. 15 minutes/day)	Dust control requires incremental set-up time and some increase in maintenance or clean-up requirements	Jackhammers and Other Powered Handheld Chipping Tools (wet methods); Heavy Equipment Operators and Ground Crew Laborers (abrade or fracture silica-containing materials or demolition)
5% (approx. 24 minutes/day)	Dust control requires incremental set-up time and regular maintenance during day	Jackhammers and Other Powered Handheld Chipping Tools (where LEV is used) Tuckpointers and Grinders

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

Productivity Impact Estimates, by Equipment Category

Rock and Concrete Drilling

This equipment category includes the following Table 1 tasks:

- Dowel drilling rigs for concrete; and
- Vehicle-mounted drilling rigs for rock and concrete

This equipment category covers a range of drilling activities using truck-mounted and similar drilling equipment, such as quarry drills and crawler-type drills. Dust control requires the use of either a dust collection system or wet drilling methods. Studies of the effectiveness of available dust collection systems have not addressed performance issues, but ERG judged that their use does not affect drilling productivity. While workers must service the dust control equipment during the workday, this activity generally does not affect the rate of drilling, except perhaps for short-duration jobs. The wet drilling methods are integrated into drilling equipment and also should not adversely affect the drilling rate. Thus, OSHA estimates that there will be no lost production time for these tasks.

Tuckpointers and Grinders

This equipment category includes the following Table 1 tasks:

- Handheld grinders for mortar removal (*i.e.,* tuckpointing); and
- Handheld grinders for uses other than mortar removal

According to ERG's search of the literature, grinding tools can be retrofitted with dust control shrouds that connect to a vacuum system (Buser, 2001 & 2002, Document ID 0577). Studies on the use of these controls indicate that extra time is required to install the shroud and periodically

clean, empty, or replace the vacuum drums, filters, or bags. The estimated time to install the shroud may be as short as five minutes, although some types of shrouds take longer to install. Once installed, however, the shroud can be left in place for the work at that location, so this activity need not take place at the initiation of each grinding job.

For interior jobs and for exterior work that requires site cleanup of grinding debris, the additional work time required to use a vacuum system might be partially offset by savings in the time required to seal work areas (to prevent dust migration) and to clean the work area after task completion. Overall, clean-up times will vary depending on the size of the job site, the quantity of grinding debris, and the strength and capacity of the vacuum.

Grinding without a dust-control shroud can generate clouds of dust that might impair a worker's views of the grinding area. Whereas metal shrouds also block the view of the grinding area, plastic shrouds allow workers a view of the work area. Some contractors have noted, however, that use of shrouds does not allow for the precision required for certain tasks, such as grinding an inside corner (Lattery, 2001, Document ID 0777).

For exterior jobs where cleanup is not required and where the work area is not sealed, the use of vacuum equipment is likely to decrease productivity for the amount of time required for servicing the vacuum collectors. If, for example, five minutes were required to empty the vacuums every two hours, production time would decline about 4 percent, due simply to dumping the accumulated dust.

At some construction sites, vacuums have been used during the grinding process, but without shrouds. In these cases, one worker typically holds the vacuum nozzle near the grinding tool, which another worker operates. Switching to shrouds with a direct vacuum attachment would eliminate the need for this assistant and is a more productive operation.

Manufacturers and vendors cited other benefits from using the shroud-vacuum systems. Because dust does not build up on and clog the surface of the grinding wheel, the wheels last longer, resulting in an approximate 40 percent savings on the grinding discs (Eurovac, 2001, Document ID 0688). Another source contacted by ERG estimated that shrouds can increase the abrasive life of a grinding wheel by more than 500 percent (Buser, 2001 & 2002, Document ID 0577). In this regard, workers would spend slightly less time replacing wheels over the life of the equipment.

OSHA concluded that while the productivity impacts of vacuum systems can sometimes be partly offset by other factors, net productivity impacts are likely to remain negative. For exterior work, productivity is clearly lower when workers use a vacuum system. Overall, based on ERG's research, OSHA's final cost estimates include a 5 percent impact for lost production time associated with grinding operations in construction. This productivity impact is identical to the impact estimated for this activity in the PEA.

For a tuckpointing project, NIOSH researchers examined the use of vacuum system controls at a large college building complex (Gressel *et al.,* 1999, Document ID 0718). Workers used a shroud-vacuum system with an integral impeller and a fabric dust collection bag. This system required emptying the collection bags about once an hour. The authors reported some problems caused by blocking and kinking of the hose and occasional separations of the hose from the tool. Some of these problems can be attributed to the design of the dust control system and might be rectified by future design innovations. Overall, the vacuum control systems appeared to reduce worker output.

Manufacturers and vendors contacted by ERG estimated that polyurethane shroud-vacuum systems with tuckpointing equipment, similar to those used with hand-held grinders, actually enhance productivity. Among the reasons provided for productivity improvements were: (1) Fewer workers were required; (2) cleanup times were reduced; (3) workers had improved visibility of the work surface; and (4) blades last longer (Buser, 2001 & 2002, Document ID 0577; Caperton, 2002, Document ID 0580; Eurovac, 2001, Document ID 0688; Nash and Williams, 2000, Document ID 0829). These observations on productivity applied to tuckpointers with 2- to 8-inch diameter wheels. In addition, positive effects on worker productivity have also been reported for shrouds that fit on 5-inch and 7- to 8-inch (18-lb) tuckpointers with integrated dust-collection systems since equipment without integrated dust-collection systems require that an additional worker be present to continually vacuum dust away from the work area (Document ID 0577). On the equipment that can be used with the tuckpointers with 5- to 8-inch wheels, an impeller inside the tool housing pushes dust down a hose into a reusable dust-collection bag (Document ID 0577). One vendor estimated that the operational productivity of these tools is no different from that of the same tool without dust control capability. Workers would still be required to periodically empty dust bags, although other clean-up time might be somewhat reduced (Document ID 0580). Because tuckpointing work is almost exclusively exterior work, however, clean-up is often not required.

Based on the considerations for hand-held grinding tools discussed above and the findings from the NIOSH tuckpointing study, OSHA judged in the PEA that use of a vacuum system during tuckpointing operations would impose, on average, a 5 percent negative productivity impact. Based on these findings and because manufacturer optimism about any positive productivity impacts has not been documented in controlled studies, OSHA included the same 5 percent negative productivity impact for tuckpointing tasks in the FEA.

Heavy Equipment Operators and Ground Crew Laborers

This activity includes the following Table 1 tasks:

- Heavy equipment and utility vehicles used to abrade or fracture silica-containing materials (*e.g.,* hoe-ramming, rock ripping) or used during demolition; and
- Heavy equipment and utility vehicles for tasks such as grading and excavating but not including: Demolishing or abrading or fracturing silica-containing materials [41]

The control method proscribed in the proposed silica standard was to enclose and ventilate the operator's cab. The requirement for an enclosed cab is only retained in the final standard with respect to the use of heavy equipment used to abrade or fracture silica-containing materials or used during demolition. Final Table 1 allows employers to control dust from heavy equipment used for other purposes (*e.g.,* grading or excavating) by using wet methods.

Using an enclosed cab on heavy construction equipment will not require maintenance beyond the general maintenance necessary to maintain the integrity of the cab enclosure. Therefore, OSHA estimated in the PEA that no productivity loss will be incurred for this control.

In the case of heavy equipment operations, CISC/Environomics estimated that there would be a one percent productivity penalty for

[41] Heavy equipment operations (grading and excavating) was referred to as earth moving in the PEA and in comments. The term has been updated for this analysis and used throughout for the sake of consistency and to avoid confusion.

enclosed cabs, due to communication issues and the need to unclog HEPA filters (Document ID 4217, p. 93). For several reasons OSHA is not persuaded that the factors CISC cites would result in a net productivity loss for enclosed cabs on heavy equipment.

First, it is not clear that communication issues are being created by setting some minimal standards for enclosed cabs. Information supplied in the record indicates that there are alternate means of communication beyond shouting from the cab to the front-line workers outside the cab, including hand signals (Document ID 3583, Tr. 2441) and existing wireless communication systems (Document ID 0805, p. 4; 2262, p. 28). Many of these work environments are noisy, which seems to make alternate means of communication desirable, if not required.

Second, it appears that it may be more economical and desirable for workers to operate in a climate-controlled cab and that equipment with enclosed cabs has become standard in the construction industry. In fact, OSHA has determined that relevant heavy equipment currently comes with an enclosed cab as standard equipment (Document ID 3813, 3814, 3815, 3816), and in pricing construction jobs, RS Means included a cab as a standard equipment (meaning that it was already included in the equipment cost, not an added engineering control). In any case, the fact that cabs are standard suggests that potential buyers do not view the presence of a cab to be undesirable. While Environomics acknowledged this possibility at the hearings, their judgment remained that there would be a net productivity loss (without providing information on how these offsetting considerations were being incorporated) (Document ID 3580, Tr. 1434–1435). While OSHA is not persuaded that the evidence in the record supports Environomics conclusions, their argument is largely moot. Any productivity impact would result only from the addition of new controls, but enclosed cabs appear to have become standard on the relevant equipment, meaning that in most cases employers would not have the option of using open cabs even if OSHA's new rule was not in effect. Thus, there can be no productivity impact attributed to the requirement for a cab.

Although OSHA is not including any productivity impact to account for enclosed cabs, final Table 1 requires water, or other dust suppressants, during specified heavy equipment operations in order to protect workers outside the cab and as an alternative method of protecting operators for activities that do not involve silica abrading or fracturing. OSHA has therefore, as indicated in Table VII–12, added a 2 percent productivity impact for heavy equipment tasks involving grading and excavating, and 3 percent during demolishing, abrading or fracturing silica-containing materials. OSHA judged that the abrading, fracturing, and demolition-related tasks tend to be relatively dustier, and would therefore require relatively more labor to administer.

Hole Drilling Using Handheld or Stand-mounted Drills

This equipment category includes the Table 1 task ''handheld and stand-mounted drills (including impact and rotary hammer drills).''

This category includes workers in the construction industry who use handheld drills to create clearly defined holes for attachments (*e.g.,* anchors, bolts, hangers) or for small openings for utility pass-throughs in concrete and other silica-containing construction materials. Workers use common electric drills, pneumatic drills, handheld core drills, stand-mounted drills, rotary drills, rotary hammers, percussion hammer drills, or other impact drills to drill holes. With regard to core drills, only small, handheld core drills with bits up to a few inches in diameter are included in this category. This discussion does not address the use of portable and mobile hole saws used to produce large holes or openings. That equipment is covered in the discussion of Masonry and Concrete Cutters Using Portable Saws.

Handheld and rig-mounted drills can be equipped with local exhaust ventilation to effectively capture dust generated when drilling small diameter holes. Larger core drills, also referred to as core saws, are more frequently used with water as a coolant to extend the service life of the drill bit, as well to suppress dust.

One rock-drill manufacturer asserts that use of vacuum systems speeds drilling by continuously removing the drill cuttings from the hole, making it unnecessary for workers to periodically stop drilling to accomplish this task (Atlas-Copco, 2001, Document ID 0542). On the other hand, the connection and servicing of the vacuum equipment requires incremental work that could reduce productivity. If the construction project at hand involves interior work, this impact might be offset by reductions in the time necessary for cleanup (*i.e.,* interior work would require cleanup, while exterior drilling probably would not). In the PEA, OSHA applied a 2 percent productivity impact where this task is performed and did not receive comment suggesting that this estimate was too low, so OSHA retains the same 2% productivity impact in estimating compliance costs in the FEA.

Jackhammers and Other Powered Handheld Chipping Tools

This equipment category includes the Table 1 task ''Jackhammers and handheld powered chipping tools.''

Silica exposures generated during pavement breaking, concrete demolition, and other concrete work using jack hammers and other handheld powered chipping tools (including pavement breakers and other similar tools) are controlled through the use of wet or dry methods.

Regarding wet methods, because the work area generally cannot be presoaked effectively (*i.e.,* dust is generated once impact drillers break through the surface), OSHA judged that adequate dust control requires a constant spray of water to the work area. Thus, dust control requires that a water sprayer be mounted onto the jackhammer (or that a mobile sprayer be set up that can move along with the work). Alternatively, a crew member can use a water hose to spray and wet the concrete and asphalt surfaces being broken, although the associated productivity loss could be substantial, and, for that reason, OSHA believes that construction firms would likely try to avoid that approach.

However, OSHA judged that the incremental productivity impact from the spraying activity is modest because various crew members could occasionally be enlisted to keep the water spray directed in the correct location. Further, because of the interactive nature of the various crew member activities, the time to move the water sprayer is unlikely to affect the overall crew output. In addition, incremental cleanup costs generally would not be significant since most drilling projects are performed outside. Nevertheless, to allow for some incremental work related to supplying water and positioning the spray when wet methods are used, as was the case in the PEA, for the FEA OSHA estimated a 3 percent productivity impact for this equipment category when wet methods are used.

A separate, higher, productivity impact was defined for use of dry methods for activities where jackhammers and other handheld powered chipping tools are used. Dry methods are somewhat less flexible and require a shroud for the close capture of dust as it is generated during operations. Workers also periodically have to empty

the vacuum bags in which the dust accumulates. Thus, as discussed above with respect to the use of a shroud for grinding and tuckpointing, these controls are judged to generally have a greater productivity impact during operations and, consistent with the PEA, OSHA assigned a 5 percent productivity impact to use of this control method for this equipment category.

Masonry and Concrete Cutters Using Portable Saws

This equipment category includes the following Table 1 tasks:

- Handheld power saws (any blade diameter);
- Handheld power saws for cutting fiber-cement board (with blade diameter of 8 inches or less);
- Rig-mounted core saws or drills;
- Walk-behind saws; and
- Drivable saws

Drivable saws and walk-behind saws have an integrated water tank, and the sawing is almost always done wet (*see* FEA Chapter IV, Technological Feasibility). Wet sawing keeps the blade from overheating, with the water acting as coolant. Rig-mounted core saws used to drill larger diameter holes in concrete are typically used with water as a coolant to extend the service life of the bit, as well as to suppress dust.

As has been noted, most portable hand-held concrete saws are designed with wet-sawing capability (see Chapter IV, Technological Feasibility of the FEA). These saws have a water hookup for a hose attachment, but might also be used for dry cutting. (Dry-cut diamond blades for dry cutting are available; these are made especially so that the tips do not separate during dry cutting.)

A construction equipment distributor judged that there are no operational productivity advantages for dry cutting, as opposed to wet cutting (Healy, 2002, Document ID 0726). Wet cutting, however, requires access to water (water line or pressurized tank), and some time is needed to connect the equipment (although OSHA received a number of comments saying that this hook up is very simple and not time consuming—*see* ''Public comments suggesting that OSHA underestimated the productivity impacts associated with engineering controls'' earlier in this section for more detail). In addition, the water hose hookup may be cumbersome and interfere with the work (Healy, 2002, Document ID 0726). For these reasons, as was estimated in the PEA, for the FEA, OSHA assigned a cost of 2 percent in lost production time for equipment in this category.

For the final rule, the Agency has clarified in Table 1 that hand-held circular saws with a blade diameter of eight inches or less specially designed for cutting fiber cement board can be used outdoors without respiratory protection, when equipped with a local exhaust ventilation. The productivity impact for this group is also estimated at 2 percent because, although it does not have an impact on job performance, it involves some set-up time and incremental maintenance.

Masonry Cutters Using Stationary Saws

This equipment category includes the Table 1 task ''Stationary masonry saws.'' Stationary saws for masonry, brick, and tile cutting come equipped with water systems for wet cutting, which is the conventional, baseline control method for this type of work. Some modest incremental time is needed to provide for and connect the water supply and to maintain the water nozzles and spray system. This incremental time was the basis for OSHA to estimate a 2 percent cost in lost production, both in the PEA and in the FEA.

Millers Using Portable or Mobile Machines

This equipment category includes the following Table 1 tasks:

- Walk-behind milling machines and floor grinders;
- Small drivable milling machine (less than half-lane);
- Large drivable milling machines (half-lane and larger with cuts of any depth on asphalt only and for cuts of four inches in depth or less on any other substrate)

The activities performed using equipment in this category range from cold planing and cleaning of asphalt to surface planing or grinding of concrete. In large-scale projects, such as street resurfacing, baseline practices are judged to control silica dust exposures. No additional controls would be needed, and therefore no negative productivity impacts are expected.

While some grinding machines designed for milling concrete surfaces have built-in dust collection or wet-method systems, others must be attached to external vacuum equipment. ERG reviewed the available literature and found no evidence that the grinding operation is slowed when such vacuum equipment is attached. Nevertheless, workers must devote some time to setting up equipment, changing vacuum bags or barrels, and cleaning filters. On the other hand, using an LEV system to capture dust as it is generated reduces the time required for cleaning up the settled dust from the surfaces following completion of the grinding task. OSHA estimated in the PEA that there would be a 2 percent productivity impact for milling using wet methods and a 5 percent productivity impact when using LEV systems.[42] These estimates have been retained for the FEA.

Mobile Crushing Machine Operators and Tenders

This equipment category comprises the Table 1 task ''Crushing machines.''

OSHA projected in the PEA that there would be no productivity impact for this equipment category. The Table 1 requirements for this machinery have changed in the final rule, but OSHA's conclusion that there will be no productivity impact remains the same. Final Table 1 requires employers to protect employees through a combination of sprayers and requiring the operator to operate the machinery from within a ventilated booth or at a remote control station. Once installed, the sprayer systems will be part of the crushing machine operation and will not impact production rates. For the purpose of the economic analysis of this rule, OSHA has accounted for additional costs for use of the ventilated booth. Because the booth can be located close to the machinery, there would not be productivity loss from the operator having to travel to a different location for operation. In most cases the booth can be set up quickly once at each location, so in most cases there will not be any significant productivity loss associated with the use of the booth.

Baseline and Incremental Unit Control Costs

Table V–34 in the FEA, and presented as Table VII–13 in this section, summarizes the control method and costs per day for each representative construction job. These costs include incremental equipment costs and indirect labor costs due to productivity impacts (decreases in productivity associated with the use of the control equipment).

Note that the only silica tasks in Table V–34 of the FEA considered to have short-term infrequent work where the employee would own the equipment are Task 11: Hole drilling using hand-held or stand-mounted drills and Task 18: Masonry cutting using portable saws—II. Note also that all the indoor tasks in Table V–34 of the FEA have an additional daily control equipment cost of $1.67 for a fan.

[42] For the FEA, milling operations using LEV are accounted for under grinding operations, as indicated in Table V–24.

Table V–35 of the FEA summarizes the baseline costs and incremental control costs from Tables V–30 and V–34, of the FEA, respectively, for each representative silica-related job in OSHA's silica construction cost analysis. The control cost (defined as incremental control costs per day) are shown in Table V–35 of the FEA as a percentage of the baseline daily job costs. As the incremental control costs were obtained from Table V–34, they are just the sum of additional labor and equipment costs associated with the use of silica controls, including the labor and equipment productivity impacts of the use of the silica controls.

As is evident from Table V–35 of the FEA, these incremental control costs can range from 0.3 percent to 7.8 percent of the baseline job cost. The magnitude of the productivity impacts can substantially change the estimate of the overall cost increase associated with the silica dust controls.

Table V–36a of the FEA presents the weighted average of control costs by task category for outdoor tasks. OSHA defined ''weights'' for each job category (column ''Relative Frequency Within Categories'') based on the projected relative applicability of the controls and/or tasks within each category (as determined in the technological feasibility analysis in Chapter IV of the FEA). These percentages did not change from the PEA except for the two tasks that have each been further partitioned into multiple tasks in the final rule: Heavy construction operators and masonry cutters using portable saws. Heavy equipment operators are subdivided into tasks that involve fracturing, abrading, or demolishing silica-containing materials such as masonry or concrete, that require use of wet methods whenever workers other than the equipment operator are present, and tasks that involve use of heavy equipment for earthmoving and excavation of soil, that require wet methods only as necessary to minimize fugitive dust. Masonry cutters using portable saws are subdivided into five categories: (1) Handheld power saws such as cutoff saws; (2) handheld power saws for cutting fiber-cement board with blade diameters of less than eight inches; (3) walk-behind saws; (4) drivable saws; and (5) rig-mounted core saws. Wet methods are specified as a control method for all use of portable saws except for handheld power saws for cutting fiber-cement board, for which LEV rather than use of water to suppress dust is required. The labor cost as a percentage of project costs—which, as subsequently shown, is a critical factor in calculating the total value of all silica-generating construction activities—is derived from Table V–30 of the FEA.

Table V–36b of the FEA presents the weighted average of control costs by task category for tasks indoors or in enclosed areas (''indoor tasks''). The procedures are identical to those used in Table V–36a of the FEA, and the only difference is that the total incremental costs as a percentage of baseline costs are higher due to the addition of the cost of a fan for indoor tasks.

Once the total value of all silica-generating construction activity is calculated for each task, as shown in Table V–44 of the FEA, the incremental costs associated with each task category as a percentage of baseline costs (from Tables V–36a and V–36b of the FEA) will determine the costs that the engineering control requirements in the final construction standard add to the costs of construction activity—that is, the incremental costs of the resulting reduction in silica exposure.

Aggregate ''Key'' and ''Secondary'' Labor Costs for Representative Projects

To estimate aggregate labor costs or value for each equipment category, OSHA first matched OES occupational classifications with the labor requirements for each equipment category (*e.g.,* hole drillers using hand-held or stand-mounted drills). These matching occupations are shown in Table V–37 of the FEA. In order to estimate the percentage of time during each work day that workers spend on activities using equipment in the relevant categories, OSHA designated some occupations as ''key'' and others as ''secondary.'' The key field in Table V–37 is set to ''1'', if a key occupation and to ''0'' if a secondary one. Even those employees who are engaged in tasks on Table 1 typically spend only a portion of their workdays engaged in silica-generating tasks, so the distinction between ''key'' and ''secondary'' is needed in order to estimate the amount of time workers participate in silica-generating tasks. In the preliminary and final cost analyses, OSHA applied ERG's occupation designation, as explained in greater detail below. OSHA requested comment on the designations of ''key'' and ''secondary'' designations in the PEA, but did not receive any comments challenging those designations.

''Key'' occupations refer to the worker or workers on each crew who perform the principal silica-generating activity using the equipment in each equipment category. For each equipment category, ERG estimated the overall percentage of time that workers in key occupations devote to the activity.

Other ''secondary'' crew members (*e.g.,* first-line supervisors/managers and construction laborers) were estimated in terms of their ratio to the number of key workers required for given task areas. The secondary crew ratios range from 0 percent (no one in a secondary occupation engaged in silica-generating tasks) to 300 percent (three times the number of secondary occupation workers, in relation to the number of key workers, exposed to silica-generating tasks). As noted above, OSHA used these percentages and ratios to estimate (on an annual basis) the amount of time these employees are using relevant equipment to engage in work that causes silica exposures. The estimate of the percentage of time performing the silica-generating activity can be viewed in terms of the full-time-equivalent (FTE) employees engaged in work that utilizes equipment in each equipment category. These estimates and the corresponding ratios for secondary workers are shown in Table V–37 of the FEA.

For the key occupations, OSHA was able to obtain some data with which to estimate the proportion of time workers perform activities using silica-generating equipment. For the secondary occupations, such estimates were generally not possible. Thus, the participation of secondary occupations in silica-generating activities was defined based on their relationship to the key occupations. This participation is defined by their presence in the job crews, as shown in Table V–30 of the FEA. To illustrate the need for this approach, consider the difficulty in predicting how often construction foremen of all types are present during activities where silica-generating equipment is used. BLS data, for example, provide only a total number of foremen, but no information about how they might spend their time. It is reasonable to forecast, however, using the job-crew definitions, that foremen will be present in some proportion to the number of workers in key occupations using jackhammers and other powered handheld chipping tools, rock and concrete drillers, and other silica-generating equipment. OSHA presented these data in the PEA and requested comments, but did not receive any on this aspect of the analysis. Therefore, OSHA is retaining its estimates from the PEA, except as noted.

For some activities, the crew size and composition vary among the jobs defined in the equipment category. In those cases, OSHA used ERG determinations as to the most representative crew composition and used that crew model to define the ratio

of secondary to key occupations (ERG, 2007a, Document ID 1709).

The estimates of the number of FTE employees engaged in activities using silica-generating equipment are one of many factors that influence the final cost estimates. There are few data, however, on the breakdown of time spent by construction workers in various activities. The following discussion presents the basis for the time-on-task estimates for the key occupations as included in the PEA and the FEA (except where noted). OSHA presented most of these estimates for public comment in the PEA but did not receive any comments challenging them.

Rock and Concrete Drillers

A review of NIOSH reports covering rock and concrete drillers showed that over 75 percent of driller time was spent on actual drilling (NIOSH 1992a, Document ID 0911, NIOSH 1992b, Document ID 0910, NIOSH 1995, Document ID 0907) and is supported by updated data in NIOSH, 1999b (Document ID 0220). Therefore, for the PEA and FEA, OSHA used 75 percent as the best indication of the time spent using dust-generating equipment for workers in this category.

Tuckpointers and Grinders

Grinding and tuckpointing are only two of the numerous jobs performed by brickmasons, cement masons, and their helpers. Workers in those trades are much more frequently performing bricklaying, cement work, and masonry construction. Where tuckpointers and grinders are being used, a review of the OSHA Special Emphasis Program reports revealed that the time spent using tuckpointers and grinders varied widely (*see* the technological feasibility analysis for this activity in Chapter IV of the FEA). In both the PEA and in the FEA, OSHA used ERG's estimate that 2.5 percent of the time for workers in each of the applicable occupations would be spent on using this equipment.

Heavy Equipment Operators and Ground Crew Laborers

For the final rule, heavy equipment operators and ground crew laborers were split into two categories in Table 1 based on how the heavy equipment and utility vehicles are being used, which reflects distinctions added in the final rule. This equipment is considered to either be used a) to abrade or fracture silica-containing materials (*e.g.,* hoe-ramming, rock ripping) or used during the demolition of concrete or masonry structures; or b) for tasks such as grading and excavating but not including: demolition of concrete or masonry structures or abrading or fracturing silica-containing materials.

ERG estimated that workers using heavy equipment to abrade or fracture silica-containing materials or for demolition devoted only 2.5 percent of their time, on an FTE-equivalent basis, to doing this work.

Key workers in the companion group using heavy equipment for grading and excavating often spend the bulk of their work shift on the equipment itself, engaged in construction work. OSHA Inspection Reports and other documentation consistently show that heavy equipment operators perform their tasks for more than 7 hours per shift (OSHA SEP Inspection Reports 122212079, 116179359; Greenspan, *et al.,* 1995; NIOSH HETA 93–0696–2395, 1999; NIOSH, 1999b; NIOSH ECTB 233–120, 1999c.).[43] Nevertheless, the heavy equipment operator occupational category also includes operators of such equipment as pile drivers, cranes, and air compressors that are not generally associated with silica dust generation. For the PEA, OSHA used ERG's estimate of 75 percent for operating engineers and 50 percent for excavating and loading machine and dragline operators in this category to estimate the number of heavy equipment operators performing silica-generating activities. OSHA did not receive any comment on these estimates and therefore has retained their substance for the FEA.

Hole Drilling Using Handheld or Stand-Mounted Drills

While many workers might occasionally be assigned to drill holes in concrete, this equipment category represents a very small part of the activities of the occupational groups performing this work. ERG judged that carpenters, electricians, plumbers, sheet metal workers, and helpers (construction laborers) spend one percent of their time drilling holes in silica-containing materials in the affected industries. OSHA presented this estimate in the PEA and did not receive comment or alternate estimates and has therefore retained the estimate for the FEA.

Jackhammers and Other Powered Handheld Chipping Tools

OSHA estimated in the PEA that in the key occupation of construction laborers, relatively few use equipment in this category. In developing the estimate of time spent using equipment in this category for the PEA, ERG examined a snapshot of construction activities from the BLS publication, *Injuries to Construction Laborers* (BLS, 1986, Document ID 0559). That source presents a survey of injured construction workers and includes questions about their activities at the time they were injured. The survey indicated that 3 percent of construction workers were using jackhammers at the time they were injured. ERG judged that, while the survey was not intended to characterize typical construction activities, and a survey of injured workers introduces considerable potential bias into the observations, this estimate was useful as an observation of representative construction activities. ERG also judged that, because jackhammers are heavier, more cumbersome, and more powerful than much construction equipment, workers are probably injured more frequently while using jackhammers, on average, than when using all other construction equipment. Thus, the 3 percent figure is likely to be an upper bound of the amount of time spent using jackhammers and other powered handheld chipping tools. In the absence of other data, OSHA used ERG's estimate that 3 percent of laborers are using this equipment for the PEA. The Agency received no additional data or comment on this estimate and has therefore retained this estimate for the FEA.

Masonry and Concrete Cutters Using Portable Saws—I

The key occupations using portable saws to cut masonry and concrete, namely brickmasons, blockmasons, stonemasons, and their helpers, spend, on average, a small share of their time cutting these materials with portable saws. In Table 1, OSHA notes three types of portable saws: (1) Hand-held saws, (2) walk-behind saws, and (3) drivable saws. Each of those is encompassed in this analysis, although small-diameter handheld saws are addressed separately. According to OSHA and NIOSH reports, the workers in these occupations perform multiple masonry activities and might engage in cutting for only a small portion of their shift (OSHA SEP Inspection Report 300646510; NIOSH, 1999a) (Document ID 0084). Another glimpse of this activity can be gleaned from the BLS injury report for construction laborers, where 3 percent of workers were injured while breaking up or cutting concrete, asphalt, brick, rocks, etc. For each of the applicable occupations, OSHA estimated in the PEA that 10 percent of the workers' time would be spent using

[43] Document ID 0133, 0192, 0716, 0220, and 0266, respectively.

the equipment in this category. The Agency received no comment on this estimate and has therefore retained this estimate for the FEA.

Masonry and Concrete Cutters Using Portable Saws—II—Small Diameter Saws for Cutting Fiber-Cement Board

The task of using handheld power saws for cutting fiber-cement board (with blade diameter of 8 inches or less) was separated out in Table 1 in the final rule to recognize portable saws used for cutting cement fiberboard or cement fibersiding as a potential source of silica-containing dust. OSHA judged that portable saws would be used by carpenters or their helpers to cut fiber-cement board and that, on average, they would spend 2.5 percent of their time using equipment in this category to cut the referenced materials.

Masonry Cutters Using Stationary Saws

As noted earlier, OSHA and NIOSH surveillance publications report that saw operators perform multiple masonry cutting activities and might engage in cutting silica-containing materials for only a small portion of their shift (OSHA SEP Inspection Report 300646510; NIOSH, 1999a). For the PEA, OSHA used ERG's estimate that workers in mason occupations spend 10 percent of their time cutting silica-containing materials with stationary saws. The Agency received no comment on this estimate and has therefore retained this estimate for the FEA.

Millers Using Portable or Mobile Machines

In the PEA, ERG identified two key occupation groups where millers are using portable or mobile machines: (1) Cement masons and (2) paving, surfacing, and tamping equipment operators. In response to comments (*see* Document ID 3585, Tr. 3036; 4220, p. 9; 3756, Attachment 1), for the FEA, OSHA added a third key occupation group: Terrazzo workers and finishers. Milling using this equipment represents a small share of the overall job duties of these applicable key occupations: In the PEA OSHA judged that 5 percent of all work for the first two occupation groups is spent using this equipment, and OSHA is retaining that estimate in the FEA because there were no comments challenging that estimate. OSHA estimates that terrazzo workers use the equipment about half as much as the other two occupation groups, so OSHA estimates that 2.5 percent of all work time spent by terrazzo workers and finishers will be spent using this equipment.

Rock Crushing Machine Operators and Tenders

According to information collected from ERG communication and OSHA SEP inspection reports, rock crushing machine operators spend most, if not all, of their shifts at and around the rock crushing process (Polhemus, 2000, Document ID 0958; Haney, 2001, Document ID 0721; OSHA SEP Inspection Report 2116507, Document ID 0186; OSHA SEP Inspection Report 300441862, Document ID 0030). OSHA estimated in the PEA that this occupational group spends 75 percent of its time using rock crushing machines and did not receive any comment on the estimate. OSHA has retained this estimate for the FEA.

Tunnel Boring

Underground workers perform both tunnel work and other types of construction work. The majority of these underground tasks still fall under Table 1 and have been accounted for elsewhere in the appropriate construction task analysis. However, a small amount of silica-generating underground construction work outside the scope of Table 1, primarily in tunnel boring, is expected to occur. The cost of engineering controls for this activity (to comply with the new PEL) is presented after the total engineering control costs to comply with Table 1 are presented.

SBREFA Panel Comments on Key and Secondary Occupations

As stated in the comments during the Silica SBREFA process, one SBREFA commenter was ''unable to reconcile ERG's statement that 'the amount of time . . . grinders and tuck-pointers perform grinding ranges widely, from about 1 hour per shift up to a full 8-hour shift (or longer)' [*see* the discussion on technological feasibility in Chapter IV of the FEA] with the 2.5% estimate in Table 4–8 [in the ERG report (2007a); Table V–26 in the PEA]'' (Document ID 0004; 1709). The commenter also asserted that masonry cutters use stationary saws approximately 20 to 30 percent of their working time (rather than 10 percent), and that masonry cutters use portable saws approximately 5 percent of their working time (rather than 10 percent) (Document ID 0004).

In response, OSHA reiterated in the PEA that Table V–26 of the PEA showed the estimates of the full-time-equivalent number of workers in key and secondary occupations using equipment to perform silica-generating tasks. These occupations are taken from the BLS *Occupational Employment Survey* classification system and are much broader than the ''masonry cutter'' category referred to by the commenter, implying a lower percentage of time devoted to tasks involving masonry cutting.

OSHA did not receive further comment on this explanation. Therefore, OSHA has not changed these estimates in the FEA. For each occupation the estimates in Table V–37 of the FEA are meant to reflect the typical or average amount of a worker's time (over a year) devoted to the listed tasks.

FTE At-Risk Employment by Task Category

Tables V–38a and V–38b of the FEA provide estimates, by occupation, of the full-time-equivalent (FTE) number of key and secondary workers, respectively, for each task category, using the percentages and ratios from Table V–37 of the FEA. These tables are relatively direct compilations from previous tables with adjustments needed, in a few cases, to assure that the industry-specific FTE occupational totals did not exceed the total occupational employment for any industry.

Table V–39 of the FEA shows the corresponding estimates by NAICS code for the construction industry.

OSHA distributed FTE at-risk workers across NAICS codes according to the combination of task categories and occupational (key and secondary) categories (from BLS, 2012, Document ID 1560) derived and updated by ERG for each industry group (ERG, 2007a, Document ID 1709).

Overall, a full-time equivalent of 374,003 workers is estimated to use equipment to perform work on silica-containing materials in construction, ranging from 1,135 FTEs for rock crushing machine operators and tenders to 198,585 FTEs for heavy equipment operators and ground crew laborers (grading and excavating).

Total At-Risk Employment

In the PEA, OSHA used a relatively crude approach to convert the estimated number of FTE affected construction workers to the number at-risk construction workers. There, OSHA used a multiplier of 2 or 5, depending on the industry, to convert the number of FTEs to the number of at-risk workers (in Table V–37 of the PEA).

OSHA received several comments regarding the analysis used in the PEA as being too simplistic. Joseph Liss challenged OSHA's methodology:

> Even though OSHA estimates the number of workers needing training for silica exposure under the proposed rule by

multiplying full-time equivalents by a factor of either 2 or 5, depending upon the sub-industry, the multiplicative factor for training purposes is likely to be much higher. For example, while paving, surfacing, and tamping operators spend a total of only 5% of their time on tasks exposed to silica, as estimated by ERG, it is not unlikely that many of the 51,857 workers in that industry sub-group will do silica-exposed work at some point, and, thus, require training. There are 823,737 construction laborers, and ERG estimated that 3% of their time is spent on silica-exposed work, but the severe turnover in that industry means firms may need to train many of those workers in silica safety procedures and health effects. OSHA estimates the nation's 575,000 residential construction workers spend 5% of their time on construction work and uses a multiplicative factor of two, thus assuming that only 10% of those workers require training and exposure monitoring. Costs may increase if the number of workers exposed increases, since OSHA requires training for all newly hired workers as well as all initial training for all workers exposed to silica (citations omitted) (Document ID 1950, p. 9).

Additionally, the Construction Industry Safety Coalition (CISC) submitted calculations to arrive at their own results of at-risk workers. They note:

> These percentages represent our quick judgement across both the key occupations and the secondary occupations that OSHA identifies as participating in the crew when the at-risk task is performed. If we had more time, we would like to make this judgement more carefully (Document ID 4032, Tab 6).

For the FEA, in response to comments, OSHA refined its process, as described below, to allow for a more nuanced approach to estimating the number of affected workers. As a result of this revised approach, the ratio of the estimated number of at-risk construction workers to the estimated number of FTE-affected construction workers increased from approximately three to one in the PEA to over five to one in the FEA. OSHA first assigned each of the affected NAICS construction industries to one of four subsectors in order to account for likely differences among specific industries with respect to the frequency with which silica-generating equipment is used. These subsectors are shown in Table V–40a of the FEA. Note that non-construction industries doing construction work—state and local governments and electric utilities—are included in Subsector 3.

Second, because at-risk workers do not necessarily specialize in jobs that use equipment that generates silica-containing dust, ERG independently estimated the number of ''affected'' workers based on judgments of the share of workers in each occupation that would likely ever perform these tasks. These judgments were also made on a subsector-by-subsector basis. In most cases, costs for program requirements (but not for engineering controls) are based on the numbers of affected workers performing each task in a given industry. The estimated share of affected workers for the key occupations, taking into account the specific construction subsector and task, is shown in Table V–40b of the FEA.

Using the FTE rates, secondary ratios, and affected rate parameters displayed in Table V–37 of the FEA, OSHA calculated, in Table V–39 of the FEA, that there are an estimated 374,003 FTEs affected by the rule. Table V–41 of the FEA converts these FTEs to 2.02 million affected construction workers disaggregated by occupation based on 2012 County Business Pattern (CBP) total employment of 2.93 million in affected occupations in construction industries. Thus, as shown in Table V–41 of the FEA, about 68.9 percent of construction workers in affected occupations will be affected by the final rule. Table V–42 of the FEA shows the same estimated number of affected workers, but disaggregated by NAICS industries and equipment category. There are an estimated 13.45 million workers total in the affected industries, meaning that about 15 percent of the workers in these industries are affected by the final rule. That percentage is misleading, however, because almost 7.7 million of total employment in affected industries (almost 60 percent) are employed in state and local governments, of which only 2 percent are affected by the final rule. When these public workers are removed, approximately 32 percent of the construction workers in affected private industries are affected by the final rule.

All of the above statistics do not include the estimated 11,640 at-risk abrasive blasters working in construction industries. Also, because some occupations are associated with the use of more than one equipment category, the ''affected'' totals are constrained to be less than or equal to the industry total for each at-risk occupation.

Labor Cost and Total Value of Work Performed Using Silica Exposure-Generating Equipment

To derive labor costs and project value for construction work done using the specified equipment where occupational exposure to silica is found, OSHA multiplied the mean hourly wage, as reported by OES (BLS, 2012, Document ID 1560), for each affected occupation within each affected industry, by 2,000 hours. Then, to derive the total value of annual wages expended for work done using specified equipment to perform silica exposure-generating activities, OSHA multiplied that product by the number of affected full-time-equivalent employees. These estimates were then inflated to adjust for fringe benefits. These loaded-wage costs, totaled by industry and equipment category, are summarized in Table V–43 of the FEA as the annual labor value (or labor cost) of silica-generating projects. Overall, OSHA estimated the labor value of all silica-generating construction work performed with the specified equipment to be $21.8 billion annually.

OSHA then converted the labor values for each industry and task category from Table V–43 of the FEA to the total project value by dividing by the labor share of project costs. This conversion is possible because the labor share for each task category equals the labor value divided by project value, so dividing the labor value by the labor share generates an estimate of project value. The corresponding estimates of total project value for each industry and equipment category are shown in Table V–44 of the FEA. Overall, OSHA estimated the value of silica-generating construction work performed with the specified equipment at $41.2 billion. The values for specific equipment categories ranged from $136.2 million for rock crushing machine operators and tenders to $28.0 billion for heavy construction equipment operations-II.

The value of work performed using the specified equipment was then summed by NAICS industry to derive the total value of at-risk projects, a base from which OSHA calculated control costs associated with compliance with Table 1 or the final PEL.

Aggregate Control Costs in Construction To Comply With Table 1 or the New PEL

For the final rule, OSHA revised Table 1 to include separate engineering control and respirator requirements for tasks indoors or in enclosed areas (''indoor tasks'') to provide a means of exhaust as needed to minimize the accumulation of visible airborne dust. As a result, indoor tasks will have an additional cost to reflect use of control equipment (*e.g.*, a fan or ''blower'') providing a means of exhaust as needed to minimize the accumulation of visible airborne dust. These additional indoor costs were included in Table V–34 of the FEA. However, to properly reflect these costs in the aggregate control costs in construction, OSHA had to add an additional methodological step. OSHA's Office of Technological Feasibility

helped to develop estimates of the distribution of silica-related work disaggregated by the type of control equipment used, the duration of the task, and the location of the task (*i.e.*, indoors or outdoors). The resulting distribution of silica-related work, which is later used to weight costs by the percentage of tasks performed indoors or outdoors, is displayed in Table V–45 of the FEA.

To derive estimates in Table V–46 of the FEA of aggregate incremental compliance costs to meet final Table 1, the total value of construction work using the specified equipment and requiring controls (in Table V–44 of the FEA) was multiplied by the percentage of incremental cost associated with the controls required for each equipment category (in Tables V–36a and V–36b of the FEA), weighted by the percentage of work using each type of equipment performed outdoors and indoors (in Table V–45 of the FEA), and reduced by the percentage of baseline compliance.

As indicated in Table V–46 of the FEA, OSHA estimates that the incremental compliance costs for engineering controls (excluding tunnel boring and abrasive blasting) will total $386.4 million for construction work performed using the specified equipment affected by the final standard.

Control Costs for Construction Tasks Not Under Table 1

Abrasive Blasting

In the PEA, OSHA estimated that some abrasive blasting crews were not currently using all feasible engineering controls and added costs for wet methods for them to achieve the proposed PEL. OSHA did not receive comments on the PEA estimates of engineering control costs for abrasive blasting crews and has retained the same methodology to estimate costs for the FEA.

Consistent with what was done in the PEA, Table V–47a of the FEA presents the unit costs and analytical assumptions applied in OSHA's cost analysis of controlling silica exposures during abrasive blasting operations. As shown in the table, after accounting for the number of affected workers, crew size, daily output, blasting cost per square foot, number of blasting days per year, and the percentage of crews using sand, OSHA estimates that baseline annual costs for sand blasting total $126.7 million. As in the PEA, ERG estimated that the incremental cost for wet blasting is 30 percent of baseline costs and that 50 percent of crews currently use wet methods. Therefore, the annual costs to comply with the final standard by using wet methods during sand blasting are expected to total $19.0 million, or $2,366 per worker for the approximately 8,033 workers exposed to silica dust.

Distributing these annualized costs by industry, OSHA estimates that employers in NAICS 238200, Building Finishing Contractors, will incur compliance costs of $12.1 million annually, while firms in NAICS 238900, Other Specialty Trade Contractors, will incur compliance costs of $6.9 million annually.

Tunnel Boring

Tunnel boring is not included on Table 1 of the final rule. An employer engaged in tunnel boring must comply with the PEL of 50 μg/m^3 specified in § 1926.1153(d). Employers in tunnel boring must already comply with the ventilation and dust suppressant requirements in subpart S of Part 1926 (Underground construction), which would have allowed those employers to meet the previous PEL of 250 μg/m^3. Therefore, OSHA calculates the additional controls necessary to reduce exposures from the preceding PEL to the new PEL of 50 μg/m^3.

In most cases, employers are able to reduce exposures to the preceding PEL by providing suction at the drill head, removing the dust as soon as it is generated. The technological feasibility chapter of the FEA demonstrates that employers can do so by extending the existing suction controls as the drill head progresses. There are limits on these extensions, however, and the amount of worker exposure can increase if the suction is not extended frequently enough to keep it at the drill head. This extension does not require additional machinery, but it is likely to require the employer to invest more labor time to extend the suction device more frequently to meet the new PEL than previously necessary to meet the preceding PEL. OSHA has estimated in Table V–47 of the FEA the control costs for tunnel boring using the same cost methodology applied in the PEA (see Tables V–21 and V–24 in the PEA) to calculate the incremental cost as a percentage of baseline control costs (0.013%). The rest of the calculations in Table V–47 reflect 2012 data on the number of affected FTE tunnel workers and 2012 hourly wage rates. The resulting estimate of annualized incremental control costs for tunnel boring is about 0.02 million.

Table V–48 of the FEA adds the abrasive blasting and the tunnel boring control costs in construction to the control costs for Table 1 tasks presented in Table V–46 of the FEA.

Adjustment for Self-Employed Workers on a Multi-Employer Worksite

The OSH Act provides authority for OSHA to regulate employers for the protection of their employees. Because sole proprietors without employees, referred to as ''self-employed workers'' for the purposes of this discussion, are not ''employers'' under the Act, OSHA cannot require them to comply with the silica standard. On a multi-employer worksite, however, their silica activities could expose employees protected by the Act to respirable crystalline silica.

Employers must still protect their employees from exposure to silica in accordance with the standard, whether it is generated by work performed by their own employees or by the work performed by a sole proprietor not regulated by the Act (*see* the summary and explanation of the written exposure control plan requirements in paragraph § 1926.1153(g)(1)(iv)). Under OSHA's multi-employer citation policy (CPL 02–00–124), employers of workers who may be exposed to silica are considered ''exposing employers'' who have a duty to protect their employees, even from hazards they do not correct themselves. However, the controlling employer, the employer in overall charge of the worksite or project, also has a duty to exercise reasonable care to prevent and detect violations of the silica standard on the multi-employer worksite. The silica standard does not limit the means by which either employer may fulfill this duty, and in many cases the issue may be resolved if the work schedule does not place the self-employed worker in the same area of the worksite at the same time as employees, thereby avoiding the need for additional measures.

As discussed in Chapter III of the FEA, CISC requested that the Agency account for the costs arising from self-employed workers separately based on the theory that self-employed workers will use the controls necessary to comply with Table 1 to reduce exposures to others when working on a multi-employer worksite where employees are present (Document ID 4217, p. 80). CISC identified several reasons why this might happen, including self-interested recognition of ''Table 1 specifications as the safe way to perform their work''; demands by construction general contractors that anyone working on their site, whether self-employed or not, conform to regulatory requirements; and demands by nearby employers that their employees ''not suffer increased silica

exposures from inappropriate practices by self-employed workers.''

While these are not costs that OSHA typically includes in its analysis, OSHA recognizes that Table 1 is unique among OSHA standards, and that it is possible that controlling employers on a multi-employer construction worksite may assume some costs of engineering controls—either by providing the controls or by reimbursing the self-employed persons for the costs of the controls through increased fees—when they cannot resolve the issue through simple scheduling choices. Therefore, OSHA is estimating the additional cost of the engineering controls in that scenario.

In order to estimate the number of self-employed persons in construction, CISC's contractor, Environomics, Inc., took the following approach:

> The U.S. Census Bureau, in Revised 2008 Nonemployer Statistics Reflecting 2009 Methodology Changes, provides information on the number of self-employed individuals (''nonemployers'') working in each of the 4-digit construction industries (total of 2.52 million self-employed construction workers), but no further information on the occupations of these self-employed workers. In order to estimate the number of self-employed workers in each of the various at-risk construction occupations that OSHA identified and that we added, we simply assumed that these 2.52 million ''nonemployers'' are distributed among occupations within each construction NAICS in the same proportion as employed workers are distributed among occupations within the NAICS (Document ID 4217, p. 80).

Note that the Census data that Environomics used provides detail on self-employed persons by 4-digit NAICS construction industries but not by occupation. Hence, in the absence of occupational data, Environomics simply assumed that the number of self-employed persons by occupation was proportional to the number of employees by occupation—which implies that the ratio of the number of self-employed persons to employees was the same for each occupation. Using this database and approach, Environomics estimated that the ratio of self-employed persons to employees for all occupations affected by the rule was 40.1 percent (1,811,009 self-employed relative to 4,519,889 employees). Based on the full-time-equivalent (FTE) number of workers—which, in OSHA's estimation methodology, determines the amount of engineering control equipment used—Environomics calculated that the ratio of FTE self-employed persons to FTE employees for all occupations affected by the rule was 35.7 percent.

Having reviewed the Environomics self-employment analysis, OSHA has concluded that the occupation of the self-employed persons is a much more relevant factor for estimating costs than the 4-digit construction industry in which self-employed persons work. Therefore, for its analysis, OSHA has chosen to rely on data from the 2013 BLS Current Population Survey, with the goal of estimating the ratio of the number of self-employed persons to the number of employees by occupation. Table V–49 of the FEA presents data from the 2013 BLS Current Population Survey with the focus on the ratio of the self-employed to the non-self-employed (*i.e.*, employees).[44] Note that this table includes many occupations that do not involve silica exposure (*e.g.*, boilermakers, paperhangers, glaziers) and others that are not covered by OSHA (*e.g.*, mining machine operators; roof bolters, mining—covered by MSHA).

Table V–50 of the FEA presents the same data as shown in Table V–49 of the FEA, but restricted to just those occupations where OSHA estimated that workers are potentially exposed to hazardous levels of respirable crystalline silica. One thing that is immediately obvious in this table is the very wide variation from occupation to occupation in the ratio of the self-employed to the employed, with the ratio ranging from 0 percent to 47.53 percent. This wide variation is clearly incompatible with the assumption made by Environomics that the ratio of the number of self-employed to employees is the same for all occupations. Table V–50 of the FEA also shows that average ratio of self-employed to employees over all construction occupations involving silica exposure (when the ratio is allowed to vary by occupation) is 22.82 percent when weighted by the number of employees (as compared to 40.1 percent as estimated by Environomics).

As noted above, in OSHA's methodology, the amount of engineering control equipment used is based on the FTE number of workers. In Table V–51 of the FEA, OSHA multiplied the FTE rate for each occupation (from Tables V–38a and V–38b of the FEA) by the number of self-employed workers and employees in that occupation (from Table V–48 of the FEA). As shown in Table V–51 of the FEA, there are an estimated 69,461 FTE self-employed workers in at-risk occupations, relative to the total of 377,913 FTE employees in at-risk occupations. In other words, the number of at-risk FTE self-employed workers is 18.38 percent of the number of at-risk FTE employees (as compared to 35.7 percent as estimated by Environomics).

The analysis of the number of self-employed persons conducted by Environomics stopped at this point. However, as OSHA explained in Chapter III of the FEA, self-employed workers are not required to comply with the final rule and are only likely to do so in two situations: (1) Where self-employed workers are generating silica dust while working in a multi-employer construction worksite such that their activities could expose the employees of others, and (2) where the host employer (or competent person) is unable to schedule the self-employed worker's activities or location so as to prevent the exposure or overexposure of other, covered workers. OSHA does not have data on the likelihood of either of these two conditions. OSHA judges that self-employed workers work at multi-employer construction sites at the same times as others a minority of their worktime, and work even less frequently within the same area such that covered employees could be exposed. Nevertheless, OSHA is conservatively estimating here that they do so 50 percent of the time. OSHA also judges that the host contractor (with the assistance of the competent person) would be able to schedule the self-employed workers' activities or location so as to prevent the exposure or overexposure of other, covered workers a majority of the time. This makes sense because self-employed workers would often be used on multi-employer sites when they possess special skills not otherwise available onsite. Therefore, their work frequently could be performed at a different time or location from the other work. In any case, for costing purposes, OSHA is conservatively estimating that the work of self-employed persons cannot be isolated in time or space so as to prevent the exposure or overexposure of other, covered workers 50 percent of the time that those self-employed workers are on the multi-employer worksite.

Based on these estimates, OSHA calculates that only 25 percent of the at-risk work of self-employed workers would meet the conditions in which a host or controlling employer would incur engineering control costs to mitigate the exposures to employees on the site. At the bottom of Table V–51 of the FEA, OSHA has accordingly reduced the number of FTE self-

[44] The absolute number of self-employed and employed in construction by occupation from this survey is not, itself, relevant for this analysis. What matters is the ratio of self-employed to non-self employed in construction where the estimates of both types of workers are derived from a single source.

employed workers using equipment to perform silica-dust-producing work relative to the number of FTE at-risk employees to 25 percent of the earlier estimate of 18.38 percent. OSHA therefore concludes that the number of FTE at-risk self-employed workers imposing costs on host employers is equal to 4.60 percent of the number of FTE at-risk employees. This result is shown at the bottom of Table V–51 of the FEA.

Finally, in Table VII–13, OSHA increased the estimates of the control costs for work performed using the specified equipment in construction presented in Table V–48 of the FEA by 4.60 percent to include the engineering control costs that would be incurred by host or controlling employers to control the exposures caused by self-employed workers. This increases the annualized cost of engineering controls needed in construction to comply with the final rule from $405.5 million to $423.4 million.

Table VII-13

Estimated Annualized Control Costs for All Silica Activities, by Construction Industry and Task Area ($millions) [Self-employment Covered]

NAICS	Industry	Total	Rock and concrete drillers	Heavy construction equipment operators - I	Heavy construction equipment operators - II	Tuck pointers and grinders (hand-held)	Hole drillers using hand-held drills	Jackhammers and other powered chipping tools	Millers using portable or mobile machines	Masonry cutters using portable saws – I	Masonry cutters using portable saws - II	Masonry cutters using stationary saws	Rock crushing machines and tenders	Underground tunnel work	Abrasive Blasting
236100	Residential Building Construction	$23.7	$0.0	$0.4	$0.9	$3.2	$5.4	$8.1	$1.1	$0.7	$3.7	$0.3	$0.0	$0.00	$0.00
236200	Nonresidential Building Construction	$31.6	$0.0	$1.4	$3.6	$6.9	$4.1	$9.1	$2.4	$1.3	$2.3	$0.5	$0.0	$0.00	$0.00
237100	Utility System Construction	$61.6	$27.2	$5.8	$14.5	$1.5	$1.4	$10.3	$1.0	$0.0	$0.0	$0.0	$0.0	$0.00	$0.00
237200	Land Subdivision	$1.1	$0.0	$0.2	$0.4	$0.1	$0.0	$0.3	$0.1	$0.0	$0.0	$0.0	$0.0	$0.00	$0.00
237300	Highway, Street, and Bridge Construction	$34.5	$0.8	$4.5	$11.1	$4.7	$0.5	$7.5	$5.3	$0.0	$0.0	$0.0	$0.1	$0.02	$0.00
237900	Other Heavy and Civil Engineering Construction	$8.9	$1.4	$1.2	$3.1	$0.4	$0.2	$2.3	$0.3	$0.0	$0.0	$0.0	$0.0	$0.00	$0.00
238100	Foundation, Structure, and Building Exterior Contractors	$98.3	$0.0	$0.7	$1.8	$47.2	$2.4	$8.0	$11.5	$17.0	$1.3	$8.3	$0.0	$0.00	$0.00
238200	Building Equipment Contractors	$32.8	$0.5	$0.6	$1.7	$0.3	$25.8	$3.5	$0.1	$0.1	$0.1	$0.0	$0.0	$0.00	$0.00
238300	Building Finishing Contractors	$28.0	$0.0	$0.0	$0.1	$3.9	$3.0	$2.7	$0.8	$2.1	$2.2	$0.8	$0.2	$0.00	$12.13
238900	Other Specialty Trade Contractors	$72.9	$8.0	$8.2	$20.9	$9.5	$0.5	$11.2	$6.6	$0.6	$0.3	$0.2	$0.1	$0.00	$6.88
221100	Electric Utilities	$1.8	$0.2	$0.3	$0.9	$0.0	$0.3	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.00	$0.00
999200	State Governments	$4.9	$0.1	$0.8	$2.0	$0.0	$0.1	$1.8	$0.1	$0.0	$0.0	$0.0	$0.0	$0.00	$0.00
999300	Local Governments	$23.2	$0.1	$3.9	$9.6	$0.4	$0.8	$6.7	$1.5	$0.1	$0.0	$0.0	$0.0	$0.00	$0.00
	Total	**$423.4**	**$38.3**	**$28.0**	**$70.5**	**$78.2**	**$44.5**	**$71.4**	**$30.9**	**$22.0**	**$9.9**	**$10.2**	**$0.4**	**$0.02**	**$19.01**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, (2016).

2. Respiratory Protection

OSHA's cost estimates assume that implementation of the recommended silica controls prevents workers in general industry and maritime from being exposed over the PEL in most cases. Specifically, based on its technological feasibility analysis, OSHA expects that the engineering controls are adequate to keep silica exposures at or below the PEL for an alternative PEL of 100 µg/m^3 (introduced for economic analysis purposes).[45] For the new 50 µg/m^3 PEL, OSHA's feasibility analysis

[45] As a result, OSHA expects that establishments in general industry do not currently use respirators to comply with the current OSHA PEL for quartz of approximately 100 µg/m^3.

suggests that the controls that employers use, either because of technical limitations or imperfect implementation, might not be adequate in all cases to ensure that worker exposures in all affected job categories are at or below 50 μg/m³.

For the FEA, OSHA estimates that respirators will be required: (1) For all workers that the Agency's technological feasibility analysis has determined will require respirator use; and (2) for ten percent of the remaining workers currently exposed above 50 μg/m³ at covered workplaces.

This is a change in methodology from the PEA, where OSHA estimated the percentage of workers requiring respirators in an industry as either (1) or (2), whichever was larger. The Agency believes that the FEA formula, which results in higher estimates of respirator usage, is more accurate in that it reflects the combined effects of (1) and (2) whereas the earlier methodology did not. The number of workers that the FEA estimates will need respirators is presented in Table V–13 in the FEA.

In the PEA, OSHA concluded that all maritime workers engaged in abrasive blasting were already required to use respirators under existing OSHA standards and, therefore, maritime establishments would incur no additional costs for maritime workers to use respirators as a result of this final rule. However, for the FEA, OSHA has determined from its earlier technological feasibility analysis that only abrasive blasting operators, but not abrasive blasting helpers, are already required to use respirators under existing OSHA standards. The Agency, therefore, has added respirator costs for abrasive blaster helpers in maritime (half of all the abrasive blaster workers) as a result of this final rule.

For construction, employers whose workers are exposed to respirable silica above the proposed PEL were assumed to adopt the appropriate task-specific engineering controls and, where required, respirators prescribed in Table 1 and paragraph (g)(1) in the final standard. Respirator costs in the construction industry have been adjusted to take into account OSHA's estimate (consistent with the findings from the NIOSH Respiratory Survey, 2003, Document ID 1492) that 56 percent of establishments in the construction industry are already using respirators that would be in compliance with the final silica rule.

OSHA used respirator cost information from a 2003 OSHA respirator study to estimate the annual cost of $367 (general industry) or $286 (construction) for disposable filtering facepiece respirators, $520 (general industry) or $409 (construction) for a half-mask, non-powered, air-purifying respirator and $644 (general industry) or $533 (construction) per year (in 2012 dollars) for a full-face non-powered air-purifying respirator (ERG, 2003, Document ID 1612). These unit costs reflect the annualized cost of respirator use, including accessories (*e.g.,* filters), training, fit testing, and cleaning where relevant.

The PEA estimated that (with the exception of workers who are entering regulated areas) all workers in general industry and construction who need respirators with an assigned protection factor (APF) of 10 would use non-disposable, half-face respirators. The FEA estimates that in general industry half of the workers who need respirators will use half-face elastomeric respirators and half will use disposable N95 respirators. This is because, as clarified in the final rule, both disposable and non-disposable respirators are available with an APF of 10, and, with each type of respirator offering certain advantages, OSHA accordingly estimates that about half of the employees in general industry and maritime will prefer the ease of use of disposable respirators while the other half will prefer the durability of non-disposable respirators. For the construction sector, the FEA estimates that 10 percent of workers needing respirators will use elastomeric half-face respirators and 90 percent will use disposable N95 respirators. This is because very few workers in construction engage in tasks requiring respirator use full-time. Under those circumstances, disposable respirators are both more convenient to use and much less expensive than reusable respirators.

In addition to bearing the costs associated with the provision of respirators, employers will incur a cost burden to establish respirator programs. OSHA projects that this expense will involve an initial 8 hours for establishments with 500 or more employees and 4 hours for all other firms. After the first year, OSHA estimates that 20 percent of establishments would revise their respirator program every year, with the largest establishments (500 or more employees) expending 4 hours for program revision, and all other employers expending 2 hours for program revision. Consistent with the findings from the NIOSH Respiratory Survey (2003) (Document ID 1492), OSHA estimates that 56 percent of establishments in the construction industry that would require respirators to achieve compliance with the final PEL already have a respirator program.[46] OSHA further estimates that 50 percent of firms in general industry and all maritime firms that would require respirators to achieve compliance already have a respirator program.

3. Exposure Assessment

OSHA developed separate cost estimates for (1) initial monitoring or any exposure monitoring at hydraulic fracturing sites and (2) scheduled monitoring at fixed sites (which excludes hydraulic fracturing). Costs under (2) were estimated to be lower because the exposure monitoring is expected to be of shorter duration (possibly obviating an overnight stay) and could be conducted by a lower-cost Industrial Hygienist (IH) or IH technician rather than by a CIH. Based on the comments received in the record, OSHA decided to significantly increase its estimate from $500 (in the PEA) to $2,500 for an IH consultant to perform initial exposure monitoring or to perform at sites that have not previously been well characterized. In the construction sector, the $2,500 cost estimate for IH services applies to all exposure monitoring since the worksite is not fixed and has not been previously characterized. OSHA estimates that the IH periodic exposure monitoring costs would be approximately $1,250, or half of the $2,500 estimate. These IH monitoring costs would cover 2, 6, and 8 personal breathing zone (PBZ) samples per day for small, medium, and large establishments, respectively.

For initial monitoring or any exposure monitoring at hydraulic fracturing sites, the total unit cost of an exposure sample is estimated to range from $487 to $1,425 (depending on establishment size). For periodic monitoring in general industry and maritime, excluding hydraulic fracturing sites, the total unit cost of an exposure sample is estimated to range from $328 to $796 (depending on establishment size).

Tables V–14 and V–61 in the FEA shows the unit costs and associated assumptions used to estimate exposure assessment costs. Unit costs for exposure sampling include direct sampling costs, the costs of productivity losses, and recordkeeping costs, and, depending on establishment size, range from $328 to $1,421 per sample in general industry and maritime and from $488 to $1,425 per sample in construction.

[46] OSHA's derivation of the 56 percent current compliance rate in construction, in the context of the final silica rule, is described in Chapter V in the FEA.

For costing purposes, based on OSHA (2016), OSHA estimated that there are four workers per work area. OSHA interpreted the initial exposure assessment in general industry and maritime as requiring first-year testing of at least one worker in each distinct job classification and work area who is, or may reasonably be expected to be, exposed to airborne concentrations of respirable crystalline silica at or above the action level.

For periodic monitoring, the final standard provides employers an option of assessing employee exposures either under a performance option (paragraph (d)(2)) or a scheduled monitoring option (paragraph (d)(3)). For the performance option, the employer must assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica. For the scheduled monitoring option (termed the ''periodic'' monitoring option in the proposal), the employer must perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more (PBZ) air samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform the same job tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet this requirement. In representative sampling, the employer must sample the employee(s) who are expected to have the highest exposure to respirable crystalline silica. Under the scheduled monitoring option, requirements for periodic monitoring depend on the results of initial monitoring. If the initial monitoring indicates that employee exposures are below the action level, no further monitoring is required. If the most recent exposure monitoring reveals employee exposures to be at or above the action level but at or below the PEL, the employer must repeat monitoring within six months of the most recent monitoring. If the most recent exposure monitoring reveals employee exposures to be above the PEL, the employer must repeat monitoring within three months of the most recent monitoring. OSHA used the fixed schedule option under the frequency-of-monitoring requirements to estimate, for costing purposes, that exposure monitoring will be conducted (a) twice a year where initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, and (b) four times a year where initial or subsequent exposure monitoring reveals that employee exposures are above the PEL.

As required under paragraph (d)(4) of the final rule, employers must reassess exposures whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred. In response to comments, OSHA increased its estimate from 15 percent to 25 percent of the share of workers whose initial exposure or subsequent monitoring was at or above the action level would undertake additional monitoring.

Changes from the proposed to the final rule have resulted in a significant reduction in OSHA's estimate of the annual number of samples taken by construction employers. For the final rule, employers following Table 1 are not required to engage in initial or subsequent exposure monitoring for those construction workers engaged in tasks on Table 1. Therefore, OSHA only estimated scheduled semi-annual exposure monitoring (for expected exposures at or above the action level but at or below the PEL) and scheduled quarterly exposure monitoring costs (for expected exposures above the PEL) for those operations are not listed on Table 1. In addition, OSHA estimated that some small fraction of employers—1 percent—will choose to conduct initial sampling to investigate the possibility that exposures are so low (below the action level) that Table 1 need not be followed.

A more detailed description of unit costs, other unit parameters, and methodological assumptions for exposure assessments is presented in Chapter V of the FEA.

4. Medical Surveillance

Paragraph (i) of the final standard requires the employer to make medical surveillance available for each employee occupationally exposed to respirable crystalline silica at or above the action level of 25 μg/m^3 for 30 days or more per year. ERG (2013) assembled information on representative unit costs for initial and periodic medical surveillance (Document ID 1712). Separate costs were estimated for current employees and for new hires as a function of the employment size (*i.e.,* 1–19, 20–499, or 500+ employees) of affected establishments. Table V–16 in the FEA presents ERG's unit cost data and modeling assumptions used by OSHA to estimate medical surveillance costs.

In accordance with paragraph (i)(2) of the final standard, the initial medical examination will consist of (1) a medical and work history, (2) a physical examination with special emphasis on the respiratory system, (3) a chest x-ray interpreted and classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconiosis by a NIOSH-certified B Reader, (4) a pulmonary function test administered by a spirometry technician with a current certificate from a NIOSH-approved course, (5) testing for latent tuberculosis (TB) infection, and (6) any other tests deemed appropriate by the PLHCP. In accordance with paragraph (i)(3) of the final standard, the contents of the periodic medical examinations are the same as those for the initial examination, with the exception that testing for latent tuberculosis infection is not required.

As shown in Table V–16 in the FEA, the estimated unit cost of the initial health screening for current employees in general industry and maritime ranges from approximately $415 to $435 and includes direct medical costs, the opportunity cost of worker time (*i.e.,* lost work time, evaluated at the worker's 2012 hourly wage, including fringe benefits) for offsite travel and for the initial health screening itself, and recordkeeping costs. The variation in the unit cost of the initial health screening is due entirely to differences in the percentage of workers expected to travel offsite for the health screening. In OSHA's experience, the larger the establishment the more likely it is that the selected PLHCP would provide the health screening services at the establishment's worksite. OSHA estimates that 20 percent of establishments with fewer than 20 employees, 75 percent of establishments with 20–499 employees, and 100 percent of establishments with 500 or more employees would have the initial health screening for current employees conducted onsite.

The unit cost components of the initial health screening for new hires in general industry and maritime are identical to those for existing employees with the exception that the percentage of workers expected to travel offsite for the health screening would be somewhat larger (due to fewer workers being screened annually, in the case of new hires, and therefore yielding fewer economies of onsite screening). OSHA estimates that 10 percent of establishments with fewer than 20

employees, 50 percent of establishments with 20–499 employees, and 90 percent of establishments with 500 or more employees would have the initial health screening for new hires conducted onsite. As shown in Table V–16 in the FEA, the estimated unit cost of the initial health screening for new hires in general industry and maritime ranges from approximately $417 to $437.

The unit costs of medical surveillance in construction were derived using identical methods. As shown in Table V–63 of the FEA, the estimated unit costs of the initial health screening for current employees in construction range from approximately $429 to $467; the estimated unit costs of the initial health screening for new hires in construction range from $433 to $471.

In accordance with paragraph (h)(2) of the final standard, the initial medical examination will consist of (1) a medical and work history, (2) a physical examination with special emphasis on the respiratory system, (3) a chest x-ray interpreted and classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader, (4) a pulmonary function test administered by a spirometry technician with a current certificate from a NIOSH approved course, (5) testing for latent tuberculosis (TB) infection, and (6) any other tests deemed appropriate by the physician or licensed health care professional (PLHCP). In accordance with paragraph (h)(3) of the final standard, the contents of the periodic medical examinations are the same as those for the initial examination, with the exception that testing for latent tuberculosis infection is not required.

The estimated unit cost of periodic health screening also includes direct medical costs, the opportunity cost of worker time, and recordkeeping costs. As shown in Table V–16 in the FEA, these triennial unit costs in general industry and maritime vary from $415 to $435. For construction, as shown in Table V–63 in the FEA, the triennial unit costs for periodic health screening vary from roughly $429 to $467. The variation in the unit cost (with or without the chest x-ray and pulmonary function test) is due entirely to differences in the percentage of workers expected to travel offsite for the periodic health screening. OSHA estimated that the share of workers traveling offsite, as a function of establishment size, would be the same for the periodic health screening as for the initial health screening for existing employees.

OSHA estimated a turnover rate of 75 percent in general industry and maritime and 40 percent in construction, based on estimates of the separations rate (layoffs, quits, and retirements) provided by the Bureau of Labor Statistics (BLS, 2012). However, not all new hires would require initial medical testing. As specified in paragraph (h)(2) of the final rule, employees who had received a medical examination that meets the requirements of this section within the previous three years would be exempt from undergoing a second ''initial'' medical examination. OSHA estimates that 25 percent of new hires in general industry and maritime and 60 percent of new hires in construction would be exempt from the initial medical examination.

Although OSHA believes that some affected establishments in construction currently provide some medical testing to their silica-exposed employees, there was significant testimony in the record that many employers would at least have to make changes to their existing practices in order to comply with the new standard. Therefore, for costing purposes, the Agency assumed no current compliance with the health screening requirements of the rule.

OSHA requested information from interested parties on the current levels and the comprehensiveness of health screening in general industry, maritime, and construction. Although testimony in the record indicated that current medical surveillance programs exist to a limited extent among affected employers (*see* Chapter V, Costs of Compliance) for costing purposes for the rule, OSHA has conservatively assumed no current compliance with the health screening requirements.

Finally, OSHA estimated the unit cost of a medical examination by a pulmonary specialist for those employees found to have signs or symptoms of silica-related disease or are otherwise referred by the PLHCP. OSHA estimates that a medical examination by a pulmonary specialist costs approximately $335 for workers in general industry and maritime and $364 for workers in construction. This cost includes direct medical costs, the opportunity cost of worker time, and recordkeeping costs. In all cases, OSHA anticipates that the worker will travel offsite to receive the medical examination by a pulmonary specialist (*see* Chapter V in the FEA for a full discussion of OSHA's analysis of medical surveillance costs under the final standard).

5. Familiarization Costs and Costs of Communication of Silica Hazards to Employees

OSHA did not estimate any employer familiarization costs in the PEA in support of the proposed rule. OSHA's rationale for not including familiarization costs in the PEA was that there was already an existing silica standard in place and, therefore, the Agency expected that any familiarization costs for a revised silica standard would be negligible.

However, several commenters on the proposed rule argued that employers will need to spend time to become familiar with the requirements of the final rule; that the employer time spent is the direct result of the final rule itself; and, therefore, that OSHA should include employer familiarization costs as part of the costs of the final rule.

OSHA found the comments in support of including some familiarization costs persuasive and the Agency has now concluded that employers will need to spend some time to understand the ancillary provisions and the other new and revised components of the final rule and to determine what actions they must take in order to comply. OSHA estimated that 8 hours would be spent on familiarization in its 2012 update to the Hazard Communication Standard (*see* 77 FR 17637–17638 (March 26, 2012)) and believes that this is a reasonable estimate of familiarization time for a typical firm for this final silica rule.

For the silica rule OSHA used the number of employees as a proxy for the level of familiarization that would be needed. Accordingly, OSHA has reduced the average of 8 hours of familiarization time for establishments with fewer employees and increased it significantly for establishments with a larger number of employees: 4 hours per covered employer with fewer than 20 employees; 8 hours per covered employer with 20 to 499 employees; and 40 hours per covered employer with 500 or more employees. These estimates represent average familiarization times; it is expected that some establishments will spend less time on familiarization than estimated here (*e.g.,*, if worker exposure never meets or exceeds the action level) and some will spend more time on familiarization than estimated here. The annualized costs per establishment range from $19 to $189 for establishments in general industry and maritime and from $21 to $207 for establishments in construction.

The final standard requires two forms of hazard communication to employees: Paragraph (j)(1) notes that employers

must include respirable crystalline silica in their existing hazard communication programs required by the hazard communication standard (HCS) (29 CFR 1910.1200), and paragraph (j)(3) requires that employers must provide employees with specific information and training. As specified in paragraph (j)(3)(i) of the final rule and the HCS, training is required for all employees in general industry and maritime are covered by the standard. This requirement applies to newly hired workers who would require training before starting work, workers who change jobs within their current workplace or are assigned new tasks or exposure protection, and any covered worker an employer believes needs additional training. Thus OSHA has estimated a one-time training cost for existing employees as well as recurring training costs to account for new hires.

OSHA estimated separate costs for initial training of current employees and for training new hires. Given that new-hire training might need to be performed frequently during the year, OSHA estimated a smaller class size for new hires. OSHA anticipates that training, in accordance with the requirements of the final rule, will be conducted by in-house safety or supervisory staff with the use of training modules or videos and will last, on average, one hour. OSHA judged that establishments could purchase sufficient training materials at an average cost of $2.10 per worker, encompassing the cost of handouts, video presentations, and training manuals and exercises. Included in the cost estimates for training are the value of worker and trainer time as measured by 2012 hourly wage rates (to include fringe benefits). OSHA also developed estimates of average class sizes as a function of establishment size. For initial training, OSHA estimated an average class size of 5 workers for establishments with fewer than 20 employees, 10 workers for establishments with 20 to 499 employees, and 20 workers for establishments with 500 or more employees. For new hire training, OSHA estimated an average class size of 2 workers for establishments with fewer than 20 employees, 5 workers for establishments with 20 to 499 employees, and 10 workers for establishments with 500 or more employees.

The unit costs of training are presented in Tables V–22 (for general industry/maritime) and V–69 (for construction) in the FEA. Based on ERG's work, OSHA estimated the annualized cost (annualized over 10 years) of initial training per current employee at between $3.39 and $4.10 and the annual cost of new-hire training at between $30.90 and $47.05 per employee in general industry and maritime, depending on establishment size. For construction, OSHA estimated the annualized cost of initial training per employee at between $4.21 and $4.99 and the annual cost of new hire training at between $38.14 and $55.76 per employee, depending on establishment size.

OSHA recognizes that many affected establishments currently provide training on the hazards of respirable crystalline silica in the workplace. In the PEA OSHA estimated that 50 percent of affected establishments already provide such training. However, some of the training specified in the final rule requires that workers be familiar with the training and medical surveillance provisions in the rule.

The Agency reviewed its baseline training estimates in light of comments in the record decided to take a more conservative approach to estimating current compliance with the training provisions in the final rule. Therefore, for the FEA, OSHA assumed no baseline respirable crystalline silica training (other than that already required under the HCS) and that a full hour of training, on average, will be required for all covered workers. This removal of baseline respirable crystalline silica training in estimating training costs has the effect, by itself, of increasing the effective training costs in the FEA relative to the PEA by 33 percent (from an average training time, per employee, of 45 minutes to 60 minutes). OSHA recognizes that this change may lead to an overestimation of training costs for some employers.

6. Regulated Areas

Paragraph (e)(1) of the final standard requires employers in general industry and maritime to establish a regulated area wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL. Paragraph (e)(2)(i) requires employers to demarcate regulated areas from the rest of the workplace in a manner that minimizes the number of employees exposed to respirable crystalline silica within the regulated area. Paragraph (e)(2)(ii) requires employers to post signs at all entrances to regulated areas bear the legend specified in paragraph (j)(2) of the standard. Under paragraph (e)(3), employers must limit access to regulated areas and under paragraph (e)(4), employers must provide each employee and designated employee representative entering a regulated area with an appropriate respirator (in accordance with paragraph (g) of the standard) and require each employee and designated employee representative to use the respirator while in a regulated area.

Based on OSHA (2016), OSHA derived unit cost estimates for establishing and maintaining regulated areas to comply with these requirements and estimated that one area would be necessary for every eight workers in general industry and maritime exposed above the PEL. Planning time for a regulated area is estimated to be an initial seven hours of supervisor time (initial cost of $282.67 in 2012 dollars), and one hour for changes annually (at a cost of $40.38 in 2012 dollars); material costs for signs and boundary markers (annualized at $66.93 in 2012 dollars); and costs of $526 annually for two disposable respirators per day to be used by authorized persons (other than those who regularly work in the regulated area) who might need to enter the area in the course of their job duties. Tables V–25 in the FEA shows the cost assumptions and unit costs applied in OSHA's cost model for regulated areas in general industry and maritime. Overall, OSHA estimates that each regulated area would, on average, cost employers $666 annually in general industry and maritime.

7. Written Exposure Control Plans

A written exposure control plan provision was not included in the silica proposal, and no costs for a written exposure control plan were estimated in the PEA. Paragraph (f)(2) in the final standard for general industry and paragraph (g) in the final standard for construction specify the following requirements for a written exposure control plan: (i) A description of the tasks in the workplace that involve exposure to respirable crystalline silica; (ii) a description of the engineering controls, work practices, and respiratory protection used to limit employee exposure to respirable crystalline silica for each task; (iii) a description of the housekeeping measures used to limit employee exposure to respirable crystalline silica; and (iv) for construction, a description of the procedures used to restrict access to work areas, when necessary, to minimize the number of employees exposed to respirable crystalline silica and their level of exposure, including exposures generated by other employers or sole proprietors.

In the FEA, Table V–27 shows the unit costs and assumptions for written exposure control plans in general

industry and Tables V–72 and V–74 show, respectively the unit costs for developing and implementing written exposure control plans in construction.

Unit costs for a written exposure control plan were calculated based on establishment size, and the Agency assumed, for costing purposes, that a supervisor will develop and update the written exposure control plan for each establishment, spending 1 hour for establishments with fewer than 20 employees, 4 hours for those establishments with between 20 and 499 employees, and 16 hours for those establishments with 500 or more employees. OSHA estimated that 1 hour would be sufficient for very small establishments because there is, on average, barely more than 1 worker covered by the standard per very small establishment in general industry and maritime.

OSHA further determined that the additional supervisory time needed to review and evaluate the effectiveness of the plan, and to update it as necessary, will also vary by establishment size. OSHA estimated 0.5 hours for establishments with fewer than 20 employees, 2 hours for those with between 20 and 499 employees, and 8 hours for those with 500 or more employees to perform the annual review and update. The Agency expects that no other labor or materials will be required to implement the plan, so the sole cost for this provision is the time it will take to develop, review, and update the plan.

In the context of general industry or maritime activities in permanent facilities, the implementation of the written exposure control plan will not typically involve significant time or effort above existing operations. In construction, however, employers may be faced with new costs to implement the written exposure plan as they move from site to site. OSHA has therefore included costs for implementation, in addition to the costs for development of the plan, for construction activities. The plan must be implemented by a ''competent person,'' and OSHA has addressed the additional costs for training the competent person after the discussion of the general implementation costs.

Paragraph (g)(4) requires the employer to designate a competent person to implement the exposure control plan, and restrict access to work areas, when necessary, to minimize the number of employees exposed to respirable crystalline silica and their level of exposure, including exposures generated by other employers or sole proprietors. The competent person has two broad options to restrict access to work areas when necessary: (1) Notifying or briefing employees, or (2) direct access control. The direct access control component is similar to the written access control plan included in the PEA, which OSHA has replaced with the written exposure control plan in the final rule. While the requirements for the written exposure control plan are more performance-oriented and thus should provide more flexibility for employers and reduce the cost of compliance, OSHA has estimated the costs of these options using, where appropriate, comparable components of the regulated area and written access control plan costs estimated in the PEA.

For the employee notification or briefing option, OSHA estimated that, on average, it will take the competent person 15 minutes (0.25 hours) per job to revise the briefing plan, that each job will last 10 work-days, and that there are 150 construction working days in a year (Document ID 1709, p. 4–6). OSHA further estimated that it will take the competent person 6 minutes (0.1 hours) to brief each at-risk crew member (where an at-risk crew member could be an employee, a contractor, a subcontractor, or other worker under the control of the competent person) and that each crew consists of 4 at-risk workers. As shown in Table V–74 in the FEA, the annual cost of the job briefing option is $105.25 per at-risk crew member.

For the direct access control option, OSHA estimated that, on average, it will take the competent person 15 minutes (0.25 hours) per job to revise the plan concerning direct access control and, again, that each job will last 10 work-days and that there are 150 construction working days in a year. Thus, OSHA estimates that, on average, each employer would implement a direct access control 15 times per year over a total of 3.75 hours per year.

OSHA also added the cost of signage and tape for constructing physical barriers: 100 feet of hazard tape (per job) and three warning signs. These costs are all displayed in Table V–74 in the FEA. As also shown there, the annualized cost of the direct access control option is $71.40 per at-risk crew member.

As discussed in the Summary and Explanation section of this preamble concerning the written exposure control plan, restricting access is necessary where respirator use is required under Table 1 or when an exposure assessment reveals that exposures are in excess of the PEL, or in other situations identified by the competent person. On the other hand, when exposure to respirable crystalline silica is being successfully contained by engineering controls and work practices specified in Table 1 and no respirator use is required by Table 1, implementation of access control procedures is not required.

OSHA assumed that, in restricting access, half the time employers would use the briefing option and the other half of the time they would use direct access control. Consequently, as shown in Table V–74, the annualized cost of restricting access to work areas is $88.33 per at-risk crew member.

As specified in paragraph (g)(4) of the final standard, a competent person must carry out the responsibilities of implementing the written exposure control plan. As defined in the standard, ''competent person'' means an individual who is capable of identifying existing and foreseeable respirable crystalline silica hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them, as well as has the knowledge and ability necessary to fulfill the responsibilities set forth in paragraph (g) of the standard. OSHA has utilized the competent person provision in other construction standards, such as 1926.1127, Cadmium, and 1926.1101, Asbestos, so the Agency expects that there is widespread familiarity with both the concept and the responsibilities of competent person in the construction sector. As in other OSHA construction rules, a major purpose of the competent person provision in this final silica standard is to identify who has the responsibility for inspections of the job sites, materials, and equipment. Thus, OSHA expects that most employers will have training programs in place to produce competent persons, and the cost of training someone will only be a relatively small marginal increase in the overall training cost. For that reason, the Agency expects that many employees designated as competent persons will undergo some training for the position. OSHA is estimating that each competent person will, on average, undergo two hours of training—in addition to the one hour of silica training estimated for all construction employees. OSHA does not anticipate any additional costs beyond training costs to be associated with the requirement that a competent person implement the written exposure control plan.

While the competent person provision does not specify a training requirement, the competent person is required to possess the knowledge and skills to perform the functions required by the standard. For that reason, the Agency expects that many employees designated as competent persons will undergo some training for the position.

OSHA estimates that, on average, there will be 1 competent person for each establishment with fewer than 20 employees, 5 competent persons for each establishment with 20–499 employees, and 10 competent persons for each establishment with 500 or more employees.

OSHA expects that competent persons will be trained by a supervisor, presumably one who went through the process to become familiar with the requirements of the respirable crystalline silica standard, or by a combination of supervisory and/or technical staff that are familiar with the operation of the engineering controls. While the competent persons are not required to be supervisors and some of the staff providing the training may not be supervisors, OSHA is using a supervisor's wage to estimate the costs for time spent by both the trainers and the trainees in order to provide the upper cost limit, realizing that the cost for establishments who do not designate supervisors as the competent person will be lower. OSHA estimated that the total cost per establishment to train a competent person in construction will range from $21 to $114 (*see* Chapter V in the FEA for a full discussion of OSHA's analysis of costs for written exposure control plans under the final standard).

8. Combined General Industry/Maritime Control, Respirator, and Program Costs

Table VII–14 shows that the estimated combined costs for employers in the general industry and maritime sectors to comply with the final silica rule are approximately $370.8 million annually. These costs include $238.1 million annually for engineering controls and $10.5 million annually for respirators to meet the final PEL of 50 μg/m^3. The remaining $122.2 million annually are to meet the ancillary provisions of the final rule. These ancillary annual costs consist of $79.6 million for exposure monitoring; $29.7 million for medical surveillance; $6.0 million for familiarization and training; $2.6 million for regulated areas; and $4.1 million for the written exposure control plan.

Table V–B–1 in Appendix V–B in the FEA presents estimated compliance costs by NAICS industry code and program element for small business entities (as defined by the Small Business Act and the Small Business Administration's implementing regulations; *see* 15 U.S.C. 632 and 13 CFR 121.201) in general industry and maritime, while Table V–B–2 in the FEA presents estimated compliance costs, by NAICS code and program element, for very small entities (fewer than twenty employees) in general industry and maritime.

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Table VII-14 Combined Compliance Costs for General Industry and Maritime

NAICS	Industry	Control Costs	Respirators	Exposure Assessment	Medical Surveillance	Control Plan	Regulated Area	Training & Familiarization	Total
213112	Support Activities for Oil and Gas Operations	$84,432,467	$379,743	$9,045,642	$2,869,133	$38,287	$933,458	$229,021	$97,927,752
324121	Asphalt Paving Mixture and Block Manufacturing	$199,831	$2,179	$159,722	$10,087	$46,225	$666	$94,331	$513,042
324122	Asphalt Shingle and Coating Materials Manufacturing	$1,789,474	$64,039	$1,229,578	$655,915	$14,578	$11,993	$46,315	$3,811,893
325510	Paint and Coating Manufacturing	$512,668	$17,575	$260,034	$107,267	$52,789	$3,331	$54,963	$1,008,627
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$5,955,772	$113,598	$1,745,664	$830,515	$26,640	$21,321	$94,825	$8,788,336
327120	Clay Building Material and Refractories Manufacturing	$16,423,275	$925,152	$2,528,462	$1,021,961	$73,777	$147,248	$132,328	$21,252,204
327211	Flat Glass Manufacturing	$557,199	$47,844	$73,983	$27,719	$5,798	$7,995	$4,914	$725,452
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$1,677,938	$145,188	$249,885	$85,236	$12,989	$23,320	$14,022	$2,208,578
327213	Glass Container Manufacturing	$1,709,226	$147,503	$228,292	$86,536	$6,278	$23,986	$10,850	$2,212,672
327320	Ready-Mix Concrete Manufacturing	$6,171,957	$3,540,572	$14,621,725	$4,385,169	$217,688	$569,669	$497,723	$30,004,503
327331	Concrete Block and Brick Manufacturing	$4,153,422	$327,761	$1,720,688	$609,557	$40,103	$53,302	$115,903	$7,020,737
327332	Concrete Pipe Manufacturing	$2,294,454	$180,805	$887,058	$335,464	$20,804	$29,983	$61,520	$3,810,088
327390	Other Concrete Product Manufacturing	$12,626,461	$994,723	$4,819,265	$1,844,827	$97,171	$161,906	$333,881	$20,878,235
327991	Cut Stone and Stone Product Manufacturing	$8,913,357	$239,778	$3,753,513	$1,434,031	$73,592	$43,974	$169,937	$14,628,182
327992	Ground or Treated Mineral and Earth Manufacturing	$2,295,864	$52,428	$1,256,434	$584,074	$12,996	$9,994	$76,632	$4,288,421

Table VII-14 Combined Compliance Costs for General Industry and Maritime (continued)

NAICS	Industry	Control Costs	Respirators	Exposure Assessment	Medical Surveillance	Control Plan	Regulated Area	Training & Familiarization	Total
327993	Mineral Wool Manufacturing	$2,005,181	$166,640	$286,200	$101,292	$13,842	$26,651	$15,585	$2,615,391
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$8,597,395	$76,785	$1,878,371	$855,948	$48,103	$14,658	$126,546	$11,597,806
331110	Iron and Steel Mills and Ferroalloy Manufacturing	$465,771	$6,902	$65,595	$38,017	$44,010	$1,333	$24,774	$646,402
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	$113,363	$1,678	$16,956	$9,297	$13,948	$666	$7,129	$163,038
331221	Rolled Steel Shape Manufacturing	$34,766	$514	$5,393	$2,860	$4,601	$666	$2,260	$51,060
331222	Steel Wire Drawing	$63,076	$933	$9,863	$5,192	$8,387	$666	$4,089	$92,206
331314	Secondary Smelting and Alloying of Aluminum	$23,872	$353	$3,763	$1,966	$3,161	$666	$1,530	$35,312
331420	Copper Rolling, Drawing, Extruding, and Alloying	$93,284	$1,380	$14,370	$7,669	$11,997	$666	$5,944	$135,310
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$48,440	$717	$7,533	$3,985	$6,340	$666	$3,110	$70,791
331511	Iron Foundries	$16,134,210	$858,599	$3,933,423	$2,081,869	$33,437	$141,918	$179,499	$23,362,955
331512	Steel Investment Foundries	$4,034,862	$205,024	$737,214	$356,141	$12,737	$33,314	$71,144	$5,450,435
331513	Steel Foundries (except Investment)	$7,684,814	$409,068	$1,864,039	$990,897	$16,212	$67,961	$85,376	$11,118,366
331524	Aluminum Foundries (except Die-Casting)	$2,780,798	$75,247	$787,396	$359,083	$23,450	$12,659	$82,024	$4,120,657
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$1,713,267	$46,419	$511,414	$221,703	$16,576	$7,995	$52,144	$2,569,518
332111	Iron and Steel Forging	$106,434	$1,575	$16,473	$8,753	$13,883	$666	$6,842	$154,626

Table VII-14 Combined Compliance Costs for General Industry and Maritime (continued)

NAICS	Industry	Control Costs	Respirators	Exposure Assessment	Medical Surveillance	Control Plan	Regulated Area	Training & Familiarization	Total
332112	Nonferrous Forging	$27,279	$404	$4,122	$2,239	$3,587	$666	$1,805	$40,101
332117	Powder Metallurgy Part Manufacturing	$36,052	$533	$5,682	$2,969	$4,774	$666	$2,311	$52,988
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$234,189	$3,465	$36,595	$19,275	$31,149	$666	$15,195	$340,536
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	$32,655	$483	$4,993	$2,683	$4,416	$666	$2,194	$48,090
332216	Saw Blade and Handtool Manufacturing	$123,396	$1,826	$19,137	$10,150	$16,499	$666	$8,101	$179,774
332323	Ornamental and Architectural Metal Work Manufacturing	$20,424	$735	$11,368	$4,509	$4,067	$666	$2,246	$44,015
332439	Other Metal Container Manufacturing	$51,863	$767	$8,040	$4,266	$7,054	$666	$3,460	$76,117
332510	Hardware Manufacturing	$117,483	$1,739	$18,017	$9,654	$16,055	$666	$7,949	$171,563
332613	Spring Manufacturing	$65,599	$970	$10,278	$5,400	$8,808	$666	$4,283	$96,006
332618	Other Fabricated Wire Product Manufacturing	$109,036	$1,613	$17,111	$8,978	$14,493	$666	$7,043	$158,941
332710	Machine Shops	$1,086,755	$16,077	$171,208	$89,509	$143,926	$3,331	$69,701	$1,580,507
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	$1,625,192	$75,344	$1,071,632	$461,594	$97,809	$13,992	$98,222	$3,443,786
332911	Industrial Valve Manufacturing	$157,784	$2,335	$24,178	$12,965	$20,890	$666	$10,376	$229,195
332912	Fluid Power Valve and Hose Fitting Manufacturing	$153,500	$2,273	$22,691	$12,577	$18,493	$666	$9,576	$219,774
332913	Plumbing Fixture Fitting and Trim Manufacturing	$33,527	$496	$5,069	$2,752	$4,647	$666	$2,326	$49,483

Table VII-14 Combined Compliance Costs for General Industry and Maritime (continued)

NAICS	Industry	Control Costs	Respirators	Exposure Assessment	Medical Surveillance	Control Plan	Regulated Area	Training & Familiarization	Total
332919	Other Metal Valve and Pipe Fitting Manufacturing	$63,022	$933	$9,742	$5,182	$8,669	$666	$4,260	$92,474
332991	Ball and Roller Bearing Manufacturing	$99,714	$1,476	$14,866	$8,175	$13,678	$666	$6,932	$145,507
332996	Fabricated Pipe and Pipe Fitting Manufacturing	$132,275	$1,957	$20,593	$10,884	$17,532	$666	$8,584	$192,491
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$312,979	$4,825	$51,820	$27,022	$41,896	$1,333	$20,462	$460,336
333318	Other Commercial and Service Industry Machinery Manufacturing	$241,287	$3,571	$36,661	$19,813	$31,176	$666	$15,635	$348,809
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$106,821	$1,580	$16,647	$8,790	$14,479	$666	$7,072	$156,056
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	$79,591	$1,177	$12,545	$6,556	$10,540	$666	$5,102	$116,177
333511	Industrial Mold Manufacturing	$155,856	$2,306	$24,423	$12,831	$20,782	$666	$10,110	$226,974
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	$189,400	$2,802	$29,661	$15,592	$25,405	$666	$12,362	$275,889
333515	Cutting Tool and Machine Tool Accessory Manufacturing	$125,835	$1,861	$19,834	$10,365	$16,664	$666	$8,066	$183,291
333517	Machine Tool Manufacturing	$107,566	$1,592	$16,707	$8,849	$14,302	$666	$7,016	$156,698
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	$51,625	$764	$8,013	$4,247	$7,072	$666	$3,464	$75,852
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	$71,161	$1,053	$10,842	$5,845	$8,867	$666	$4,451	$102,884
333613	Mechanical Power Transmission Equipment Manufacturing	$68,757	$1,017	$10,679	$5,656	$9,175	$666	$4,499	$100,450

Table VII-14 Combined Compliance Costs for General Industry and Maritime (continued)

NAICS	Industry	Control Costs	Respirators	Exposure Assessment	Medical Surveillance	Control Plan	Regulated Area	Training & Familiarization	Total
333911	Pump and Pumping Equipment Manufacturing	$149,614	$2,214	$22,804	$12,289	$20,221	$666	$10,073	$217,882
333912	Air and Gas Compressor Manufacturing	$93,972	$1,391	$14,260	$7,716	$11,866	$666	$5,970	$135,840
333991	Power-Driven Handtool Manufacturing	$39,303	$582	$5,873	$3,223	$4,487	$666	$2,315	$56,450
333992	Welding and Soldering Equipment Manufacturing	$69,967	$1,036	$10,264	$5,729	$7,254	$666	$3,858	$98,775
333993	Packaging Machinery Manufacturing	$88,491	$1,309	$13,792	$7,282	$11,799	$666	$5,769	$129,107
333994	Industrial Process Furnace and Oven Manufacturing	$48,741	$721	$7,682	$4,015	$6,454	$666	$3,124	$71,404
333995	Fluid Power Cylinder and Actuator Manufacturing	$107,135	$1,586	$16,112	$8,790	$12,539	$666	$6,410	$153,238
333996	Fluid Power Pump and Motor Manufacturing	$46,708	$691	$7,111	$3,836	$6,221	$666	$3,106	$68,340
333997	Scale and Balance Manufacturing	$16,433	$243	$2,590	$1,354	$2,176	$666	$1,053	$24,516
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$227,996	$3,374	$35,160	$18,745	$28,951	$666	$14,344	$329,237
334519	Other Measuring and Controlling Device Manufacturing	$153,947	$2,279	$23,409	$12,642	$19,177	$666	$9,643	$221,763
335210	Small Electrical Appliance Manufacturing	$11,066	$435	$4,813	$2,637	$3,263	$666	$1,644	$24,524
335221	Household Cooking Appliance Manufacturing	$14,018	$552	$5,521	$3,318	$3,022	$666	$1,651	$28,748
335222	Household Refrigerator and Home Freezer Manufacturing	$12,626	$497	$4,710	$2,979	$2,998	$666	$1,634	$26,111
335224	Household Laundry Equipment Manufacturing	$5,977	$235	$2,145	$1,406	$1,256	$666	$717	$12,403

Table VII-14 Combined Compliance Costs for General Industry and Maritime (continued)

NAICS	Industry	Control Costs	Respirators	Exposure Assessment	Medical Surveillance	Control Plan	Regulated Area	Training & Familiarization	Total
335228	Other Major Household Appliance Manufacturing	$12,201	$480	$4,496	$2,876	$4,006	$666	$2,103	$26,829
336111	Automobile Manufacturing	$277,561	$4,117	$36,428	$22,537	$11,520	$1,333	$9,067	$362,562
336112	Light Truck and Utility Vehicle Manufacturing	$250,233	$3,712	$32,683	$20,311	$9,362	$666	$7,768	$324,735
336120	Heavy Duty Truck Manufacturing	$135,990	$2,017	$18,173	$11,056	$9,799	$666	$6,214	$183,916
336211	Motor Vehicle Body Manufacturing	$179,484	$2,657	$27,163	$14,734	$23,748	$666	$11,925	$260,377
336212	Truck Trailer Manufacturing	$125,352	$1,856	$18,727	$10,279	$15,378	$666	$7,871	$180,129
336213	Motor Home Manufacturing	$32,725	$485	$4,519	$2,667	$2,921	$666	$1,697	$45,680
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$233,483	$3,458	$34,037	$19,108	$28,419	$666	$14,879	$334,051
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$221,367	$3,278	$32,752	$18,138	$26,084	$666	$13,531	$315,816
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$126,884	$1,879	$18,592	$10,389	$14,601	$666	$7,665	$180,676
336340	Motor Vehicle Brake System Manufacturing	$96,722	$1,432	$14,559	$7,936	$12,832	$666	$6,472	$140,620
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$257,824	$3,819	$37,205	$21,084	$28,427	$666	$15,227	$364,252
336370	Motor Vehicle Metal Stamping	$358,513	$5,308	$53,684	$29,404	$45,519	$1,333	$23,164	$516,924
336390	Other Motor Vehicle Parts Manufacturing	$540,116	$7,997	$80,172	$44,267	$68,432	$1,999	$35,101	$778,085
336611	Ship Building and Repairing	$8,005,888	$82,823	$852,445	$539,088	$39,654	$15,324	$51,162	$9,586,384
336612	Boat Building	$2,073,668	$21,464	$277,790	$141,630	$27,269	$3,998	$20,950	$2,566,768
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	$48,772	$723	$6,848	$3,980	$5,741	$666	$3,119	$69,849

Table VII-14 Combined Compliance Costs for General Industry and Maritime (continued)

NAICS	Industry	Control Costs	Respirators	Exposure Assessment	Medical Surveillance	Control Plan	Regulated Area	Training & Familiarization	Total
337110	Wood Kitchen Cabinet and Countertop Manufacturing	$81,270	$3,921	$62,553	$23,950	$19,870	$1,333	$11,557	$204,454
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$147,925	$2,189	$22,964	$12,169	$19,972	$666	$9,791	$215,675
339114	Dental Equipment and Supplies Manufacturing	$4,355,009	$90,284	$945,808	$413,018	$29,987	$16,657	$79,981	$5,930,743
339116	Dental Laboratories	$1,121,590	$39,658	$3,803,758	$1,102,926	$206,664	$7,329	$575,422	$6,857,347
339910	Jewelry and Silverware Manufacturing	$425,899	$111,723	$1,347,221	$515,353	$118,118	$20,655	$151,896	$2,690,864
339950	Sign Manufacturing	$191,729	$7,438	$114,453	$45,652	$29,966	$1,999	$17,384	$408,620
423840	Industrial Supplies Merchant Wholesalers	$550,862	$315,992	$937,093	$250,464	$114,965	$49,305	$74,236	$2,292,917
444110	Home Centers	$59,213	$1,867	$21,122	$11,309	$10,882	$666	$5,327	$110,386
482110	Rail transportation*	$16,220,542	$0	$0	$0	$35,060	$0	$306,456	$16,562,059
561730	Landscaping Services	$1,276,327	$578,330	$14,994,464	$5,255,387	$1,077,624	$105,272	$1,194,502	$24,481,907
621210	Offices of Dentists	$307,387	$10,958	$1,343,680	$308,425	$306,276	$1,999	$313,483	$2,592,207
	Totals	**$238,094,052**	**$10,493,706**	**$79,750,734**	**$29,685,587**	**$4,132,086**	**$2,637,136**	**$6,017,228**	**$370,810,530**

*Rail transportation costs reflect the Agency's judgment that employers performing construction activities will achieve compliance by following Table 1.

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, (2016).

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9. Combined Construction Control, Respirator, and Program Costs

Table VII–15 summarizes the engineering control costs, respirator costs, and program costs of the rule for the construction sector. Annualized compliance costs in construction are expected to total $659.0 million, of which $423.4 million are for engineering controls, $22.4 million are for respirators, and $213.2 million are to meet the ancillary provisions of the rule. These ancillary annual costs consist of $16.5 million for exposure monitoring; $66.7 million for medical surveillance; $89.9 million for familiarization and

training; and $40.1 million for the written exposure control plan.

Table V–B–1 in Appendix V–B in the FEA presents estimated compliance costs by NAICS industry code and program element for small entities (as defined by the Small Business Administration) in construction, while Table V–B–2 in the FEA presents estimated compliance costs, by NAICS code and program element, for very small entities (fewer than twenty employees) in construction.

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Table VII-15: Annualized Compliance Costs for Construction Employers Affected by OSHA's Silica Standard (2012 Dollars)

NAICS	Industry	Control Costs	Respirators	Exposure Assessment	Medical Surveillance	Control Plan	Training & Familiarization	Total
236100	Residential Building Construction	$23,741,539	$2,661,194	$620,700	$8,082,550	$7,953,162	$11,885,853	$54,944,997
236200	Nonresidential Building Construction	$31,622,794	$2,236,399	$449,980	$6,745,998	$2,891,594	$8,786,361	$52,733,126
237100	Utility System Construction	$61,606,007	$3,169,804	$330,103	$9,553,638	$1,616,587	$7,121,157	$83,397,297
237200	Land Subdivision	$1,060,496	$109,414	$11,827	$347,440	$166,237	$265,422	$1,960,835
237300	Highway, Street, and Bridge Construction	$34,461,947	$1,798,662	$765,640	$4,763,776	$994,496	$5,530,212	$48,314,733
237900	Other Heavy and Civil Engineering Construction	$8,916,607	$638,568	$68,136	$1,973,584	$316,982	$1,428,240	$13,342,117
238100	Foundation, Structure, and Building Exterior Contractors	$98,302,150	$5,378,378	$779,620	$14,636,135	$5,650,682	$14,480,141	$139,227,106
238200	Building Equipment Contractors	$32,764,558	$445,723	$738,704	$1,242,600	$9,182,144	$15,685,182	$60,058,912
238300	Building Finishing Contractors	$28,048,297	$1,523,769	$7,839,972	$5,410,669	$5,272,317	$7,245,153	$55,340,177
238900	Other Specialty Trade Contractors	$72,894,824	$2,135,438	$4,642,936	$6,435,850	$4,286,890	$11,434,951	$101,830,889
221100	Electric Utilities	$1,841,529	$23,173	$10,151	$71,396	$823,434	$433,566	$3,203,249
999200	State Governments	$4,906,494	$576,438	$49,609	$1,905,641	$27,759	$1,154,704	$8,620,645
999300	Local Governments	$23,195,442	$1,693,558	$183,229	$5,498,657	$958,719	$4,467,561	$35,997,165
	Totals	**$423,362,684**	**$22,390,518**	**$16,490,605**	**$66,667,933**	**$40,141,004**	**$89,918,502**	**$658,971,248**

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

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10. Total Cost Summary

As shown in Table VII–16, annualized compliance costs associated with the rule are expected to total $1,030 million. Table VII–16 also provides total annualized costs for general industry, maritime, and construction separately, by major provision or program element included in the rule. This table shows that engineering control costs represent 64 percent of the costs of the standard for all three affected industry sectors: general industry, maritime, and construction. Considering other leading cost categories, costs for exposure assessment and medical surveillance represent, respectively, 30 percent and 15 percent of the costs of the standard for general industry and maritime; costs for training and familiarization and medical surveillance represent, respectively, 14 percent and 10 percent of the costs of the standard for construction.

While the costs presented here represent the Agency's best estimate of the costs to industry of complying with the rule under static conditions (that is, using existing technology and the current deployment of workers), OSHA recognizes that actual costs could be somewhat higher or lower, depending on the Agency's possible overestimation or underestimation of various cost factors. In Chapter VII of the FEA, OSHA provides a sensitivity analysis of its cost estimates by modifying certain critical unit cost factors. Beyond this sensitivity analysis, OSHA notes that its cost estimates do not reflect the possibility that, in response to the rule, industry may find ways to reduce compliance costs.

This could be achieved in three ways. First, in construction, 36 percent of the estimated costs of the rule (all costs except engineering controls) vary directly with the number of workers exposed to silica. However, as shown in Table III–5 in the FEA, more than five times as many construction workers will be affected by the rule as will the number of full-time-equivalent construction workers necessary to do the work. This is because most construction workers currently doing work involving silica exposure perform such tasks for only a portion of their workday. In response to the rule, many employers are likely to assign work so that fewer construction workers perform tasks involving silica exposure; correspondingly, construction work involving silica exposure will tend to become a full-time job for some construction workers.[47] Were this approach fully implemented in construction, the actual cost of the rule would decline because employers would have to comply with the ancillary provisions of the final rule for fewer workers.[48] However, these workers would be subject to the full protections of the final rule.

Second, industry could demonstrate that certain construction activities result in exposures below the action level under any foreseeable conditions—in which case, workers engaged only in those silica-generating activities would not be subject to the requirements of the final rule. For example, an employer could make this demonstration by using objective data developed for short-term, intermittent tasks involving limited generation of silica dust. In estimating the costs for this final rule, however, OSHA included all costs, including ancillary costs as appropriate, associated with short-term intermittent silica tasks.

Third, the costs presented here do not take into account the possible development and dissemination of cost-reducing compliance technology in response to the rule.[49] One possible example is the development of safe substitutes for silica sand in activities such as abrasive blasting operations, repair and replacement of refractory materials, foundry operations, and in the railroad transportation industry. Another is expanded use of automated processes which would allow workers to be isolated from the points of operation that involve silica exposure (such as tasks between the furnace and the pouring machine in foundries and at sand transfer stations in structural clay production facilities). Yet another example is the further development and use of bags with valves that seal effectively when filled, thereby preventing product leakage and worker exposure (for example, in mineral processing and concrete products industries). Probably the most pervasive and significant technological advances, however, will likely come from the integration of compliant control technology into standard production equipment. Such advances would both increase the effectiveness and reduce the costs of silica controls when compared to retrofitted production equipment. Possible examples include local exhaust ventilation (LEV) systems attached to portable tools used by grinders and tuckpointers; enclosed operator cabs equipped with air filtration and air conditioning in industries that mechanically transfer silica or silica-containing materials; and machine-integrated wet dust suppression systems used, for example, in road milling operations.[50]

OSHA has decided not to include in its analysis any possible cost-reducing technological advances or worker specialization because the technological and economic feasibility of the rule can easily be demonstrated using existing technology and employment patterns. However, OSHA believes that actual costs, which will incorporate any future developments of this type, will likely be lower than those estimated here.

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[47] There are numerous instances of job reassignments and job specialties arising in response to OSHA regulation. For example, asbestos removal and confined space work in construction have become activities performed by well-trained specialized employees, not general laborers (whose only responsibility is to identify the presence of asbestos or a confined space situation and then to notify the appropriate specialist).

[48] OSHA expects that such a structural change in construction work assignments would not have a significant effect on the benefits of the rule. As discussed in Chapter VII of this PEA, the estimated benefits of the rule are relatively insensitive to changes in average occupational tenure or how total silica exposure in an industry is distributed among individual workers.

[49] Evidence of such technological responses to regulation includes Ashford, Ayers, and Stone (1985)(Document ID 0536), OTA (1995)(Document ID 0947), and OSHA's regulatory reviews of existing standards under § 610 of the Regulatory Flexibility Act (''610 lookback reviews''). On the other hand, supplemental evidence from Harrington *et al.* (2000) [Harrington, Winston, Richard D. Morgenstern and Peter Nelson. ''On the Accuracy of Regulatory Cost Estimates.'' Journal of Policy Analysis and Management, 19(2), 297–322, 2000] finds that OSHA does not systematically overestimate costs on a per-unit basis. Nevertheless, several examples of OSHA's overestimation of costs reported in the article are due to technological improvements.

[50] A dramatic example from OSHA's 610 lookback review of its 1984 ethylene oxide (EtO) standard is the use of EtO as a sterilant. OSHA estimated the costs of then existing add-on controls for EtO sterilization, but in response to the standard, improved EtO sterilizers with built-in controls were developed and widely disseminated at about half the cost of the equipment with add-on controls. (*See* OSHA, 2005.) Lower-cost EtO sterilizers with built-in controls did not exist, and their development had not been predicted by OSHA, at the time the final rule was published in 1984.

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Table VII-16: Annualized Compliance Costs for Employers in General Industry, Maritime, and Construction Affected by OSHA's Silica Standard (2012 Dollars)

Industry	Engineering Controls	Respirators	Exposure Assessment	Medical Surveillance	Exposure Control Plan	Regulated Areas	Training & Familiarization	Total
General Industry	$228,014,496	$10,389,419	$78,620,499	$29,004,870	$4,065,164	$2,617,814	$5,945,116	**$358,657,378**
Maritime	$10,079,555	$104,287	$1,130,235	$680,718	$66,922	$19,322	$72,112	**$12,153,151**
Construction	$423,362,684	$22,390,518	$16,490,605	$66,667,933	$40,141,004	Not Applicable	$89,918,502	**$658,971,248**
Total	**$661,456,736**	**$32,884,224**	**$96,241,339**	**$96,353,520**	**$44,273,091**	**$2,637,136**	**$95,935,731**	**$1,029,781,777**

Source: U.S. Dept. of Labor, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

a. Costs Under Alternative PEL (100 μg/m³) Scenario

Appendix V–C in the FEA presents, for analytical purposes, costs for an alternative PEL of 100 μg/m³. Total annualized compliance costs under this alternative are $649.3 million. Table V–C–1 displays costs for general industry, maritime, and construction by each program element. Table V–C–2 shows total costs by NAICS industry code for all affected general industry and maritime establishments, for business entities in general industry and maritime defined as small by the Small Business Administration, and for very small business entities in general industry and maritime (those with fewer than twenty employees). Table V–C–3 shows total costs by NAICS industry code for all affected construction establishments, for business entities in construction defined as small by the Small Business Administration, and for very small business entities in construction (those with fewer than twenty employees).

b. Costs Under Alternative Discount Rates

An appropriate discount rate [51] is needed to reflect the timing of costs after the rule takes effect and to allow conversion to an equivalent steady stream of annualized costs.

[51] Here and elsewhere throughout the FEA, unless otherwise noted, the term ''discount rate'' always refers to the real discount rate—that is, the discount rate net of any inflationary effects.

c. Alternative Discount Rates for Annualizing Costs

Following OMB (2003) guidelines (Document ID 1493), OSHA has estimated the annualized costs of the rule using separate discount rates of 3 percent and 7 percent. Consistent with the Agency's own practices in recent proposed and final rules,[52] OSHA has also estimated, for benchmarking purposes, undiscounted costs—that is, costs using a zero percent discount rate.

d. Summary of Annualized Costs Under Alternative Discount Rates

In addition to using a 3 percent discount rate in its main cost analysis, OSHA estimated compliance costs, in Appendix V–D in the FEA, using alternative discount rates of 7 percent and zero percent. Table V–D–1 and V–D–2 in Appendix V–D present total costs at a 7 percent discount rate for both (1) all employers by major industry category and program element, and (2) affected employers by NAICS industry code and employment size class (all establishments, small entities, and very small entities). Tables V–D–3 and V–D–4 present the same breakdowns of total costs estimated at a zero percent discount rate.

As shown in Appendix V–D, the choice of discount rate has only a minor effect on total annualized compliance costs, with annualized costs increasing from 1,030 million using a three percent discount rate to $1,056 million using a seven percent discount rate, and decreasing to $1,012 million using a zero percent discount rate.

[52] *See*, for example, 71 FR 10099, the preamble for the final hexavalent chromium rule.

e. Time Distribution of Costs

OSHA analyzed the stream of (unannualized) compliance costs, by industry sector, for the first ten years after the rule takes effect under the simplifying assumption that no provisions of the rule are phased in. As shown in Table VII–16, total compliance costs are expected to peak in Year 1 at more than $1.5 billion. After that, costs are estimated to decline and remain relatively flat after the initial set of capital and program start-up expenditures has been incurred. Costs are projected to rise somewhat in Year 4 as a result of the triennial medical examinations and in Year 6 because of a second cycle of control equipment purchases in construction for short-term, intermittent work. Thereafter there are fluctuations but no strong trend. OSHA notes that the differences between costs for Year 1 and costs for subsequent years are narrower than might otherwise be the case due to (1) the expectation that, in the construction sector, a large percentage of control equipment will be rented (leading to constant annual expenses for the rented control equipment) rather than purchased as capital in Year 1; and (2) the expectation that the only engineering controls needed in the maritime sector will be wet methods, which do not require capital expenditures. On the other hand, the ancillary provisions are expected to have a relatively large number of initial costs (mainly labor rather than capital) in Year 1.

Table VII-17: Distribution of Compliance Costs by Year for Establishments Affected by the Silica Standard (2012 Dollars)

Year	Engineering Controls	Program Requirements	Total
General Industry			
1	$351,150,221	$226,474,187	$577,624,408
2	$88,019,935	$96,902,383	$184,922,318
3	$88,335,426	$96,902,383	$185,237,809
4	$88,019,935	$128,722,760	$216,742,695
5	$88,335,426	$102,868,704	$191,204,130
6	$97,750,338	$103,313,313	$201,063,651
7	$88,335,426	$119,936,421	$208,271,847
8	$88,019,935	$106,068,901	$194,088,835
9	$88,335,426	$106,068,901	$194,404,327
10	$88,019,935	$115,223,631	$203,243,565
Maritime			
1	$3,508,723	$5,103,417	$8,612,140
2	$2,061,181	$1,479,402	$3,540,584
3	$2,061,181	$1,479,402	$3,540,584
4	$2,061,181	$2,221,245	$4,282,426
5	$2,061,181	$1,618,498	$3,679,679
6	$3,508,723	$1,503,124	$5,011,848
7	$2,061,181	$2,016,405	$4,077,586
8	$2,061,181	$1,693,105	$3,754,287
9	$2,061,181	$1,693,105	$3,754,287
10	$2,061,181	$1,906,534	$3,967,715
Construction			
1	$494,322,820	$404,082,164	$898,404,984
2	$402,508,839	$90,472,782	$492,981,621
3	$402,508,839	$90,472,782	$492,981,621
4	$402,508,839	$124,698,143	$527,206,982
5	$402,508,839	$100,096,954	$502,605,793
6	$494,322,820	$98,584,007	$592,906,827
7	$402,508,839	$112,807,735	$515,316,574
8	$402,508,839	$103,671,225	$506,180,065
9	$402,508,839	$103,671,225	$506,180,065
10	$402,508,839	$108,391,817	$510,900,656
Total			
1	$848,981,764	$635,659,768	$1,484,641,532
2	$492,589,955	$188,854,568	$681,444,523
3	$492,905,447	$188,854,568	$681,760,014
4	$492,589,955	$255,642,148	$748,232,103
5	$492,905,447	$204,584,155	$697,489,602
6	$595,581,881	$203,400,445	$798,982,326
7	$492,905,447	$234,760,561	$727,666,007
8	$492,589,955	$211,433,232	$704,023,187
9	$492,905,447	$211,433,232	$704,338,678
10	$492,589,955	$225,521,982	$718,111,937

[a] Includes costs for respirators and respirator programs.

[b] Engineering control costs for construction based on short term equipment rental rates.

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA , 2016.

F. Economic Feasibility Analysis and Regulatory Flexibility Determination

Chapter VI of the FEA presents OSHA's analysis of the economic impacts of its final silica rule on affected employers in general industry, maritime, and construction. The discussion below summarizes the findings in that chapter.

As a first step, the Agency explains its approach for achieving the two major objectives of its economic impact analysis: (1) To establish whether the final rule is economically feasible for all affected industries, and (2) to determine if the Agency can certify that the final rule will not have a significant economic impact on a substantial number of small entities. Next, this approach is applied to industries with affected employers in general industry and maritime and then to industries with affected employers in construction. Finally, OSHA examines the employment effects of the silica rule. This includes a review of estimates of employment effects that commenters provided and a summary of a report prepared for the Agency by Inforum—a not-for-profit corporation (based at the University of Maryland) specializing in the design and application of macroeconomic models of the United

States (and other countries)—to estimate the industry and aggregate employment effects of the silica rule.

Many commenters questioned OSHA's preliminary conclusions concerning economic feasibility, but did so for reasons that OSHA has responded to in previous chapters.

A variety of commenters raised issues concerning industries with possible silica exposure that were not covered in the Preliminary Economic and Initial Regulatory Feasibility Analysis (PEA). A full discussion of these comments and of industries added is provided in the FEA.

Many commenters questioned why OSHA used no data after 2006 (see comments by the Brick Industry Association (BIA) (Document ID 2300, p. 5), the American Fuel & Petrochemical Manufacturers (AFPM) (Document ID 2350, p. 6), the Belden Brick Company (Document ID 3260, p. 3), Basalite Concrete Products, LLC (Document ID 2083, p. 1), SBG Consulting (Document ID 2222, p. 1), Acme Brick (Document ID 2182, p. 4), Erie Bronze & Aluminum (Document ID 1780, p. 1), Calstone (Document ID 3391, p. 2), the Chamber of Commerce (Document ID 1782, p. 1), the Mason Contractors Association of America (MCAA) (Document ID 1767, p. 2), Scango Consulting LLC d.b.a. Capitol Hardscapes (Document ID 2241, p. 3), the National Concrete Masonry Association (NCMA) (Document ID 3585, p. 2944), the American Road and Transportation Builders Association (ARTBA) (Document ID 2245, p. 4), and the Construction Industry Safety Coalition (CISC) (Document ID 4217, Attachment 1, pp. 4 and 49–52)). As discussed in Chapter III of the FEA, OSHA is using revenue data from 2012 and profit data averaged across the years 2000 through 2012. The revenue data from 2012 represent a reasonable choice because this year was neither a peak growth year nor a recession year and was the most up-to-date data available at the time this analysis was developed. The range of years for profits assures the use of profit rates from throughout the business cycle—including two recessions and two sustained growth periods.

One commenter questioned OSHA's sources and methodology for estimating revenues (Document ID 2308, Attachment 9, pp. 7–8 and 14–16). This commenter questioned the methodology used to update revenue estimates between Economic Census years. This is no longer an issue as OSHA is using 2012 Economic Census data and using 2012 as the base year for the analysis. Therefore, there is no need for a methodology to update Economic Census revenues.

OSHA also received criticism on the choice of the data source and the methodology for estimating profits of the construction industry. These include comments from the National Association of Home Builders (NAHB) and the CISC (Document ID 2296, Attachment 1, pp. 20–22; 2308, Attachment 9, pp. 7–12).

Stuart Sessions, submitting on behalf of the CISC, criticized OSHA for using the Internal Revenue Service's (IRS) Corporation Source Book (CSB) as the source for industry profits since those data are only presented at the four-digit NAICS level instead of the five- or six-digit NAICS level. Mr. Sessions recommended that OSHA use an alternative data source for profit data and recommended Bizminer or RMA (Document ID 4231, Attachment 1, pp.12–13). OSHA investigated these sources and determined that these data were private data sources and that their publishers would not allow the data to be made publicly available. These other sources of profit data also suffered from the disadvantage of not representing adequate and random samples of the affected industries. A further discussion on this issue appears in Chapter III of the FEA.

In the PEA, OSHA used IRS data to calculate profit rates as the ratio of net income to total receipts (with the numerator including only firms with positive net income and the denominator including firms with and without net income) by NAICS industry. In response to comments criticizing this ratio as an inappropriate method to calculate industry profitability (Document ID 2308, Attachment 9, pp. 11–12; 4209, pp. 115–116), OSHA has revised the way that estimated profits are calculated. In the FEA, OSHA calculates profit rates using the method recommended by Mr. Sessions, which is discussed more fully in Chapter III. This method includes unprofitable firms and divides the ''net income'' from all firms (profitable and unprofitable) by total receipts from all firms (profitable and unprofitable), resulting in somewhat lower profit rates.

Similarly, Mr. Sessions criticized OSHA for using data that he believed were at a level that was too aggregated to show economic impacts of the costs of the rule accurately (Document ID 2319, Attachment 1, p. 71). The Portland Cement Association likewise disagreed with OSHA's presentation of costs as averages across industries. It said that ''a more focused explanation of individual plant and facility costs is relevant to those industries with significant compliance responsibilities'' (Document ID 2284, p. 6). OSHA's data sources for profile data are presented in Chapter III of the FEA. In general, OSHA has disaggregated industries to the extent that the source data will allow.

The most common criticism of OSHA's preliminary conclusions on economic feasibility was that the conclusions were based on costs that were underestimated or inaccurate (*e.g.*, Document ID 2023, p. 1; 2299, p. 15; 2379, Attachment 3, pp. 2 and 10; 2388, pp. 2 and 10; 2296, Attachment 1, p. 17; 2116, Attachment 1, p. 22; and 3378, Attachment 2). For example, Wayne D'Angelo of the American Petroleum Institute (API) and the Independent Petroleum Association of America (IPAA) (API/IPAA or ''the Associations'') critiqued OSHA's feasibility analysis for the hydraulic fracturing industry, stating that OSHA had not met its obligations due to inaccurate cost data and an industry profile that, they asserted, did not ''reasonably represent the typical firms in the various segments of the industry, given varying operations, exposure levels, and processes'' (Document ID 2301, Attachment 1, pp. 62–63).

OSHA responded to comments on its preliminary cost estimates in Chapter V of the FEA. In the aggregate, OSHA increased its cost estimate by approximately 46 percent, in part, as a result of changes in cost estimates made in response to comments and, in part, as a result of changes in the rule.

Some commenters argued that OSHA had not adequately considered the possibility that smaller establishments might have higher costs or that the costs have a greater impact on small businesses (Document ID 4231, Attachment 1, p. 11; 2379, Attachment 2, p. 7; 3582, Tr. 2107–2109; 2203, p. 1; 2351, p. 8; 3433, p. 9; 3580, Tr. 1398). As discussed in Chapter V, OSHA has made a number of changes to the costs analysis to reflect higher costs for small establishments.

1. Analytic Approach

a. Economic Feasibility

The Court of Appeals for the D.C. Circuit has long held that OSHA standards are economically feasible so long as their costs do not threaten the existence of, or cause massive economic dislocations within, a particular industry or alter the competitive structure of that industry. *American Iron and Steel Institute.* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991); *United Steelworkers of America, AFL–CIO–CLC* v. *Marshall*, 647 F.2d 1189, 1265 (D.C. Cir. 1980); *Industrial Union Department*

v. *Hodgson*, 499 F.2d 467, 478 (D.C. Cir. 1974).

In practice, the economic burden of an OSHA standard on an industry—and whether the standard is economically feasible for that industry—depends on the magnitude of compliance costs incurred by establishments in that industry and the extent to which they are able to pass those costs on to their customers. That, in turn, depends, to a significant degree, on the price elasticity of demand for the products sold by establishments in that industry.

The price elasticity of demand refers to the relationship between the price charged for a product and the demand for that product: The more elastic the relationship, the less an establishment's compliance costs can be passed through to customers in the form of a price increase and the more it has to absorb compliance costs in the form of reduced profits. When demand is inelastic, establishments can recover most of the variable costs of compliance (*i.e.*, costs that are highly correlated with the amount of output) by raising the prices they charge; under this scenario, if costs are variable rather than fixed, profit rates are largely unchanged and the industry remains largely unaffected. Any impacts are primarily on those customers using the relevant product. On the other hand, when demand is elastic, establishments cannot recover all compliance costs simply by passing the cost increase through in the form of a price increase; instead, they must absorb some of the increase from their profits. Commonly, this will mean reductions both in the quantity of goods and services produced and in total profits, though the profit rate may remain unchanged. Other things being equal, higher fixed costs mean that the optimal scale of the typical establishment will be larger than it would be if fixed costs were lower. This in turn means that, where there are higher fixed costs, there will be fewer plants for the same level of production. Whether an increase in fixed costs results in closures of existing plants depends on several factors. If demand regularly increases (such as due to economic growth) or the industry regularly experiences plant closures, the optimal scale may be arrived at by reduced entry rather than premature closures. If plants are not part of a simple homogeneous market, it may not be possible to shift the scale of production. For example, if a plant provides foundry products to others in the same city, it may not be able to readily expand its scale of production. In general, ''[w]hen an industry is subjected to a higher cost, it does not simply swallow it; it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers,'' in the words of the court in *American Dental Association* v. *Secretary of Labor* (984 F.2d 823, 829 (7th Cir. 1993)).

The court's summary is in accord with microeconomic theory. In the long run, firms can remain in business only if their profits are adequate to provide a return on investment that ensures that investment in the industry will continue. As technology and costs change, however, the long-run demand for some products naturally increases and the long-run demand for other products naturally decreases. In the face of additional compliance costs (or other external costs), firms that otherwise have a profitable line of business may have to increase prices to stay viable. Increases in prices typically result in reduced quantity demanded, but rarely eliminate all demand for the product. Whether this decrease in the total production of goods and services results in smaller output for each establishment within the industry, or the closure of some plants within the industry; a reduced number of new establishments entering the industry; or a combination of the three, is dependent on the cost and profit structure of individual firms within the industry.

If demand is perfectly inelastic (*i.e.*, the price elasticity of demand is zero), then the impact of compliance costs that are 1 percent of revenues for each firm in the industry would result in a 1 percent increase in the price of the product, with the quantity demanded constant. (This outcome would hold in the long run, regardless of type of costs, but in the short run would hold with certainty only if compliance costs are strictly variable.) Such a scenario represents an extreme case, but might be observed in situations in which there were few if any substitutes for the product in question, or if the products of the affected sector account for only a very small portion of the revenue or income of its customers. Under this scenario, both profits and output of the industry would be unaffected, but customers would be worse off.

If the demand is perfectly elastic (*i.e.*, the price elasticity of demand is infinitely large), then no increase in price is possible and before-tax profits would be reduced by an amount equal to the costs of compliance (net of any cost savings—such as reduced workers' compensation insurance premiums—resulting from the final standard) if the industry attempted to maintain production at the same level. Under this scenario, if the costs of compliance are such a large percentage of profits that some or all plants in the industry could no longer operate with the hope of an adequate return on investment, then some or all of the firms would close. Similarly, if compliance costs are fixed, such costs may result in premature closures or reduced entry into the market in some circumstances.

A commonly discussed intermediate case would be a price elasticity of demand of one.[53] In this scenario, if the costs of compliance amount to 1 percent of revenues, then production would decline by 1 percent and prices would rise by 1 percent. (As before, this outcome would hold in the long run, regardless of type of costs, but in the short run would hold with certainty only if compliance costs are variable.) Under this scenario, and if marginal costs of the regulation fall proportionally with output, then industry revenues would remain the same, with somewhat lower production, but with similar profit rates. Customers would, however, receive less of the product for their (same) expenditures, and firms would have lower total profits; this, as the court described in *Am. Dental Ass'n* v. *Sec'y of Labor*, 984 F.2d 823 (7th Cir. 1993), is the more typical case.

A decline in output as a result of an increase in price may occur in a variety of ways: Individual establishments could each reduce their levels of production; some marginal plants could close; or, in the case of an industry with high turnover of establishments, new entry may be delayed until demand equals supply. In many cases a decrease in overall output for an industry will be a combination of all three kinds of reductions. Which possibility is most likely depends on the rate of turnover in the industry and on the form that the costs of the regulation take.

When turnover in an industry is high, or an industry is expanding rapidly, then the key issue is the long run costs as determined by the cost of entry into the industry. For example, if there is annual turnover in an industry of ten percent per year, and a price elasticity of one, then a single year without new entry would result in a price rise of ten percent. Such a rise would be more than enough to compensate existing employers for a cost increase of one percent of revenues. If the costs are variable costs (*i.e.*, costs that vary with the level of production at a facility), then economic theory suggests that any reductions in output will take the form

[53] Here and throughout this section, the price elasticity of demand is reported as an abosulte value.

of reductions in output at each affected facility, with few, if any, plant closures. If the costs of a regulation primarily take the form of fixed costs (*i.e.*, costs that do not vary with the level of production at a facility), and assuming perfect competition, then reductions in overall output are more likely to can only take the form of plant closures or delays in new entry. Most of the costs of this regulation, as estimated in Chapter V of the FEA, are variable costs. Almost all of the major costs of program elements, such as medical surveillance and training, will vary in proportion to the number of employees (which is a rough proxy for the amount of production). Exposure monitoring costs will vary with the number of employees, but do have some economies of scale to the extent that a larger firm need only conduct representative sampling rather than sample every employee. The costs of engineering controls in construction also vary by level of production because almost all necessary equipment can readily be rented and the productivity costs of using some of these controls vary proportionally to the level of production. Finally, the costs of operating engineering controls in general industry (the majority of the annualized costs of engineering controls are in general industry) vary by the number of hours the establishment works, and thus vary by the level of production and are not fixed costs in the strictest sense.

This leaves two kinds of costs that are, in some sense, fixed costs—capital costs of engineering controls in general industry and certain initial costs that new entrants to the industry will not have to bear.

Fixed costs in the form of capital costs of engineering controls in general industry and maritime due to this standard are relatively small as compared to the total costs, representing less than 21 percent of total annualized costs and approximately $1,019 per year per affected establishment in general industry.

There are some initial fixed costs in the sense that they might only be borne by firms in the industry today. For example, costs for general training not currently required and initial costs of medical surveillance may not be borne by establishments new to the industry to the extent they can hire from a workforce that may have already had this training and/or initial medical surveillance. An initial thorough facility cleaning is not a cost a new establishment would need to bear. These costs will disappear after the initial year of the standard and thus would be difficult to pass on. These costs, however, represent less than two percent of total costs and less than $58 per affected establishment. These initial fixed costs that may be borne by firms in the affected industries today, together with capital costs, give a total fixed cost of approximately 22 percent of total annual costs.

Because the remaining three-fourths of the total annual costs are variable, OSHA expects it is somewhat more likely that reductions in industry output resulting from the increase in costs associated with this rule will be met by reductions in output at each affected facility rather than as a result of plant closures or reduced new entry. However, closures of some marginal plants or poorly performing facilities are always possible. To determine whether a rule is economically feasible, OSHA begins with two screening tests to consider minimum threshold effects of the rule under two extreme cases: (1) All costs are passed through to customers in the form of higher prices (consistent with a price elasticity of demand of zero), and (2) all costs are absorbed by the firm in the form of reduced profits (consistent with an infinite price elasticity of demand).

In the former case, the immediate impact of the rule would be observed in increased industry revenues. While there is no hard and fast rule, in the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of one percent of annual revenues. Retrospective studies of previous OSHA regulations have shown that potential impacts of such a small magnitude are unlikely to eliminate an industry or significantly alter its competitive structure,[54] particularly since most industries have at least some ability to raise prices to reflect increased costs and, as shown in the FEA, normal price variations for products typically exceed three percent a year.[55] Of course, OSHA recognizes that even when costs are within this range, there could be unusual circumstances requiring further analysis.

In the latter case, the immediate impact of the rule would be observed in reduced industry profits. OSHA uses the ratio of annualized costs to annual profits as a second check on economic feasibility. Again, while there is no hard and fast rule, in the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of ten percent of annual profits. In the context of economic feasibility, the Agency believes this threshold level to be fairly modest, given that normal year-to-year variations in profit rates in an industry can exceed 40 percent or more.[56] OSHA's choice of a threshold level of ten percent of annual profits is low enough that even if, in a hypothetical worst case, all compliance costs were upfront costs, then upfront costs would still equal 88.5 percent of profits using a three percent discount rate (*see* section Normal Year-to-Year Variations in Prices and Profit Rates below) and thus would be affordable from profits alone without the need for an employer to resort to credit markets. If the threshold level were first-year costs of ten percent of annual profits, firms could even more easily expect to cover first-year costs at the threshold level out of current profits without having to access capital (including credit markets) markets and otherwise being threatened with short-term insolvency.

In general, it is usually the case that firms would be able to pass on some or all of the costs of the rule to their customers in the form of higher prices. OSHA therefore will tend to give much more weight to the ratio of industry costs to industry revenues than to the ratio of industry costs to industry profits. However, if costs exceed either the threshold percentage of revenue or the threshold percentage of profits for an industry, or if there is other evidence of a threat to the viability of an industry because of the standard, OSHA will examine the effect of the rule on that industry more closely. Such an examination would include market factors specific to the industry, such as normal variations in prices and profits, international trade and foreign competition, and any special circumstances, such as close domestic substitutes of equal cost, which might make the industry particularly vulnerable to a regulatory cost increase.

The preceding discussion focused on the economic viability of the affected industries in their entirety. However, even if OSHA found that a final standard did not threaten the survival of affected industries, there is still the question of whether the industries' competitive structure would be significantly altered. For example, if the

[54] *See* OSHA's Web page, *http://www.osha.gov/dea/lookback.html#Completed*, for a link to all completed OSHA lookback reviews.

[55] *See,* for example, Table VI–3 and the accompanying text presented in Chapter VI of the FEA.

[56] *See,* for example, Table VI–5 and the accompanying text presented in Chapter VI of the FEA.

annualized costs of an OSHA standard were equal to ten percent of an industry's annual profits, and the price elasticity of demand for the products in that industry were equal to one, then OSHA would not expect the industry to go out of business. However, if the increase in costs were such that most or all small firms in that industry would have to close, it could reasonably be concluded that the competitive structure of the industry had been altered. For this reason, OSHA also examines the differential costs by size of establishment.

Public Comments on OSHA's Approach to Economic Feasibility

Some commenters were concerned that reductions of profits of less than ten percent could still represent major losses to an employer. For example, one commenter said:

> The proposed rule states that in no cases will the amount of revenue or profits exceed 8.8% noting that this number is easily passed to consumers in the form of increased product and service costs. For a rule as specific and slight as one affecting only silica dust inhalation, a reduction in profits by 8.8% should give the government pause (Document ID 2189, p. 1).

Another commenter expressed similar concerns about a reduction in profits of 4.8 percent (Document ID 1882, Attachment 1, p. 2). OSHA is not dismissive of losses in profits of less than ten percent. However, such losses need to be weighed against the OSH Act's objectives of occupational safety and health. For purposes of assessing economic feasibility, OSHA needs to be concerned with major dislocating effects on entire industries, which will not be the result of relatively small changes in profits. Further, as will be discussed below, these costs can likely be passed on to consumers.

API/IPAA, while disagreeing with OSHA's cost estimates, acknowledged that OSHA's use of the rules of thumb of ten percent of profits or one percent of revenues has been upheld in court (Document ID 2301, Attachment 1, pp. 62–63).

Some commenters were also concerned that OSHA's screening analysis methodology did not give adequate consideration to upfront costs (Document ID 2379, Attachment 3, p. 39; 2119, Attachment 3, p. 22). As will be discussed below, OSHA's choice of a threshold level of ten percent of annual profits is low enough that even if, in a hypothetical worst case, all compliance costs were upfront costs, then upfront costs would still equal 88.5 percent of profits and thus would be affordable from profits alone without needing to resort to credit markets. (If the cost exceeds 100 percent of profits then the company would have to borrow to pay the balance. Otherwise the firm will not have to borrow but could finance the cost internally.)

While not specifically addressed to the issue of the screening analysis, Mr. Sessions provided some estimates of how various percentage cost increases might interact with demand and supply elasticities to produce estimates of declines in total industry output. His estimates show that the decline in total revenues (and, in this situation, total production) associated with increased costs of one percent of revenues ranges from zero to 0.83 percent of total production (the range depending on the elasticities of supply and demand, with the highest impact on total revenues associated with a very unlikely price elasticity of ten) (Document ID 4231, Attachment 1, p. 31). Even the largest decline in revenues would result in only a 0.83 percent decline in revenues, which would not represent a major dislocation of any affected industry. While OSHA does not necessarily endorse this particular approach to calculating changes in total revenue for given percentage change in costs, the calculation confirms OSHA's general view that increases of less than one percent of costs do not render a standard economically infeasible.

After reviewing these comments, OSHA has decided to retain its screening test of ten percent of profits and one percent of revenues as levels below which significant dislocation of an industry is extremely unlikely.

b. Regulatory Flexibility Screening Analysis

The Regulatory Flexibility Act (RFA), Public Law 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601), requires Federal agencies to consider the economic impact that a final rulemaking will have on small entities. The RFA states that whenever an agency ''promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, the agency shall prepare a final regulatory flexibility analysis'' (FRFA). 5 U.S.C. 604(a). Pursuant to section 605(b), in lieu of an FRFA, the head of an agency may certify that the final rule will not have a significant economic impact on a substantial number of small entities. A certification must be supported by a factual basis. If the head of an agency makes a certification, the agency shall publish such certification in the **Federal Register** at the time of publication of general notice of final rulemaking or at the time of publication of the final rule. 5 U.S.C. 605(b). Thus, if OSHA cannot issue the required certification, it must prepare a FRFA.

OSHA makes its determination about whether it can issue the required certification by applying screening tests to consider minimum threshold effects of the rule on small entities. These screening tests are similar in concept to those OSHA described above to identify minimum threshold effects for the purposes of demonstrating economic feasibility and are discussed below.

There are, however, two differences. First, for each affected industry, the screening tests are applied, not to all establishments, but to small entities (defined as ''small business concerns'' by the Small Business Administration (SBA)) and also to very small entities (as defined by OSHA as small businesses with fewer than 20 employees). Second, although OSHA's regulatory flexibility screening test for revenues also uses a minimum threshold level of annualized costs equal to one percent of annual revenues, OSHA has established a minimum threshold level of annualized costs equal to five percent of annual profits for the average small entity or very small entity (rather than the ten percent threshold applicable for general economic feasibility screening). The Agency has chosen a lower minimum threshold level for the profitability screening analysis and has applied its screening tests to both small entities and very small entities in order to ensure that certification will be made, and an FRFA will not be prepared, only if OSHA can be highly confident that a final rule will not have a significant economic impact on a substantial number of small entities or very small entities in any affected industry.

OSHA has prepared separate regulatory flexibility screening tests for general industry, maritime, and construction.

2. Impacts in General Industry and Maritime

In this section, OSHA will determine whether (1) the rule is economically feasible for all affected industries in general industry and maritime, and (2) the Agency can certify that the rule will not have a significant economic impact on a substantial number of small entities in general industry and maritime. OSHA concludes that the rule is economically feasible, but the Agency is unable to certify that it will not have a significant economic impact on a substantial number of small entities.

a. Economic Feasibility Screening Analysis: All Establishments

Earlier chapters of the FEA identified the general industry and maritime sectors potentially affected by the final rule; presented summary profile data for affected industries, including the number of affected entities and establishments, the number of at-risk workers, and the average revenue for affected entities and establishments; and developed estimates, by affected industry, of the costs of the rule. The economic impacts of the final rule on general industry and maritime are driven, in part, by the costs of additional dust control measures, respirators, and silica program activities needed to comply with the rule.

To determine whether the final rule's projected costs of compliance would threaten the economic viability of affected industries; OSHA first compared, for each affected industry, annualized compliance costs to annual revenues and profits per (average) affected establishment. The results for all affected establishments in all affected industries in general industry and maritime are presented in Table VII–18, using annualized costs per establishment for the PEL of 50 $\mu g/m^3$. Shown in the table for each affected industry are total annualized costs, the total number of affected establishments, annualized costs per affected establishment, annual revenues per establishment, the profit rate, annual profits per establishment, annualized compliance costs as a percentage of annual revenues, and annualized compliance costs as a percentage of annual profits.

The annualized costs per affected establishment for each affected industry were calculated by distributing the industry-level (incremental) annualized compliance costs among all affected establishments in the industry, where annualized compliance costs reflect a three percent discount rate. The annualized cost of the rule for the average establishment in all of general industry and maritime is estimated to be $4,939 in 2012 dollars. It is clear from Table VII–18 that the estimates of the annualized costs per affected establishment in general industry and maritime vary widely from industry to industry. These estimates range from $220,558 for NAICS 213112 (Support Activities for Oil and Gas Operations) and $57,403 for NAICS 331511 (Iron Foundries) to $304 for NAICS 621210 (Offices of Dentists) and $377 for NAICS 324121 (Asphalt Paving Mixture and Block Manufacturing).

Table VII–18 also shows that, within the general industry and maritime sectors, there are no industries in which the annualized costs of the final rule exceed 1 percent of annual revenues and there are eight industries in which the annualized costs of the rule exceed ten percent of annual profits and none where annualized costs exceed one percent of annual revenues. NAICS 213112 (Support Activities for Oil and Gas Operations), has the highest cost impact as a percentage of revenues, of 0.56 percent. NAICS 327120 (Clay Building Material and Refractories Manufacturing) has the highest cost impact as a percentage of profits, of 31.08 percent. For all affected establishments in general industry and maritime, the estimated annualized cost of the rule is, on average, equal to 0.06 percent of annual revenue and 2.43 percent of annual profits.

The industries with costs that exceed ten percent of profits are: NAICS 327110—Pottery, Ceramics, and Plumbing Fixture Manufacturing, 31 percent; NAICS 327120—Clay Building Material and Refractories Manufacturing, 31 percent; NAICS 327991—Cut Stone and Stone Product Manufacturing, 24 percent; NAICS 327390—Other Concrete Product Manufacturing, 17 percent; NAICS 327999—All Other Miscellaneous Nonmetallic Mineral Product Manufacturing, 16 percent; NAICS 327332—Concrete Pipe Manufacturing, 13 percent; NAICS 327331 Concrete Block and Brick Manufacturing, 13 percent; and NAICS 327320 Ready-Mix Concrete Manufacturing, 10 percent.

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Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard

NAICS	Industry	Total Annualized Costs	Number of Affected Establish-ments	Annualized Costs per Affected Establish-ment	Revenues per Establish-ment	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
213112	Support Activities for Oil and Gas Operations	$97,927,752	16,960	$220,558	$39,182	7.09%	$2,777,295	0.56%	7.94%
324121	Asphalt Paving Mixture and Block Manufacturing	$513,042	4,737	$377	$9,646	5.96%	$574,834	0.00%	0.07%
324122	Asphalt Shingle and Coating Materials Manufacturing	$3,811,893	3,158	$17,094	$47,115	5.96%	$2,807,740	0.04%	0.61%
325510	Paint and Coating Manufacturing	$1,008,627	2,511	$1,306	$20,352	3.86%	$786,325	0.01%	0.17%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$8,788,336	6,269	$13,417	$3,255	1.34%	$43,558	0.41%	30.80%
327120	Clay Building Material and Refractories Manufacturing	$21,252,204	7,893	$36,267	$8,720	1.34%	$116,694	0.42%	31.08%
327211	Flat Glass Manufacturing	$725,452	221	$13,063	$37,273	2.63%	$978,432	0.04%	1.34%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$2,208,578	674	$12,935	$7,550	2.63%	$198,200	0.17%	6.53%
327213	Glass Container Manufacturing	$2,212,672	686	$35,667	$51,795	2.63%	$1,359,618	0.07%	2.62%
327320	Ready-Mix Concrete Manufacturing	$30,004,503	27,123	$5,580	$3,787	1.43%	$54,169	0.15%	10.30%
327331	Concrete Block and Brick Manufacturing	$7,020,737	7,182	$8,593	$4,763	1.43%	$68,135	0.18%	12.61%

Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	Number of Affected Establish-ments	Annualized Costs per Affected Establish-ment	Revenues per Establishment	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
327332	Concrete Pipe Manufacturing	$3,810,088	3,967	$10,824	$5,720	1.43%	$81,834	0.19%	13.23%
327390	Other Concrete Product Manufacturing	$20,878,235	21,832	$10,582	$4,379	1.43%	$62,650	0.24%	16.89%
327991	Cut Stone and Stone Product Manufacturing	$14,628,182	9,429	$7,869	$1,890	1.75%	$33,122	0.42%	23.76%
327992	Ground or Treated Mineral and Earth Manufacturing	$4,288,421	5,432	$17,223	$13,360	1.75%	$234,143	0.13%	7.36%
327993	Mineral Wool Manufacturing	$2,615,391	789	$15,065	$17,671	1.75%	$309,697	0.09%	4.86%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$11,597,806	7,952	$25,659	$8,951	1.75%	$156,869	0.29%	16.36%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	$646,402	594	$2,307	$201,471	1.35%	$2,728,087	0.00%	0.08%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	$163,038	145	$1,476	$54,855	2.14%	$1,175,284	0.00%	0.13%
331221	Rolled Steel Shape Manufacturing	$51,060	44	$1,235	$35,875	2.14%	$768,643	0.00%	0.16%
331222	Steel Wire Drawing	$92,206	81	$1,185	$19,233	2.14%	$412,064	0.01%	0.29%
331314	Secondary Smelting and Alloying of Aluminum	$35,312	30	$1,159	$49,325	2.52%	$1,243,421	0.00%	0.09%
331420	Copper Rolling, Drawing, Extruding, and Alloying	$135,310	119	$1,269	$93,805	2.14%	$2,009,801	0.00%	0.06%

Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	Number of Affected Establish-ments	Annualized Costs per Affected Establish-ment	Revenues per Establishment	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$70,791	62	$1,218	$55,758	2.14%	$1,194,643	0.00%	0.10%
331511	Iron Foundries	$23,362,955	13,583	$57,403	$26,576	4.36%	$1,157,952	0.22%	4.96%
331512	Steel Investment Foundries	$5,450,435	5,487	$42,582	$29,129	4.36%	$1,269,196	0.15%	3.35%
331513	Steel Foundries (except Investment)	$11,118,366	6,469	$53,454	$21,811	4.36%	$950,345	0.25%	5.62%
331524	Aluminum Foundries (except Die-Casting)	$4,120,657	5,601	$10,149	$6,972	4.36%	$303,783	0.15%	3.34%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$2,569,518	3,451	$8,565	$8,043	4.36%	$350,441	0.11%	2.44%
332111	Iron and Steel Forging	$154,626	136	$1,239	$29,983	3.81%	$1,141,045	0.00%	0.11%
332112	Nonferrous Forging	$40,101	35	$1,404	$38,519	3.81%	$1,465,896	0.00%	0.10%
332117	Powder Metallurgy Part Manufacturing	$52,988	46	$1,152	$15,217	3.81%	$579,097	0.01%	0.20%
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$340,536	299	$1,182	$7,883	3.81%	$300,003	0.01%	0.39%
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	$48,090	42	$1,315	$19,914	4.12%	$820,139	0.01%	0.16%

Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	Number of Affected Establish-ments	Annualized Costs per Affected Establish-ment	Revenues per Establishment	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
332216	Saw Blade and Handtool Manufacturing	$179,774	157	$1,223	$6,670	4.12%	$274,708	0.02%	0.45%
332323	Ornamental and Architectural Metal Work Manufacturing	$44,015	40	$1,098	$2,623	2.70%	$70,844	0.04%	1.55%
332439	Other Metal Container Manufacturing	$76,117	66	$1,228	$10,764	2.93%	$315,184	0.01%	0.39%
332510	Hardware Manufacturing	$171,563	150	$1,283	$12,347	4.63%	$572,156	0.01%	0.22%
332613	Spring Manufacturing	$96,006	84	$1,172	$9,172	4.63%	$425,023	0.01%	0.28%
332618	Other Fabricated Wire Product Manufacturing	$158,941	139	$1,163	$5,920	4.63%	$274,353	0.02%	0.42%
332710	Machine Shops	$1,580,507	1,387	$1,142	$2,015	4.63%	$93,386	0.06%	1.22%
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	$3,443,786	4,113	$2,126	$5,226	2.96%	$154,661	0.04%	1.37%
332911	Industrial Valve Manufacturing	$229,195	201	$1,292	$23,997	5.95%	$1,428,175	0.01%	0.09%
332912	Fluid Power Valve and Hose Fitting Manufacturing	$219,774	196	$1,579	$27,901	5.95%	$1,660,504	0.01%	0.10%
332913	Plumbing Fixture Fitting and Trim Manufacturing	$49,483	43	$1,383	$32,065	5.95%	$1,908,358	0.00%	0.07%
332919	Other Metal Valve and Pipe Fitting Manufacturing	$92,474	80	$1,240	$19,968	5.95%	$1,188,418	0.01%	0.10%

Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	Number of Affected Establish-ments	Annualized Costs per Affected Establish-ment	Revenues per Establishment	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
332991	Ball and Roller Bearing Manufacturing	$145,507	127	$1,472	$38,700	5.95%	$2,303,203	0.00%	0.06%
332996	Fabricated Pipe and Pipe Fitting Manufacturing	$192,491	169	$1,203	$11,163	5.95%	$664,344	0.01%	0.18%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$460,336	405	$1,163	$4,158	5.95%	$247,481	0.03%	0.47%
333318	Other Commercial and Service Industry Machinery Manufacturing	$348,809	308	$1,350	$12,612	3.05%	$384,822	0.01%	0.35%
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$156,056	136	$1,195	$12,256	3.00%	$367,965	0.01%	0.32%
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	$116,177	102	$1,144	$11,241	3.00%	$337,472	0.01%	0.34%
333511	Industrial Mold Manufacturing	$226,974	199	$1,168	$3,653	3.82%	$139,525	0.03%	0.84%
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	$275,889	242	$1,170	$3,106	3.82%	$118,634	0.04%	0.99%
333515	Cutting Tool and Machine Tool Accessory Manufacturing	$183,291	161	$1,141	$3,474	3.82%	$132,676	0.03%	0.86%
333517	Machine Tool Manufacturing	$156,698	137	$1,216	$10,853	3.82%	$414,454	0.01%	0.29%

Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	Number of Affected Establish-ments	Annualized Costs per Affected Establish-ment	Revenues per Establishment	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	$75,852	66	$1,220	$8,534	3.82%	$325,928	0.01%	0.37%
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	$102,884	91	$1,346	$20,704	1.99%	$411,587	0.01%	0.33%
333613	Mechanical Power Transmission Equipment Manufacturing	$100,450	88	$1,219	$19,069	1.99%	$379,071	0.01%	0.32%
333911	Pump and Pumping Equipment Manufacturing	$217,882	191	$1,321	$28,279	3.80%	$1,074,041	0.00%	0.12%
333912	Air and Gas Compressor Manufacturing	$135,840	120	$1,367	$34,028	3.80%	$1,292,380	0.00%	0.11%
333991	Power-Driven Handtool Manufacturing	$56,450	50	$1,515	$28,169	3.80%	$1,069,870	0.01%	0.14%
333992	Welding and Soldering Equipment Manufacturing	$98,775	89	$1,706	$17,097	3.80%	$649,359	0.01%	0.26%
333993	Packaging Machinery Manufacturing	$129,107	113	$1,199	$9,812	3.80%	$372,657	0.01%	0.32%
333994	Industrial Process Furnace and Oven Manufacturing	$71,404	62	$1,148	$7,795	3.80%	$296,067	0.01%	0.39%
333995	Fluid Power Cylinder and Actuator Manufacturing	$153,238	137	$1,448	$20,250	3.80%	$769,086	0.01%	0.19%
333996	Fluid Power Pump and Motor Manufacturing	$68,340	60	$1,341	$27,468	3.80%	$1,043,257	0.00%	0.13%

Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	Number of Affected Establish-ments	Annualized Costs per Affected Establish-ment	Revenues per Establishment	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
333997	Scale and Balance Manufacturing	$24,516	21	$1,169	$11,016	3.80%	$418,388	0.01%	0.28%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$329,237	291	$1,261	$9,113	3.80%	$346,116	0.01%	0.36%
334519	Other Measuring and Controlling Device Manufacturing	$221,763	196	$1,354	$12,673	4.51%	$571,009	0.01%	0.24%
335210	Small Electrical Appliance Manufacturing	$24,524	24	$1,207	$26,870	4.01%	$1,078,458	0.00%	0.11%
335221	Household Cooking Appliance Manufacturing	$28,748	30	$1,956	$45,715	4.01%	$1,834,780	0.00%	0.11%
335222	Household Refrigerator and Home Freezer Manufacturing	$26,111	27	$2,363	$117,769	4.01%	$4,726,688	0.00%	0.05%
335224	Household Laundry Equipment Manufacturing	$12,403	13	$3,929	$101,337	4.01%	$4,067,200	0.00%	0.10%
335228	Other Major Household Appliance Manufacturing	$26,829	26	$2,273	$125,405	4.01%	$5,033,174	0.00%	0.05%
336111	Automobile Manufacturing	$362,562	354	$9,291	$600,655	-0.50%	-$3,026,184	0.00%	-0.31%
336112	Light Truck and Utility Vehicle Manufacturing	$324,735	319	$11,927	$1,521,927	-0.50%	-$7,667,681	0.00%	-0.16%
336120	Heavy Duty Truck Manufacturing	$183,916	174	$4,548	$354,849	-0.50%	-$1,787,779	0.00%	-0.25%
336211	Motor Vehicle Body Manufacturing	$260,377	229	$1,371	$15,229	1.30%	$197,621	0.01%	0.69%

Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	Number of Affected Establish-ments	Annualized Costs per Affected Establish-ment	Revenues per Establishment	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
336212	Truck Trailer Manufacturing	$180,129	160	$1,486	$19,658	1.30%	$255,102	0.01%	0.58%
336213	Motor Home Manufacturing	$45,680	42	$2,828	$39,044	1.30%	$506,657	0.01%	0.56%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$334,051	298	$1,705	$37,520	1.30%	$486,887	0.00%	0.35%
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$315,816	283	$1,576	$30,162	1.30%	$391,403	0.01%	0.40%
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$180,676	162	$1,677	$48,080	1.30%	$623,914	0.00%	0.27%
336340	Motor Vehicle Brake System Manufacturing	$140,620	123	$1,411	$51,448	1.30%	$667,628	0.00%	0.21%
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$364,252	329	$1,859	$68,201	1.30%	$885,017	0.00%	0.21%
336370	Motor Vehicle Metal Stamping	$516,924	458	$1,457	$40,671	1.30%	$527,778	0.00%	0.28%
336390	Other Motor Vehicle Parts Manufacturing	$778,085	689	$1,527	$38,534	1.30%	$500,038	0.00%	0.31%
336611	Ship Building and Repairing	$9,586,384	3,038	$27,183	$36,357	6.06%	$2,204,764	0.07%	1.23%
336612	Boat Building	$2,566,768	787	$8,195	$8,054	6.06%	$488,437	0.10%	1.68%
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	$69,849	62	$2,229	$81,906	4.03%	$3,304,704	0.00%	0.07%

Table VII-18: Screening Analysis for Establishments in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	Number of Affected Establishments	Annualized Costs per Affected Establishment	Revenues per Establishment	Profit Rate [a]	Profits per Establishment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
337110	Wood Kitchen Cabinet and Countertop Manufacturing	$204,454	223	$993	$1,555	2.77%	$43,087	0.06%	2.31%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$215,675	189	$1,215	$5,949	2.77%	$164,853	0.02%	0.74%
339114	Dental Equipment and Supplies Manufacturing	$5,930,743	4,956	$8,158	$7,145	7.32%	$523,086	0.11%	1.56%
339116	Dental Laboratories	$6,857,347	31,105	$1,006	$676	7.32%	$49,470	0.15%	2.03%
339910	Jewelry and Silverware Manufacturing	$2,690,864	6,772	$1,270	$3,549	3.92%	$139,242	0.04%	0.91%
339950	Sign Manufacturing	$408,620	384	$1,124	$1,925	3.92%	$75,524	0.06%	1.49%
423840	Industrial Supplies Merchant Wholesalers	$2,292,917	1,773	$1,362	$8,430	2.98%	$251,560	0.02%	0.54%
444110	Home Centers	$110,386	107	$1,033	$2,122	6.05%	$128,360	0.05%	0.80%
482110	Rail transportation [b]	$16,562,059	16,895	N/A	N/A	6.23%	N/A	N/A	N/A
561730	Landscaping Services	$24,481,907	43,033	$942	$566	2.96%	$16,767	0.17%	5.62%
621210	Offices of Dentists	$2,592,207	8,525	$304	$787	7.78%	$61,216	0.04%	0.50%
	Total	**$370,810,530**	**75,074**						

[a] Profit rates were calculated as the average of profit rates for 2000 through 2012, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2015).

[b] Costs and impact to rail transportation were estimated separately. See the discussion in Chapter VI, Economic Feasibility Analysis and Regulatory Flexibility Determination, in the FEA, for more information.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

b. Normal Year-to-Year Variations in Prices and Profit Rates

The United States has a dynamic and constantly changing economy in which an annual percentage changes in industry revenues or prices of one percent or more is common. Examples of year-to-year changes in an industry that could cause such variations in revenues or prices include increases in

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fuel, material, real estate, or other costs; tax increases; and shifts in demand.

Methodology

To demonstrate the normal year-to-year variation in prices for all the manufacturers in general industry and maritime affected by the rule, OSHA developed in the FEA year-to-year producer price indices and year-to-year percentage changes in producer prices, by industry, for the years 2004 through 2014. As shown in Table VI–3 in the FEA, for the combined affected manufacturing industries in general industry and maritime over the 12-year period, the average change in producer prices was 2.7 percent a year. For the industries in general industry and maritime with the largest estimated potential annual cost impact as a percentage of revenue—NAICS 213112—Support Activities for Oil and Gas Operations, 0.56 percent; and NAICS 327991—Cut Stone and Stone Product Manufacturing, 0.42 percent—the average annual changes in producer prices in these industries over the 12-year period were, respectively, 3.8 percent, and 0.5 percent.

Based on these data, it is clear that the potential cost impacts of the final rule in general industry and maritime are all well within normal year-to-year variations in prices in those industries. The maximum cost impact of the rule as a percentage of revenue in any affected industry is 0.56 percent, while the average annual change in producer prices for affected industries was 2.7 percent for the period 2004 through 2014 (changed from 1998 to 2009 in the PEA). Furthermore, even a casual examination of Table VI–3 of the FEA reveals that annual changes in producer prices in excess of five or even ten percent are possible without threatening an industry's economic viability. Thus, OSHA concludes that the potential price impacts of the final rule would not threaten the economic viability of any industries in general industry and maritime.

Changes in profit rates are also subject to the dynamics of the U.S. economy. A recession, a downturn in a particular industry, foreign competition, or the increased competitiveness of producers of close domestic substitutes are all easily capable of causing a decline in profit rates in an industry of well in excess of ten percent in one year or for several years in succession.

To demonstrate the normal year-to-year variation in profit rates for all the manufacturers in general industry and maritime affected by the rule, OSHA in the FEA developed Table VI–4 and Table VI–5, which show, respectively, year-to-year profit rates and year-to-year percentage changes in profit rates, by industry, for the years 2000 through 2012. For the combined affected manufacturing industries in general industry and maritime over the thirteen-year period, OSHA calculated an average change in profit rates of 138.5 percent a year (average for all industries calculated from the per-NAICS averages shown in Table VI–5 in the FEA). For the industries in general industry and maritime with the largest estimated potential annual cost impacts as a percentage of profit—NAICS 327120—Clay Building Material and Refractories Manufacturing, 31 percent; NAICS 327110—Pottery, Ceramics, and Plumbing Fixture Manufacturing, 31 percent; and NAICS 327991—Cut Stone and Stone Product Manufacturing, 24 percent—the average annual percentage changes in profit rates in these industries over the 13-year period were, respectively, 951 percent, 951 percent, and 113 percent.

One complicating factor is that the annualized costs of the rule, if absorbed in lost profits, would involve not just a temporary loss of profits but a longer term negative effect on profits relative to the baseline. To address this issue, the Agency compared the effect of a longer term reduction in profits to much larger reductions in profits but over shorter periods. Assuming a three-percent discount rate, the Agency determined a ten percent decline in profit rates relative to the original baseline, which remains constant at that lower level over a ten-year period, would be equivalent to: [57]

- An 88.5 percent decline in profit rates for one year;
- a 44.5 percent decline in profit rates that remains constant at the lower level for two years; or
- a 30 percent decline in profit rates that remains constant at the lower level for three years.[58]

An examination of Table VI–5, for the thirteen year period from 2000 to 2012, clearly shows that short-run changes in average industry profit rates of the above magnitudes have occurred on numerous occasions in general industry and maritime, without threatening the economic viability of the affected industries. For this reason, OSHA is confident that potential profit rate impacts of ten percent or less as a result of the rule would not threaten the economic viability of the affected industries in general industry and maritime.

A longer-term loss of profits in excess of ten percent a year could be more problematic for some affected industries and might conceivably, under sufficiently adverse circumstances, threaten an industry's economic viability. In OSHA's view, however, affected industries would generally be able to pass on most or all of the costs of the final rule in the form of higher prices rather than bear the costs of the final rule in reduced profits. In other words, the demand for the goods and services produced by affected industries in general industry and maritime do not appear to be perfectly elastic or close to it. While there are substitutes for these products, there are no perfect substitutes that would lead the price elasticity to be extremely high. As a result, the demand for quantities of brick and structural clay, vitreous china, ceramic wall and floor tile, other structural clay products (such as clay sewer pipe), and the various other products manufactured by affected industries would not significantly contract in response to a 0.48 percent (or lower) price increase for these products. It is of course possible that such price changes will result in some reduction in output, and the reduction in output might be met through the closure of a small percentage of the plants in the industry. However, the only realistic circumstance under which an entire industry would be significantly affected by small price increases would be the availability in the market of a very close or perfect substitute product not subject to OSHA regulation. The classic example, in theory, would be foreign competition. In the following discussion OSHA examines the threat of foreign competition for affected U.S. establishments in general industry and maritime and concludes that it is unlikely to threaten the viability of any affected industry.

Public Comments on Year-to-Year Variations in Prices and Profit Rates

The American Chemistry Council (ACC) stated, with respect to a similar analysis in the PEA, that short-term volatility within an industry sector is of little value in projecting what will

[57] Note that the reduction in profits rates over time, as a result of the rule, is being measured here relative to the baseline. If the reduction in profit rates were made relative to the previous year, as is done in Table VI–5 in the FEA, then there would be only a one-time reduction in the profit rate in year one as a result of the rule, after which the profit rate would reach a new (lower) level but would not change from year to year.

[58] Assuming a seven-percent discount rate, a ten-percent decline in profit rates over the ten-year annualization period would be equivalent to: A 75-percent decline in profit rates for one year; a 39-percent decline in profit rates that remains constant at the lower level for two years; or a 27-percent decline in profit rates that remains constant at the lower level for three years.

happen when a new regulation resets the baseline for profits and revenue because OSHA is comparing short-term changes to long-term changes (Document ID 2307, Attachment 2, p. 196). Another commenter made the similar point that year-to-year fluctuations cannot be compared to long-term changes (Document ID 2308, Attachment 9, p. 7).

OSHA first examines the issue of changes in prices over time. Such changes, on the whole, represent pass through of changes in costs, since profits are not continually rising. These changes in costs are not ''fluctuations'' with upward and downward shifts in prices. For almost all industries these changes in costs are continuing upward shifts that average each year much larger changes than the maximum price change any industry will need to incur in order to comply with the silica rule.

For variations in profits, these are indeed fluctuations and profits do indeed both rise and fall. However, if, as the commenters argue only long-term average profits matter, then we could reach the very counterintuitive result that there should be no excess plant closures during recessions. This is not the case because long-term profits are, in fact, nothing more than a prediction and the present value of long term profits will be different at the beginning than at the end of a recession. Recognizing these timing effects is why OSHA examined the annualized value of losses in profits associated with the recession beginning 2008 and compared it to the annualized value of the loss in profits as result of costs of this standard. While temporary and permanent losses are different, the use of discounting enables us to compare short- and long-term losses.

c. International Trade Effects

The magnitude and strength of foreign competition is an important factor in determining the ability of firms in the U.S. to pass on (part or all of) the costs of the rule in the form of higher prices for their products. If firms are unable to do so, they must absorb the costs of the rule out of profits, possibly resulting in the business failure of individual firms or even, if the cost impacts are sufficiently large and pervasive, causing significant dislocations within an affected industry.

As in the PEA, OSHA in the final economic analysis examined how likely such an outcome is. The analysis there included a review of trade theory and empirical evidence and the estimation of impacts. Throughout, the Agency drew on ERG (2007c) (Document ID 1710), which was prepared specifically to help analyze the international trade impacts of OSHA's final silica rule. A summary of the FEA results is presented below.

OSHA focused its analysis on eight of the industries likely to be most affected by the final silica rule and for which import and export data were available. OSHA combined econometric estimates of the elasticity of substitution between foreign and domestic products, Annual Survey of Manufactures data, and assumptions concerning the values for key parameters to estimate the effect of a range of hypothetical price increases on total domestic production. In particular, OSHA estimated the domestic production that would be replaced by imported products and the decrease in exported products that would result from a 1 percent increase in prices—under the assumption that firms would attempt to pass on all of a 1 percent increase in costs arising from the final rule. The sum of the increase in imports and decrease in exports represents the total loss to industry attributable to the rule. These projected losses are presented as a percentage of baseline domestic production to provide some context for evaluating the relative size of these impacts.

The effect of a 1 percent increase in the price of a domestic product is derived from the baseline level of U.S. domestic production and the baseline level of imports. The baseline ratio of import values to domestic production for the eight affected industries ranges from 0.04 for iron foundries to 0.547 for ceramic wall and floor tile manufacturing—that is, baseline import values range from 4 percent to more than 50 percent of domestic production in these eight industries. OSHA's estimates of the percentage reduction in U.S. production for the eight affected industries due to increased domestic imports (arising from a 1 percent increase in the price of domestic products) range from 0.013 percent for iron foundries to 0.237 percent for cut stone and stone product manufacturing.

OSHA also estimated the baseline ratio of U.S. exports to consumption in the rest of the world for the sample of eight affected industries. The ratios range from 0.001 for other concrete manufacturing to 0.035 percent for nonclay refractory manufacturing. The estimated percentage reductions in U.S. production due to reduced U.S. exports (arising from a 1 percent increase in the price of domestic products) range from 0.014 percent for ceramic wall and floor tile manufacturing to 0.201 percent for nonclay refractory manufacturing.

The total percentage change in U.S. production for the eight affected industries is the sum of the loss associated with increased imports and the loss resulting from reduced exports. The total percentage reduction in U.S. production arising from a 1 percent increase in the price of domestic products range from a low of 0.085 percent for other concrete product manufacturing to a high of 0.299 percent for porcelain electrical supply manufacturing.

These estimates suggest that the final rule would have only modest international trade effects. It was previously hypothesized that if price increases resulted in a substantial loss of revenue to foreign competition, then the increased costs of the final rule would have to come out of profits. That possibility has been contradicted by the results reported in this section. The maximum loss to foreign competition in any affected industry due to a 1 percent price increase was estimated at approximately 0.3 percent of industry revenue. Because, as reported earlier in this section, the maximum cost impact of the final rule for any affected industry would be 0.56 percent of revenue, this means that the maximum loss to foreign competition in any affected industry as a result of the final rule would be 0.2 percent of industry revenue —which would hardly qualify as a substantial loss to foreign competition. This analysis cannot tell us whether the resulting change in revenues will lead to a small decline in the number of establishments in the industry or slightly less revenue for each establishment. However it can reasonably be concluded that revenue changes of this magnitude will not lead to the elimination of industries or significantly alter their competitive structure.

Based on the Agency's preceding analysis of economic impacts on revenues, profits, and international trade, along with the discussion of industry concerns below, OSHA concluded that the annualized costs of the final rule are below the threshold level that could threaten the economic viability of any industry in general industry or maritime. OSHA further noted that while there would be additional costs (not attributable to the final rule) for some employers in general industry and maritime to come into compliance with the new silica standard, these costs would not affect the Agency's determination of the economic feasibility of the final rule.

Public Comment on International Trade Effects

Foundries

The following comments discuss the loss of business to foreign competition in the foundry industry. The comments have been grouped together by issue and are followed by OSHA's response. The first group of commenters used impact numbers from an alternative cost model to discuss the loss of business to foreign competition.

The United States Chamber of Commerce (''the Chamber'') stated that additional costs of the rule's ancillary provisions along with engineering controls will result in reduced competitiveness relative to foreign foundries (Document ID 2288, pp. 27–28). The Chamber also critiqued OSHA's inability to determine feasibility because of a lack of data to analyze economic impacts across facilities by age, design, operations, condition and region (Document ID 2288, pp. 29–30).

In the comments above, the negative economic effect of losing business to foreign competition is based on an alternative cost model report prepared for the American Foundry Society (AFS) by Environomics. This report is addressed in the Engineering Control Costs section in Chapter V of the FEA, where OSHA concluded that the costs in that report were inflated. Because these inflated costs also underpin the Chamber's claim that the rule will reduce competitiveness with foreign foundries, OSHA does not accept that claim. In response to the Chamber's criticism of OSHA's data sources, the Agency notes that Chapter III, the section on Survey Data and OSHA Economic Analyses, discusses why it was infeasible to collect and compile a full-scale national survey of the kinds of baseline conditions and practices that the Chamber of Commerce urged OSHA to consider.

The following comments from foundry firms and associations address foreign competition in metalcasting from China and India along with the inability to pass the cost on to their customers.

AFS submitted comments that the metalcasting industry would lose business to foreign competition as follows:

> Many foundries have closed in recent years with foreign competition assuming much of that business. Five of the eleven identifiable foundries used in the PEA to support OSHA's assertion of feasibility have closed. Because castings are the starting point of many manufacturing processes, loss of foundry jobs also means loss of other manufacturing jobs.
>
> The U.S. metalcasting industry is made up of 1,978 facilities, down from 2,170 five years ago. This reduction can be attributed to the recession, technological advancements, foreign competition and tightening regulations (Document ID 2379, Attachment 3, p. 42; 4035, p. 5).

The Indiana Cast Metals Association concurred with these comments and also suggested that other industries would also be negatively impacted if U.S. foundries shut down (Document ID 2049, p. 1). The Ohio Cast Metals Association submitted two comments stating that the rule will increase costs and undermine the Ohio-based metalcasting industry's ability to compete in the global marketplace:

> [The silica rule] will significantly increase costs, slow down or eliminate hiring, reduce the number of foundry jobs and undermine our industry's ability to compete in the global marketplace. For some foundries, the rulemaking could be the final straw that destroys their business.
>
> . . . Over the past two decades Ohio foundries along with other manufacturers throughout the United States have faced tremendous international competition from China, Brazil, and India and many foundries have closed and thousands of employees have lost their jobs during this period. To suggest that Ohio foundries can just pass on the tremendous costs associated with compliance with the proposed silica rule with ''minimal loss of business to foreign competition'' indicates that the individuals performing this analysis were driven by other agendas or misinformed (Document ID 2119, Attachment 3, pp. 1–2).

Grede Holdings L.L.C. submitted a comment expressing its view that it would be difficult for foundries to pass the cost of compliance to the customer because of international competition, and that the number of foundries in the U.S. has dropped by more than half since 1980, going from 4,200 foundries to 2,050 foundries (Document ID 2298, p. 3).

Sawbrook Steel submitted two comments voicing concern that the implementation of the regulation will cause jobs to move overseas, resulting in a shrinking of the domestic casting manufacturing (Document ID 2227, p. 2; 1995, p. 1).

In the comments above, businesses and associations state that the costs of the rule will be too high and they will lose business to foreign competition. The chief advantage of foreign imports to downstream users, as reported to the U.S. International Trade Commission (ITC) during an investigation they conducted into the competitive conditions in the U.S. foundry market, is their low pricing. Respondents to the investigations said the cost of foreign produced products ranged from ten percent to forty percent less than the cost of U.S. products (Document ID 0753, table 5–60, p. 5–53 as referenced in Document ID 1710, pp. 5–4). U.S. producers have responded to competition with a broad array of initiatives, such as implementing lean manufacturing, improving customer service, and increasing automation (Document ID 0753, pp. 10–14 and 10–15). According to the ITC study:

> The use of technology may also be influenced by the type of castings produced and relative wage rates. Low-value, low-quality castings, for example, generally require a lower level of technology and relatively more semi-skilled labor than foundries producing more complex castings. To lower labor costs, foundries in developed countries with higher wage rates may install more automation and technological improvements, whereas foundries in developing countries with relatively lower wage rates may substitute labor for relatively high-cost capital investments (Document ID 0753, p. 2–11).

Before addressing issues on international competition for metalcasters, it should be noted that all foundry industries affected by this rule are below the ten percent cost to profit threshold and one percent cost to revenue threshold. This means that even if the argument that costs cannot be passed on were to be correct, the loss in profits would be less than ten percent and unlikely to effect the feasibility of the industry. Further the costs to be passed on would require less than one percent price increases. In general, metalcasters in the U.S. have shortened lead times, improved productivity through computer design and logistics management, provided expanded design and development services to customers, and provided a higher quality product than foundries in China and other nations where labor costs are low (Document ID 0753, p. 3–12). All of these measures, particularly the higher quality of many U.S. metalcasting products and the ability of domestic foundries to fulfill orders quickly, are substantial advantages for U.S. metalcasters that may outweigh the very modest price increases projected in Tables VI–3 and VI–4 of the FEA (Document ID 1710, p. 5–4). According to the ITC study, quality was the number one purchasing decision factor for the majority of purchasers, with price and lead times ranking lower, and U.S. metalcasters are able to deliver that quality (Document ID 0753, p. 4–5). The ITC report noted:

> Certain purchasers noted that when inventory management and complex manufacturing skills are required, U.S. foundries excel. U.S. foundries were also cited by responding U.S. purchasers as manufacturing with a low defect (rejection) rate. (Id.)

Purchaser responses to the ITC's survey stated that some U.S. foundries are also completely inoculated against foreign competition, even if the prices of U.S. foundry products rise:

> As noted in questionnaire responses, certain purchasers are committed to buying solely U.S.-made castings. One U.S. foundry official noted that if downstream customers require castings to be made in the United States, then U.S. foundries are guaranteed that business. This situation often occurs when foundries supply castings for federally funded operations, such as construction projects (Document ID 0753, p. 4–5).

Foundries in China and India, while expanding their capacities, are also faced with rising domestic demand due to their own rapidly expanding domestic industrial economies, which affect their ability to fulfill export demand (Document ID 0753, p. 5–16). ERG's research noted a growth in U.S. foundry exports, which could help to offset some of the foreign imports entering the U.S. market. According to one report cited by ERG, U.S. foundry exports were roughly equivalent to 53 percent of the imports (Document ID 1710, p. 5–5).

ERG's research also provided some evidence that the combination of U.S. and foreign demand for metalcasting may outstrip the supply to such a degree that, even if the U.S. foundries operated at full capacity, their maximum output would fail to meet the demand from the U.S. and foreign markets (Document ID 1710, p. 5–5). The U.S. foundry industry is unlikely to face any significant economic impacts if there is ample demand and a limited supply because such a condition makes it easier to pass along any costs of the rule.

Tile Production

The following comments discuss the difficulties of competing with foreign tile producers followed by OSHA's response.

Tile Council of North America (TCNA) noted the import price sensitivity between domestic tile and imported tile as follows:

> The low cost of imported tile places an enormous burden on U.S. tile manufacturers to maintain current pricing to remain competitive. According to the latest data collected by TCNA, the average price per square foot of U.S. tile shipments is $1.43. The average price per square foot of Chinese imports is $0.86. With Chinese imports 60% less expensive than U.S. tile in what is an extremely price-competitive market, OSHA's claim that ''any price increases would result in minimum loss of business to foreign competition'' strains credulity.
>
> To illustrate the tremendous import/price sensitivity between domestic tile and imports, we note the increase in imports from Peru as a result of a bilateral free trade agreement between Peru and the United States eliminating duty on tile from Peru. Although only amounting to a price change of 4—5 cents per square foot, from 2008, the year before the bilateral agreement to the end of 2011, tile imports from Peru into the United States grew by 59%. This illustrates how even a small change in price due to modest increases in operating costs and raw material costs pose an existential threat to the tile manufacturing industry.
>
> The import sensitivity of domestic tile manufacturing operations is well known by the United States International Trade Commission (USITC) and the office of the United States Trade Representative (USTR). The assertion made by OSHA that cost increases will not result in lost market share to foreign competition is in direct conflict with information known by USITC and the USTR and contrary to established public policy (as reflected in existing Free Trade Agreements) and industry testimony.
>
> Contrary to the assertion made by OSHA, the marginal price increases anticipated by required conformance to the rule as proposed would make the domestic tile manufacturing industry highly uncompetitive threatening the very viability of this import-sensitive industry (Document ID 2363, p. 9).

The National Tile Contractors Association also questioned OSHA's preliminary determination that the tile industry could pass on most or all costs through higher prices, calling the claim ''wildly erroneous'':

> Implementation of the proposed rule's requirements would increase both production and installation costs, and would put pressure on consumer prices. At a time when U.S. consumption of ceramic tile is more than 25% below its peak level (2006), this is a serious concern. The U.S. market is already flooded with lower quality, lower priced imports from many countries that likely do not respect the health, safety, and rights of workers. The low cost of imported tile places an enormous burden on U.S. tile manufacturers to maintain current pricing to remain competitive (Document ID 2267, p. 8).

Dal-Tile echoed the TCNA comments regarding the inability to pass costs onto the customer (Document ID 2147, p. 3).

OSHA does not dispute the commenters' information indicating that Chinese and Peruvian tile are significantly cheaper than U.S. tile, but that point actually undercuts their claim that a small change in the price of U.S. tile would place an ''enormous burden'' on U.S. tile manufacturers. The commenters note that Chinese tile is already available in the U.S. at just over half the price of U.S. tile. If the market was actually as sensitive as the commenters suggest, and the Chinese tile was competing for the same market share as U.S. tile, under the commenter's logic the U.S. tile industry would have already gone out of business. But that has not happened, suggesting that U.S. tile manufacturers have been able to identify customers for whom the tile price is not the predominant factor. Likewise, the example of Peruvian tile demonstrates only that the lower-priced imported tile is sensitive to small price changes. The commenter provides no evidence that the Peruvian tile is competing for the same customers as the U.S. tile industry.

In summary, the TCNA's argument that cost increases will result in lost market share to foreign competition is unconvincing because it is not clear that there is a strong relationship between the price of the foreign tile and the price of the U.S. tile. One likely cause for this disconnect is that, as TCNA notes, the market is ''already flooded with lower quality, lower priced'' imports (Document ID 2363, p. 8), suggesting that tile from China, Peru, and the other lower-priced foreign importers are of a lower quality that may be targeted at a different customer base than the higher-quality U.S. tile. This perception that tile from China and other low-cost tile producing countries may be of lower quality produces an imperfect substitution scenario and adds to the inelasticity of demand for domestic tiles, enabling producers to pass some of the costs on to the consumer.

On the other end of the tile price range are the Italian tiles. Italy and China are the top countries of origin for tiles imported into the U.S., but tiles from these countries command very different prices. In terms of general tile products, one source indicates that the average prices of tiles imported by the U.S. in 2012 were $20.20 to $20.90 per square meter for Italian tiles and between $8.30 and $8.70 per square meter for Chinese tiles imported by the U.S., a significant price difference that could be explained by a difference in quality.[59] TCNA stated above that the average price of tile from China is $0.86 per square foot or $9.25 ($10.76 \times 0.86$) per square meter. TCNA's average price of American tile is $1.43 per square foot or $15.39 ($10.76 \times 1.43$) per square meter (Document ID 2363, p. 9), which shows the U.S. producers to be supplying a mid-priced product. Although Italy is also a major source of tile imports in the U.S. despite their higher price, the commenters did not suggest that an increase in U.S. tile prices would cause the U.S. to lose market share to the Italian tile; nor did the commenters suggest that lower-priced U.S. tile could be exported to dominate the Italian market. The implication is, again, that different

[59] *http://www.scirp.org/journal/PaperInformation.aspx?PaperID=43515.*

customers are willing to pay different prices for different quality tile.

Using price as an indicator of quality, the tile market can be segmented into three categories: Low quality, mid-grade, and high quality. The U.S. tile industry has located a niche between the lowest quality/lowest priced tile and the highest quality/highest priced tile. While it is possible that a few tile firms that produce very low-quality or very high-quality tile may be negatively impacted by an increase in the price of their tile, OSHA concludes that the majority of firms would not experience a significant negative economic impact. This is along with the fact that the increase in price from this rule is expected to be minimal. TCNA commented that the average price per square foot of U.S. tile shipments is $1.43. The cost to revenue ratio for NAICS 327122 Ceramic Wall and Floor Tiles is 0.35 percent, meaning this final rule will increase the average cost of U.S. tile by five hundredths of a cent (or $0.0005 per square foot). It is therefore fair to say this extremely modest increase in the average price of U.S. tile would not have a significant economic impact on the U.S. tile industry as a whole.

Brick Industry

During the public hearing Belden Tri-State Building Materials stated that the brick industry has foreign competition, mostly from Canada, and some from Mexico (particularly in Texas, Oklahoma or Arkansas), and Germany (Document ID 3586, Tr. 3457). They indicated that their competition includes not only imported brick but also ''other cladding materials like vinyl siding and HardiePlank,'' but the competition from imported brick is typically ''more expensive brick'' because of ''innovations in Europe that we just haven't caught up to, different sizes, different colors, different processes'' (Id.).

Acme Brick Company representatives indicated in testimony that oversees competition was virtually nonexistent because it is ''hard to get that across the ocean economically'' and noted that they generally locate their production facilities strategically to be near their markets because ''[p]roduction costs really are about a third of the cost of the brick when we have them close . . . [The] farther away [the bricks come from]—there are some distinctions in the quality or the makeup of a brick'' (Document ID 3577, Tr. 736).

This testimony indicates to OSHA that international competitors will not be able to take advantage of any potential price increases made by U.S. producers in the U.S. domestic brick market. The brick making industry will therefore be able to pass on most, if not all, of the costs of complying with the rule.

Hydraulic Fracturing

To determine the economic impacts for most industries, OSHA used the Census Bureau's Statistics of U.S. Businesses to estimate revenues on a six-digit NAICS basis but these revenue data were not sufficiently precise to isolate the hydraulic fracturing component from the larger industry (NAICS 213112). As a result, instead of using data from the Economic Census, revenues for hydraulic fracturing firms were based on estimated utilization rates and per stage revenues. As discussed in Chapter III of the FEA, Profile of Affected Industries, the data on this industry have been updated to reflect the comments in the record and the best data available in 2012. The cost to profit percentage for the hydraulic fracturing industry estimated in the FEA is 7.67 percent (below OSHA's ten percent threshold) for fleets of all sizes. The ratio of costs to revenues for hydraulic fracturing firms in the FEA is estimated to be 0.54 percent for all establishments in the industry, 0.17 percent for small entities and 0.24 percent for very small entities. Although the costs as a percent of revenue increased for all establishments, the impacts still remain well below the one percent threshold.

However, these estimates are based on the state of the industry in the base year of 2012 supplemented with data provided in comments to the proposed rule in 2013 and early 2014. When the PEA was published in 2006, the price of oil fluctuated between $70 and $80 a barrel. During the years following the publication of the PEA the price of oil has had some large fluctuations. Before the recession of 2008 the price of oil peaked at $146 per barrel but dropped to $44 dollars per barrel during the economic downturn in 2008.[60] As the price of oil steadily increased during 2009, there was an influx of money invested in the hydraulic fracturing industry. The FEA uses revenue data from 2012 when the price per barrel fluctuated between $90 and $100. However, in the fourth quarter of 2014, the price of oil dropped to $49 per barrel. The price of oil in 2015 has oscillated between approximately $45 and $60 per barrel.[61] Because of this major change in the industry since the record closed in 2012, OSHA has supplemented its feasibility analysis with more current data.

The Structure of the Hydraulic Fracturing Industry

Hydraulic fracturing nearly doubled U.S. oil production from 5.6 million barrels a day in 2010 to a rate of 9.3 million barrels a day in 2015. Up until the drop in oil prices during the fourth quarter of 2014, the expected annual increase in production was one million barrels. The economics of hydraulic fracturing wells is much different than conventional wells.[62] The marginal cost of producing a barrel of oil from a conventional well for large oil producing countries is around $15 to $30.[63] Therefore, the owners of conventional wells continue to produce even as the price per barrel decreased from $100 to $40, and would remain in business at costs down to $30. The traditional oil drilling business is driven by marginal costs, not costs spent to drill the well. This means that supply is inelastic relative to demand. This has not been true for the hydraulic fracturing industry.

Hydraulic fracturing wells have a very short life compared to conventional wells. For example, a well in the Bakken region straddling Montana and North Dakota may start out producing 1,000 barrels a day then decline to 280 barrels at the beginning of year two. By year three, more than half of the reserves will be depleted. Therefore, to generate revenue, producers need to constantly drill new wells. In this sense, hydraulic fracturing wells are more like gold or silver mines than conventional oil production.[64] The recent drop in oil prices has caused a series of bankruptcies and closures across the oil industries. Although there was a reduction in the number of rigs from about 1,600 to 800,[65] hydraulic fracturing still accounted for 4.6 million barrels a day out of a total of 9.4 million barrels or 49 percent of total oil produced in February 2015. Hydraulic fracturing also accounted for 54 percent of natural gas output.

The Energy Information Administration (EIA) projects the Brent crude oil price will average $40 a barrel in 2016 and $50 a barrel in 2017. However, EIA expects crude oil prices

[60] *http://www.macrotrends.net/1369/crude-oil-price-history-chart.*

[61] *http://www.macrotrends.net/1369/crude-oil-price-history-chart.*

[62] *http://fortune.com/2015/01/09/oil-prices-shale-fracking/.*

[63] *http://knoema.com/vyronoe/cost-of-oil-production-by-country.*

[64] *http://fortune.com/2015/01/09/oil-prices-shale-fracking/.*

[65] *http://www.economist.com/node/21648622/print.*

to rise in future years, rising to over $70 per barrel by 2020 and to $100 per barrel by 2028. EIA's crude oil price forecast remains subject to significant uncertainties as the oil market moves toward balance and could continue to experience periods of heightened volatility.[66] Thus, industry implementation of OSHA's engineering control requirements, which are not required until five years after the effective date of the rule, may come during a period of much higher and rising energy prices. In any case, the price increase required by this rule is a very small fraction of the fluctuation in energy prices during the past several years.

However, the possibility that oil prices are not going to increase in the near future has spurred a new wave of innovation in energy exploration. Now that prices have dropped to around $50 a barrel, companies are focusing on efficiency and getting the most petroleum for the least amount of money. With the effective date of this rule on the horizon, it is possible that some of this innovation will lead to technologies that not only increase efficiency but reduce worker exposures to silica at the same time.

Through the application of new technology OSHA believes that, even in a lower price environment, hydraulic fracturing entrepreneurs will be able to implement the controls required by this final rule without imposing significant costs, causing massive economic dislocations to the hydraulic fracturing industry, or imperiling the industry's existence. Big oil-field-services like Haliburton Co. and Schlumberger Ltd. report that they have witnessed customers concentrating on using technology such as lasers and other high-tech equipment and data analytics before they drill to make sure new wells deliver the most crude for the investment cost. The application of this new technology as well as fiber-optic tools that help monitor a well during hydraulic fracturing to make sure that it's working as well as possible and new techniques to stimulate microbes already present that attach themselves to bits of oil, essentially breaking it up and making it easier for the crude to flow through rock[67] have had positive quantitative results. Productivity at some ''super-fracking'' wells has increased 400–600 barrels a day per rig from just a few years ago. Drilling efficiency in some areas has increased as much as 26 percent in a single year[68] while the time to drill and fracture a well has come down from an average of 32 days in 2008 to now only about half that time: 14–16 days from start to finish and in some cases even less. These increased efficiencies result in significant cost savings.[69] Also, the lower demand by hydraulic fracturing companies for equipment rental, trucking, and labor has caused a decrease in their prices, reducing the overall cost of hydraulic fracturing.[70]

Although the drop in the price of oil has caused an initial reduction in hydraulic fracturing operations, the application of recently developed technology to new wells has increased per well production. One expert was quoted in Fortune magazine as saying ''[t]here tailing off in U.S. drilling activity, but I expect continued development drilling in major new areas, particularly the Bakken, even at $50 (a barrel).''[71] In the Bakken region in 2015 the decrease in oil production resulting from the reduction of rigs was substantially offset by increases in new well oil production per rig. There are reasons to believe in the continuance of tight oil growth. An analysis by IHS shows that most of the potential U.S. tight oil capacity additions in 2015 have a break-even price in the range of $50 to $69 per barrel. Continued productivity gains, such as improvements in well completion and downspacing, also support the continuation of U.S. production growth at lower prices.[72] Based on these advances, it is plausible that hydraulic fracturing shale operations may achieve break-even costs of $5-$20 per barrel.[73]

A sign of the ongoing effectiveness of upgrades in efficiency in the hydraulic fracturing business is evident in the projections for U.S. crude production. The EIA's Annual Energy Outlook for 2015 has projected that the U.S. is on track to hit reach a record for crude output at 10.6 million barrels a day in 2020.[74]

While the economic conditions faced by the hydraulic fracturing industry have changed significantly since the publication of the proposed rule, this discussion shows that there is significant reason to believe that this rule will not have a significant impact on the hydraulic fracturing industry. Advancements in technology and the application of new efficient drilling methods continue to increase the per-rig production capacity of new-well oil drilling rigs while lowering the costs of operating these rigs. These technological changes increase the energy recovered through hydraulic fracturing, and thus the value of fracturing services, without increasing the costs per well associated with controlling silica exposures. Further, the demand for fracturing services will depend, in part, on energy prices. The costs associated with complying with the silica rule are a minor issue by comparison. Thus, OSHA's conclusion that this rule is economically feasible for the hydraulic fracturing industry has not changed.

Railroads

In the PEA, OSHA did not include any estimates of costs as percentage of revenues or as a percentage of profits for railroads. This was due to the fact that the standard sources of economic statistics that were used for data on revenues and employment for all other affected industries do not include railroads. The Association of American Railroads (AAR) expressed concern about the impact of the rule on small railroads (although not on larger railroads), but did not provide any estimates or analysis, or suggest that OSHA use any specific sources to conduct such an analysis. For the FEA, OSHA did examine costs as percentage of revenues and profits for the railroad industry as a whole using supplemental information from sources typically relied on by the industry.

For the FEA, OSHA estimated that 16,895 workers in the rail transportation industry (NAICS 4821; ''railroads'') will be covered by the final standard, including 7,239 workers employed as Ballast Dumpers and 9,656 workers employed as Machine Operators (for the purposes of this analysis, OSHA assumed that the machine operators would be conducting at least some work outside of the cab of the equipment). The Agency estimated that compliance costs for railroads will total $16.6 million, or $980 per affected worker.

Based on these estimates, OSHA judged that the final rule is feasible for railroads because combining

[66] *http://www.eia.gov/forecasts/steo/report/prices.cfm.*

[67] *http://www.wsj.com/articles/oil-companies-tap-new-technologies-to-lower-production-costs-1442197712/.*

[68] *http://www.forbes.com/sites/judeclemente/2015/05/07/u-s-oil-production-forecasts-continue-to-increase/.*

[69] *http://www.aei.org/publications/top-10-things-i-learned-on-my-summer-trip-to-the-bakken-oil-fields-part-ii/.*

[70] *http://fortune.com/2015/01/09/oil-prices-shale-fracking/.*

[71] *http://fortune.com/2015/01/09/oil-prices-shale-fracking/.*

[72] *http://press.ihs.com/press-release/energy-power/tight-oil-test-us-production-growth-remains-resilient-amid-lower-crude-oi.*

[73] *http://economics21.org/commentary/shale-2.0-big-data-revolution-america-oil-fields-05-20-2015.*

[74] *http://www.forbes.com/sites/judeclemente/2015/05/07/u-s-oil-production-forecasts-continue-to-increase/.*

supplemental data from BLS [75] and the Association of American Railroads [76] for the estimated 105 rail transportation establishments in NAICS 4821 with a reported revenue of $72.9 billion, the cost-to-revenue impacts are an estimated 0.02 percent and cost-to-profit impacts are an estimated 0.4 percent. In addition, the per-worker cost for railroads ($980) is lower than the average per-worker cost ($1,231) across all affected NAICS industries in general industry and for 2000–2012, the average profit rate for rail transportation, 6.2 percent, was significantly higher than the average profit rate for all affected NAICS industries throughout general industry (3.4 percent).

The AAR noted that small railroads had not been covered in the Initial Regulatory Flexibility Analysis (Document ID 2366, p. 4). The commenter is correct that OSHA did not examine small entities in this sector but has done so for the FEA using supplemental information on railroads.

In 2012, 574 U.S. freight rail establishments, employing 181,264 workers, operated on roughly 169,000 miles of track.[77] The Surface Transportation Board in the U.S. Department of Transportation classifies railroads into three groups based on annual revenues:

- Class I for freight railroads defined as railroads with annual operating revenues above $467.1 million ($2013)
- Class II, includes some regional railroads, defined as railroads each with operating revenues between $37.4 million and $467.1 million ($2013)
- Class III for all other freight rail operations (including smaller regional, short-line, switching, and terminal).[78]

In 2013, in addition to the seven Class I freight railroad systems, there were 21 regional railroads (line-haul railroads operating at least 350 miles of road and/or earning revenue between roughly $40 million and the Class I threshold), and over 500 local railroads (line-haul or short-line railroads smaller than regional railroads).[79] Among the 567 railroads that fell below the Class I revenue threshold, 11 qualified as Class II and the remainder (556, including 10 regional railroads) qualified as Class III (FRA, 2015). Class III railroads are typically local short-line railroads serving a small number of towns and industries or hauling cars for one or more larger railroads. Many Class III railroads were once branch lines of larger railroads or abandoned portions of main lines.

In 2012, employment within 546 local railroad companies totaled 12,293 workers and employment within 21 regional railroads totaled 5,507 workers. Line Haul Railroads are classified in NAICS 482111 and entities within this industry with 1,500 or fewer workers are classified as small by SBA size standards. Local/Short Line Railroads are classified in NAICS 482112 and entities within this industry with 500 or fewer workers are classified as small by the SBA size standard. For 2012, OSHA estimated that all 567 Class II and Class III railroads (combined total of 17,800 workers) qualified as small entities according to the SBA definitions.

In a recent study prepared for Congress,[80] the Federal Railroad Administration reported that in 2013, 546 Local/Short Line Railroads employed 12,293 workers and earned $2.6 billion in revenue. OSHA estimates that of the 16,895 affected employees throughout rail transportation, 1,146 employees of Short-Line railroads are affected by the final rule.[81] According to the BLS Quarterly Census of Employment and Wages, on average 32 establishments were identified within NAICS 482112, Short-Line Railroads (an establishment can operate more than one railroad). Therefore, if all 546 Class III railroads are controlled by 32 establishments, OSHA estimates that revenue per establishment is approximately $81.3 million.

OSHA estimated that compliance costs for rail transportation will total $16,562,059. Therefore, if costs per affected worker ($980 per worker) are apportioned to the establishments operating Short-Line Railroads, OSHA estimates that costs for these local railroads will total $1.1 million, or roughly $35,100 per establishment. As noted above, annual revenues among Short-Line rail operations total approximately $2.6 billion, or $81.3 million per establishment. Applying the industry-wide profit rate of 6.23 percent for NAICS 4821, OSHA estimated that profits per establishment in NAICS 482112 are $5.1 million. Therefore, OSHA estimates that impacts measured as costs as a percent of revenues will not exceed 0.04 percent, and that impacts measured as costs as a percent of profits will not exceed 0.69 percent. Thus, OSHA concludes that the silica standard will not impose a significant impact on a substantial number of small entities in rail transportation and therefore will not threaten the competitive structure or viability of small entities in NAICS 482110.

d. Economic Feasibility Screening Analysis: Small and Very Small Businesses

The preceding discussion focused on the economic viability of the affected industries in their entirety. Even though OSHA found that the final standard did not threaten the survival of these industries, there is still the possibility that the competitive structure of these industries could be significantly altered.

To address this possibility, OSHA followed its normal rulemaking procedure for examining the annualized costs per affected small entity and per very small entity for each affected industry in general industry and maritime. Again, OSHA used its typical minimum threshold level of annualized costs equal to one percent of annual revenues—and, secondarily, annualized costs equal to ten percent of annual profits—below which the Agency has concluded that the costs are unlikely to threaten the survival of small entities or very small entities or, consequently, to alter the competitive structure of the affected industries.

Compliance costs for entities with fewer than 20 employees were estimated, in many cases, using a derived compliance cost per employee. Assuming costs to be equally distributed among all employees, OSHA estimated the compliance cost per employee by dividing total costs for each NAICS by the number of employees. OSHA then multiplied the compliance cost per employee with the ratio of the average number of employees per entity with fewer than 20 employees. Similarly, compliance costs per small entity were estimated from the product of compliance costs per employee and the

[75] Bureau of Labor Statistics, Quarterly Census of Employment and Wages, Series ID ENUUS0002054821, NAICS 4821, Rail Transportation. Accessed November 6, 2015.

[76] Railroad Statistics. Association of American Railroads. AAR Policy and Economics Department. July 15, 2014. *http://www.aar.org/StatisticsAndPublications/Documents/AAR-Stats.pdf.*

[77] Class I Railroad Statistics. Association of American Railroads. AAR Policy and Economics Department. July 15, 2014.

[78] Federal Register, Volume 79, No. 111, June 10,2014, p. 33257, cited in Summary of Class II and Class III Railroad Capital Needs and Funding Sources—A Report to Congress, Federal Railroad Administration, October 2014, p. 2 *http://www.fra.dot.gov/Elib/Document/14131.*

[79] Freight Railroads Background. (FR, 2015) Stephanie Lawrence, Office of Policy, Office of Rail Policy and Development, Federal Railroad Administration April 2015. *http://www.fra.dot.gov/eLib/Details/L03011.* These regional railroads are almost evenly divided between Class II (11 railroads) and Class III (10 railroads).

[80] Summary of Class II and Class III Railroad Capital Needs and Funding Sources, Federal Railroad Administration, Report to Congress, October 2014.*http://www.fra.dot.gov/Elib/Document/14131.*

[81] (16,895 affected workers/181,264 total employees in NAICS 4821) * 12,293 total Short-Line employees = 1,146 affected Short-Line employees.

average number of employees in entities within the SBA classification for the given NAICS. However, some compliance costs, such as some engineering control costs, were modified to reflect diseconomies of scale for very small establishments.

As shown in Table VII–19 and Table VII–20, the annualized cost of the final rule is estimated to be $2,967 for the average small entity in general industry and maritime and $1,532 for the average very small entity in general industry and maritime. These tables also show that the only industry in which the annualized costs of the final rule for small entities exceed one percent of annual revenues is NAICS 213112 (Support Activities for Oil and Gas Operations), which is estimated to be 1.29 percent. There are two industries for very small entities exceeding one percent of annual revenues—NAICS 213112 (Support Activities for Oil and Gas Operations), 2.09 percent and NAICS 327110 (Pottery, Ceramics, and Plumbing Fixture Manufacturing), 1.21 percent.

Small entities in nine industries in general industry and maritime are estimated to have annualized costs in excess of ten percent of annual profits; NAICS 327110: Pottery, Ceramics, and Plumbing Fixture Manufacturing (38.6 percent); NAICS 327120: Clay Building Material and Refractories Manufacturing (33.6 per cent); NAICS 327991: Cut Stone and Stone Product Manufacturing (24.7 percent); NAICS 327999: All Other Miscellaneous Nonmetallic Mineral Product Manufacturing (20.9 percent); NAICS 327390: Other Concrete Product Manufacturing (18.6 percent); NAICS 213112: Support Activities for Oil and Gas Operations (18.2 percent); NAICS 327332: Concrete Pipe Manufacturing (14.5 percent); NAICS 327331: Concrete Block and Brick Manufacturing (13.1 percent); and NAICS 327320: Ready-Mix Concrete Manufacturing (11.5 percent).

Very small entities in sixteen industries are estimated to have annualized costs in excess of ten percent of annual profit: NAICS 327110: Pottery, Ceramics, and Plumbing Fixture Manufacturing (90.6 percent); NAICS 327120 Clay Building Material and Refractories Manufacturing (58.5 percent); NAICS 327999: All Other Miscellaneous Nonmetallic Mineral Product Manufacturing (51.1 percent); NAICS 327991: Cut Stone and Stone Product Manufacturing (30.8 percent); NAICS 213112: Support Activities for Oil and Gas Operations (29.5 percent); NAICS 327390: Other Concrete Product Manufacturing (29.2 percent); NAICS 327212: Other Pressed and Blown Glass and Glassware Manufacturing (22.7 percent); NAICS 327332: Concrete Pipe Manufacturing (22.1 percent); NAICS 327211: Flat Glass Manufacturing (20.4 percent); NAICS 327331: Concrete Block and Brick Manufacturing (19.5 percent); NAICS 327993: Mineral Wool Manufacturing (17.4 percent); NAICS 327992: Ground or Treated Mineral and Earth Manufacturing (16.3 percent); NAICS 327320: Ready-mix Concrete Manufacturing (15.9 percent); NAICS 331513: Steel Foundries (except investment) (12.3 percent); NAICS 331524: Aluminum Foundries (except die-casting) (11.3 percent); and NAICS 331511: Iron Foundries (10.0 percent).

In general, cost impacts for affected small entities or very small entities will tend to be somewhat higher, on average, than the cost impacts for the average business in those affected industries. That is to be expected. After all, smaller businesses typically suffer from diseconomies of scale in many aspects of their business, leading to lower revenue per dollar of cost and higher unit costs. Small businesses are able to overcome these obstacles by providing specialized products and services, offering local service and better service, or otherwise creating a market niche for themselves. The higher cost impacts for smaller businesses estimated for this rule generally fall within the range observed in other OSHA regulations for which there is no record of major industry failures.

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Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
213112	Support Activities for Oil and Gas Operations	$24,247,594	150	$161,651	$12,562	7.09%	$890,424	1.29%	18.15%
324121	Asphalt Paving Mixture and Block Manufacturing	$257,611	422	$610	$13,668	5.96%	$814,552	0.00%	0.07%
324122	Asphalt Shingle and Coating Materials Manufacturing	$1,272,241	118	$10,782	$22,415	5.96%	$1,335,765	0.05%	0.81%
325510	Paint and Coating Manufacturing	$572,603	646	$887	$7,831	3.86%	$302,569	0.01%	0.29%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$5,059,640	620	$8,161	$1,581	1.34%	$21,157	0.52%	38.57%
327120	Clay Building Material and Refractories Manufacturing	$13,647,591	393	$34,727	$7,725	1.34%	$103,384	0.45%	33.59%
327211	Flat Glass Manufacturing	$129,486	39	$3,282	$7,263	2.63%	$190,646	0.05%	1.72%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$970,207	157	$6,171	$3,134	2.63%	$82,278	0.20%	7.50%
327213	Glass Container Manufacturing	$2,113,092	26	$81,273	$140,781	2.63%	$3,695,528	0.06%	2.20%
327320	Ready-Mix Concrete Manufacturing	$20,250,184	2,062	$9,821	$5,963	1.43%	$85,310	0.16%	11.51%
327331	Concrete Block and Brick Manufacturing	$4,550,565	486	$9,363	$4,991	1.43%	$71,399	0.19%	13.11%
327332	Concrete Pipe Manufacturing	$1,900,067	147	$12,926	$6,217	1.43%	$88,933	0.21%	14.53%

Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
327390	Other Concrete Product Manufacturing	$14,539,705	1,591	$9,139	$3,436	1.43%	$49,155	0.27%	18.59%
327991	Cut Stone and Stone Product Manufacturing	$13,106,845	1,785	$7,343	$1,696	1.75%	$29,730	0.43%	24.70%
327992	Ground or Treated Mineral and Earth Manufacturing	$2,075,935	123	$16,878	$10,030	1.75%	$175,783	0.17%	9.60%
327993	Mineral Wool Manufacturing	$990,251	113	$8,768	$8,687	1.75%	$152,242	0.10%	5.76%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$5,872,264	277	$21,200	$5,787	1.75%	$101,425	0.37%	20.90%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	$146,290	122	$1,194	$56,635	1.35%	$766,888	0.00%	0.16%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	$83,666	66	$1,262	$34,245	2.14%	$733,719	0.00%	0.17%
331221	Rolled Steel Shape Manufacturing	$42,989	36	$1,210	$34,746	2.14%	$744,455	0.00%	0.16%
331222	Steel Wire Drawing	$67,130	54	$1,254	$15,478	2.14%	$331,630	0.01%	0.38%
331314	Secondary Smelting and Alloying of Aluminum	$19,590	16	$1,249	$28,369	2.52%	$715,137	0.00%	0.17%
331420	Copper Rolling, Drawing, Extruding, and Alloying	$68,335	53	$1,280	$53,174	2.14%	$1,139,277	0.00%	0.11%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$37,734	31	$1,218	$46,028	2.14%	$986,159	0.00%	0.12%

Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
331511	Iron Foundries	$12,442,276	327	$38,050	$13,689	4.36%	$596,447	0.28%	6.38%
331512	Steel Investment Foundries	$2,672,675	100	$26,727	$13,221	4.36%	$576,068	0.20%	4.64%
331513	Steel Foundries (except Investment)	$5,503,027	175	$31,446	$10,361	4.36%	$451,441	0.30%	6.97%
331524	Aluminum Foundries (except Die-Casting)	$3,130,109	371	$8,437	$4,768	4.36%	$207,744	0.18%	4.06%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$1,693,459	278	$6,092	$5,236	4.36%	$228,132	0.12%	2.67%
332111	Iron and Steel Forging	$79,975	67	$1,199	$16,362	3.81%	$622,676	0.01%	0.19%
332112	Nonferrous Forging	$13,664	12	$1,186	$16,835	3.81%	$640,665	0.01%	0.19%
332117	Powder Metallurgy Part Manufacturing	$29,903	25	$1,174	$8,871	3.81%	$337,580	0.01%	0.35%
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$266,352	226	$1,179	$6,052	3.81%	$230,329	0.02%	0.51%
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	$27,196	23	$1,181	$6,259	4.12%	$257,752	0.02%	0.46%
332216	Saw Blade and Handtool Manufacturing	$120,315	100	$1,203	$3,769	4.12%	$155,218	0.03%	0.77%
332323	Ornamental and Architectural Metal Work Manufacturing	$35,067	32	$1,081	$2,053	2.70%	$55,457	0.05%	1.95%

Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
332439	Other Metal Container Manufacturing	$42,327	35	$1,221	$5,492	2.93%	$160,829	0.02%	0.76%
332510	Hardware Manufacturing	$91,570	78	$1,178	$6,321	4.63%	$292,894	0.02%	0.40%
332613	Spring Manufacturing	$63,105	51	$1,245	$6,356	4.63%	$294,524	0.02%	0.42%
332618	Other Fabricated Wire Product Manufacturing	$126,762	104	$1,213	$5,118	4.63%	$237,167	0.02%	0.51%
332710	Machine Shops	$1,463,233	1,275	$1,147	$1,815	4.63%	$84,115	0.06%	1.36%
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	$2,755,111	1,488	$1,851	$3,276	2.96%	$96,939	0.06%	1.91%
332911	Industrial Valve Manufacturing	$100,135	83	$1,213	$11,863	5.95%	$706,011	0.01%	0.17%
332912	Fluid Power Valve and Hose Fitting Manufacturing	$88,050	73	$1,211	$11,055	5.95%	$657,958	0.01%	0.18%
332913	Plumbing Fixture Fitting and Trim Manufacturing	$29,537	25	$1,198	$15,381	5.95%	$915,393	0.01%	0.13%
332919	Other Metal Valve and Pipe Fitting Manufacturing	$48,163	40	$1,193	$11,510	5.95%	$685,015	0.01%	0.17%
332991	Ball and Roller Bearing Manufacturing	$28,037	23	$1,237	$10,082	5.95%	$600,001	0.01%	0.21%
332996	Fabricated Pipe and Pipe Fitting Manufacturing	$116,327	99	$1,172	$6,952	5.95%	$413,773	0.02%	0.28%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$398,663	346	$1,153	$3,452	5.95%	$205,448	0.03%	0.56%

Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
333318	Other Commercial and Service Industry Machinery Manufacturing	$220,586	190	$1,162	$7,989	3.05%	$243,775	0.01%	0.48%
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$75,552	63	$1,202	$6,962	3.00%	$209,005	0.02%	0.58%
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	$76,185	65	$1,166	$7,664	3.00%	$230,099	0.02%	0.51%
333511	Industrial Mold Manufacturing	$196,365	169	$1,161	$3,300	3.82%	$126,016	0.04%	0.92%
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	$239,261	208	$1,150	$2,584	3.82%	$98,690	0.04%	1.17%
333515	Cutting Tool and Machine Tool Accessory Manufacturing	$148,284	127	$1,166	$2,711	3.82%	$103,519	0.04%	1.13%
333517	Machine Tool Manufacturing	$120,338	103	$1,169	$6,857	3.82%	$261,856	0.02%	0.45%
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	$52,800	45	$1,171	$5,856	3.82%	$223,651	0.02%	0.52%
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	$48,595	39	$1,235	$11,287	1.99%	$224,368	0.01%	0.55%

Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
333613	Mechanical Power Transmission Equipment Manufacturing	$43,878	37	$1,196	$9,584	1.99%	$190,516	0.01%	0.63%
333911	Pump and Pumping Equipment Manufacturing	$79,486	67	$1,195	$10,819	3.80%	$410,898	0.01%	0.29%
333912	Air and Gas Compressor Manufacturing	$61,295	51	$1,201	$14,580	3.80%	$553,744	0.01%	0.22%
333991	Power-Driven Handtool Manufacturing	$16,285	14	$1,160	$7,003	3.80%	$265,967	0.02%	0.44%
333992	Welding and Soldering Equipment Manufacturing	$48,996	42	$1,159	$6,852	3.80%	$260,251	0.02%	0.45%
333993	Packaging Machinery Manufacturing	$82,146	70	$1,170	$6,103	3.80%	$231,807	0.02%	0.50%
333994	Industrial Process Furnace and Oven Manufacturing	$52,056	44	$1,188	$6,101	3.80%	$231,716	0.02%	0.51%
333995	Fluid Power Cylinder and Actuator Manufacturing	$64,620	53	$1,210	$9,999	3.80%	$379,750	0.01%	0.32%
333996	Fluid Power Pump and Motor Manufacturing	$22,056	19	$1,158	$7,985	3.80%	$303,270	0.01%	0.38%
333997	Scale and Balance Manufacturing	$11,603	10	$1,184	$4,768	3.80%	$181,100	0.02%	0.65%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$197,602	171	$1,156	$4,790	3.80%	$181,927	0.02%	0.64%
334519	Other Measuring and Controlling Device Manufacturing	$115,924	100	$1,163	$5,613	4.51%	$252,930	0.02%	0.46%

Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
335210	Small Electrical Appliance Manufacturing	$17,998	17	$1,077	$17,135	4.01%	$687,713	0.01%	0.16%
335221	Household Cooking Appliance Manufacturing	$13,297	14	$968	$19,226	4.01%	$771,634	0.01%	0.13%
335222	Household Refrigerator and Home Freezer Manufacturing	$4,707	5	$1,005	$31,527	4.01%	$1,265,353	0.00%	0.08%
335224	Household Laundry Equipment Manufacturing	$157	0	$958	$4,818	4.01%	$193,379	0.02%	0.50%
335228	Other Major Household Appliance Manufacturing	$3,765	4	$986	$21,020	4.01%	$843,659	0.00%	0.12%
336111	Automobile Manufacturing	$20,482	20	$1,031	$13,043	-0.50%	-$65,710	0.01%	-1.57%
336112	Light Truck and Utility Vehicle Manufacturing	$7,727	8	$1,017	$17,387	-0.50%	-$87,598	0.01%	-1.16%
336120	Heavy Duty Truck Manufacturing	$36,819	32	$1,164	$47,396	-0.50%	-$238,787	0.00%	-0.49%
336211	Motor Vehicle Body Manufacturing	$164,332	136	$1,207	$10,198	1.30%	$132,333	0.01%	0.91%
336212	Truck Trailer Manufacturing	$97,653	80	$1,220	$9,886	1.30%	$128,290	0.01%	0.95%
336213	Motor Home Manufacturing	$10,810	9	$1,139	$9,051	1.30%	$117,450	0.01%	0.97%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$116,317	102	$1,144	$7,952	1.30%	$103,191	0.01%	1.11%
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$157,980	134	$1,179	$14,601	1.30%	$189,469	0.01%	0.62%

Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$58,720	51	$1,151	$21,278	1.30%	$276,115	0.01%	0.42%
336340	Motor Vehicle Brake System Manufacturing	$60,248	49	$1,241	$23,834	1.30%	$309,289	0.01%	0.40%
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$129,753	110	$1,178	$21,926	1.30%	$284,525	0.01%	0.41%
336370	Motor Vehicle Metal Stamping	$310,283	247	$1,254	$23,754	1.30%	$308,249	0.01%	0.41%
336390	Other Motor Vehicle Parts Manufacturing	$366,093	305	$1,199	$18,685	1.30%	$242,469	0.01%	0.49%
336611	Ship Building and Repairing	$2,404,761	309	$7,778	$9,902	6.06%	$600,482	0.08%	1.30%
336612	Boat Building	$1,969,321	301	$6,551	$6,023	6.06%	$365,244	0.11%	1.79%
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	$23,894	20	$1,186	$24,833	4.03%	$1,001,935	0.00%	0.12%
337110	Wood Kitchen Cabinet and Countertop Manufacturing	$155,433	173	$900	$1,002	2.77%	$27,765	0.09%	3.24%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$156,085	133	$1,177	$4,398	2.77%	$121,873	0.03%	0.97%
339114	Dental Equipment and Supplies Manufacturing	$4,331,589	697	$6,215	$4,359	7.32%	$319,165	0.14%	1.95%
339116	Dental Laboratories	$5,719,685	6,518	$878	$514	7.32%	$37,622	0.17%	2.33%

Table VII-19: Screening Analysis for Small Entities in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Small Entities	Annualized Cost per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
339910	Jewelry and Silverware Manufacturing	$2,065,825	2,091	$988	$1,971	3.92%	$77,339	0.05%	1.28%
339950	Sign Manufacturing	$354,823	326	$1,088	$1,644	3.92%	$64,505	0.07%	1.69%
423840	Industrial Supplies Merchant Wholesalers	$1,287,104	876	$1,469	$4,693	2.98%	$140,037	0.03%	1.05%
444110	Home Centers	$6,043	5	$1,219	$3,327	6.05%	$201,237	0.04%	0.61%
482110	Rail transportation [b]	$16,562,059	N/A	N/A	N/A	6.23%	N/A	N/A	N/A
561730	Landscaping Services	$18,249,100	25,500	$716	$440	2.96%	$13,032	0.16%	5.49%
621210	Offices of Dentists	$2,432,481	7,784	$312	$781	7.78%	$60,727	0.04%	0.51%
	Total	$186,093,853	62,730						

[a] Profit rates were calculated by OSHA, as the average of profit rates for 2000 through 2012, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2015).

[b] Costs shown apply to the entire NAICS industry. See Chapter VI, Economic Feasibility Analysis and Regulatory Flexibility Determination, in the FEA, for OSHA's regulatory flexibility analysis of NAICS 482110, Rail transportation.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entities	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
213112	Support Activities for Oil and Gas Operations	$11,907,226	100	$119,072	$5,703	7.09%	$404,248	2.09%	29.46%
324121	Asphalt Paving Mixture and Block Manufacturing	$57,921	248	$234	$5,359	5.96%	$319,386	0.00%	0.07%
324122	Asphalt Shingle and Coating Materials Manufacturing	$267,935	73	$3,670	$4,278	5.96%	$254,917	0.09%	1.44%
325510	Paint and Coating Manufacturing	$96,372	297	$325	$1,765	3.86%	$68,185	0.02%	0.48%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$2,389,156	526	$4,542	$374	1.34%	$5,011	1.21%	90.64%
327120	Clay Building Material and Refractories Manufacturing	$1,765,486	217	$8,136	$1,039	1.34%	$13,906	0.78%	58.51%
327211	Flat Glass Manufacturing	$11,319	3	$3,969	$740	2.63%	$19,420	0.54%	20.44%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$276,747	70	$3,951	$664	2.63%	$17,432	0.59%	22.66%
327213	Glass Container Manufacturing	$23,711	6	$3,927	$2,248	2.63%	$58,998	0.17%	6.66%
327320	Ready-Mix Concrete Manufacturing	$5,616,970	1,309	$4,291	$1,885	1.43%	$26,966	0.23%	15.91%
327331	Concrete Block and Brick Manufacturing	$1,383,138	320	$4,322	$1,548	1.43%	$22,139	0.28%	19.52%
327332	Concrete Pipe Manufacturing	$336,697	73	$4,612	$1,458	1.43%	$20,858	0.32%	22.11%

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
327390	Other Concrete Product Manufacturing	$4,568,859	1,168	$3,912	$935	1.43%	$13,376	0.42%	29.24%
327991	Cut Stone and Stone Product Manufacturing	$5,664,898	1,477	$3,835	$710	1.75%	$12,449	0.54%	30.81%
327992	Ground or Treated Mineral and Earth Manufacturing	$426,975	64	$6,671	$2,331	1.75%	$40,853	0.29%	16.33%
327993	Mineral Wool Manufacturing	$140,721	35	$3,966	$1,299	1.75%	$22,771	0.31%	17.42%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$2,430,981	199	$12,216	$1,365	1.75%	$23,930	0.89%	51.05%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	$0	0	N/A	$2,565	1.35%	$34,731	N/A	N/A
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	$0	0	N/A	$1,477	2.14%	$31,641	N/A	N/A
331221	Rolled Steel Shape Manufacturing	$0	0	N/A	$3,901	2.14%	$83,577	N/A	N/A
331222	Steel Wire Drawing	$0	0	N/A	$1,555	2.14%	$33,313	N/A	N/A
331314	Secondary Smelting and Alloying of Aluminum	$0	0	N/A	$3,655	2.52%	$92,146	N/A	N/A
331420	Copper Rolling, Drawing, Extruding, and Alloying	$0	0	N/A	$3,316	2.14%	$71,056	N/A	N/A

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$0	0	N/A	$4,590	2.14%	$98,343	N/A	N/A
331511	Iron Foundries	$967,507	153	$6,324	$1,447	4.36%	$63,060	0.44%	10.03%
331512	Steel Investment Foundries	$124,895	30	$4,163	$1,669	4.36%	$72,739	0.25%	5.72%
331513	Steel Foundries (except Investment)	$559,542	89	$6,287	$1,176	4.36%	$51,223	0.53%	12.27%
331524	Aluminum Foundries (except Die-Casting)	$842,096	223	$3,776	$767	4.36%	$33,434	0.49%	11.29%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$816,991	179	$4,564	$1,191	4.36%	$51,903	0.38%	8.79%
332111	Iron and Steel Forging	$0	0	N/A	$1,404	3.81%	$53,419	N/A	N/A
332112	Nonferrous Forging	$0	0	N/A	$1,309	3.81%	$49,831	N/A	N/A
332117	Powder Metallurgy Part Manufacturing	$0	0	N/A	$2,016	3.81%	$76,724	N/A	N/A
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$0	0	N/A	$1,346	3.81%	$51,241	N/A	N/A
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	$0	0	N/A	$774	4.12%	$31,865	N/A	N/A

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
332216	Saw Blade and Handtool Manufacturing	$0	0	N/A	$718	4.12%	$29,580	N/A	N/A
332323	Ornamental and Architectural Metal Work Manufacturing	$13,862	12	$1,158	$690	2.70%	$18,626	0.17%	6.22%
332439	Other Metal Container Manufacturing	$0	0	N/A	$1,110	2.93%	$32,507	N/A	N/A
332510	Hardware Manufacturing	$0	0	N/A	$1,084	4.63%	$50,228	N/A	N/A
332613	Spring Manufacturing	$0	0	N/A	$1,152	4.63%	$53,378	N/A	N/A
332618	Other Fabricated Wire Product Manufacturing	$0	0	N/A	$1,178	4.63%	$54,602	N/A	N/A
332710	Machine Shops	$0	0	N/A	$662	4.63%	$30,674	N/A	N/A
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	$949,586	825	$1,151	$707	2.96%	$20,909	0.16%	5.51%
332911	Industrial Valve Manufacturing	$0	0	N/A	$1,985	5.95%	$118,164	N/A	N/A
332912	Fluid Power Valve and Hose Fitting Manufacturing	$0	0	N/A	$1,446	5.95%	$86,038	N/A	N/A
332913	Plumbing Fixture Fitting and Trim Manufacturing	$0	0	N/A	$1,785	5.95%	$106,261	N/A	N/A
332919	Other Metal Valve and Pipe Fitting Manufacturing	$0	0	N/A	$2,294	5.95%	$136,557	N/A	N/A

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
332991	Ball and Roller Bearing Manufacturing	$0	0	N/A	$1,022	5.95%	$60,812	N/A	N/A
332996	Fabricated Pipe and Pipe Fitting Manufacturing	$0	0	N/A	$1,227	5.95%	$73,052	N/A	N/A
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$0	0	N/A	$817	5.95%	$48,638	N/A	N/A
333318	Other Commercial and Service Industry Machinery Manufacturing	$0	0	N/A	$1,377	3.05%	$42,030	N/A	N/A
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$0	0	N/A	$1,447	3.00%	$43,427	N/A	N/A
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	$0	0	N/A	$1,452	3.00%	$43,591	N/A	N/A
333511	Industrial Mold Manufacturing	$0	0	N/A	$938	3.82%	$35,810	N/A	N/A
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	$0	0	N/A	$772	3.82%	$29,477	N/A	N/A
333515	Cutting Tool and Machine Tool Accessory Manufacturing	$0	0	N/A	$747	3.82%	$28,513	N/A	N/A

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
333517	Machine Tool Manufacturing	$0	0	N/A	$1,353	3.82%	$51,656	N/A	N/A
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	$0	0	N/A	$1,306	3.82%	$49,863	N/A	N/A
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	$0	0	N/A	$1,462	1.99%	$29,062	N/A	N/A
333613	Mechanical Power Transmission Equipment Manufacturing	$0	0	N/A	$1,889	1.99%	$37,559	N/A	N/A
333911	Pump and Pumping Equipment Manufacturing	$0	0	N/A	$2,499	3.80%	$94,924	N/A	N/A
333912	Air and Gas Compressor Manufacturing	$0	0	N/A	$1,833	3.80%	$69,607	N/A	N/A
333991	Power-Driven Handtool Manufacturing	$0	0	N/A	$1,483	3.80%	$56,334	N/A	N/A
333992	Welding and Soldering Equipment Manufacturing	$0	0	N/A	$1,280	3.80%	$48,624	N/A	N/A
333993	Packaging Machinery Manufacturing	$0	0	N/A	$1,119	3.80%	$42,493	N/A	N/A
333994	Industrial Process Furnace and Oven Manufacturing	$0	0	N/A	$1,668	3.80%	$63,337	N/A	N/A
333995	Fluid Power Cylinder and Actuator Manufacturing	$0	0	N/A	$1,296	3.80%	$49,222	NA	NA

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
333996	Fluid Power Pump and Motor Manufacturing	$0	0	N/A	$1,774	3.80%	$67,384	NA	NA
333997	Scale and Balance Manufacturing	$0	0	N/A	$1,191	3.80%	$45,231	NA	NA
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$0	0	N/A	$1,331	3.80%	$50,541	NA	NA
334519	Other Measuring and Controlling Device Manufacturing	$0	0	N/A	$1,236	4.51%	$55,694	NA	NA
335210	Small Electrical Appliance Manufacturing	$1,302	1	$1,165	$1,797	4.01%	$72,115	0.06%	1.62%
335221	Household Cooking Appliance Manufacturing	$0	0	N/A	$1,093	4.01%	$43,865	N/A	N/A
335222	Household Refrigerator and Home Freezer Manufacturing	$0	0	N/A	$1,608	4.01%	$64,554	N/A	N/A
335224	Household Laundry Equipment Manufacturing	$0	0	N/A	$1,408	4.01%	$56,507	N/A	N/A
335228	Other Major Household Appliance Manufacturing	$0	0	N/A	$2,080	4.01%	$83,465	N/A	N/A
336111	Automobile Manufacturing	$0	0	N/A	$4,096	-0.50%	-$20,634	N/A	N/A
336112	Light Truck and Utility Vehicle Manufacturing	$0	0	N/A	$4,241	-0.50%	-$21,365	N/A	N/A

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
336120	Heavy Duty Truck Manufacturing	$0	0	N/A	$4,121	-0.50%	-$20,760	N/A	N/A
336211	Motor Vehicle Body Manufacturing	$0	0	N/A	$1,432	1.30%	$18,584	N/A	N/A
336212	Truck Trailer Manufacturing	$0	0	N/A	$1,193	1.30%	$15,478	N/A	N/A
336213	Motor Home Manufacturing	$0	0	N/A	$1,414	1.30%	$18,352	N/A	N/A
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$0	0	N/A	$901	1.30%	$11,693	N/A	N/A
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$0	0	N/A	$1,131	1.30%	$14,677	N/A	N/A
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$0	0	N/A	$2,015	1.30%	$26,152	N/A	N/A
336340	Motor Vehicle Brake System Manufacturing	$0	0	N/A	$1,092	1.30%	$14,166	N/A	N/A
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$0	0	N/A	$1,675	1.30%	$21,733	N/A	N/A
336370	Motor Vehicle Metal Stamping	$0	0	N/A	$2,049	1.30%	$26,584	N/A	N/A

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
336390	Other Motor Vehicle Parts Manufacturing	$0	0	N/A	$1,677	1.30%	$21,763	N/A	N/A
336611	Ship Building and Repairing	$110,154	62	$1,778	$1,382	6.06%	$83,779	0.13%	2.12%
336612	Boat Building	$156,109	88	$1,773	$1,215	6.06%	$73,653	0.15%	2.41%
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	$0	0	N/A	$2,376	4.03%	$95,875	NA	NA
337110	Wood Kitchen Cabinet and Countertop Manufacturing	$64,773	78	$828	$425	2.77%	$11,782	0.19%	7.03%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$0	0	N/A	$787	2.77%	$21,794	NA	NA
339114	Dental Equipment and Supplies Manufacturing	$1,716,366	588	$2,919	$674	7.32%	$49,335	0.43%	5.92%
339116	Dental Laboratories	$4,641,195	6,205	$748	$293	7.32%	$21,460	0.26%	3.49%
339910	Jewelry and Silverware Manufacturing	$993,578	1,862	$534	$626	3.92%	$24,561	0.09%	2.17%
339950	Sign Manufacturing	$140,698	116	$1,211	$497	3.92%	$19,492	0.24%	6.21%
423840	Industrial Supplies Merchant Wholesalers	$528,996	426	$1,241	$2,505	2.98%	$74,736	0.05%	1.66%
444110	Home Centers	$1,681	2	$935	$1,352	6.05%	$81,797	0.07%	1.14%
482110	Rail transportation [c]	N/A	N/A	N/A	N/A	6.23%	N/A	N/A	N/A

Table VII-20: Screening Analysis for Very Small Entities (fewer than 20 employees) in General Industry and Maritime Affected by OSHA's Final Silica Standard (continued)

NAICS	Industry	Total Annualized Costs	No. of Affected Entities with <20 Employees	Annualized Costs per Affected Entity	Revenues per Entity ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
561730	Landscaping Services	$15,602,766	20,258	$770	$320	2.96%	$9,472	0.24%	8.13%
621210	Offices of Dentists	$2,094,401	6,803	$308	$692	7.78%	$53,802	0.04%	0.57%
	Total	**$67,691,610**	**44,186**						

[a] Profit rates were calculated by OSHA, as the average of profit rates for 2000 through 2012, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2015).

[b] N/A = Not applicable.

[c] Costs shown apply to the entire NAICS industry. See Chapter VI, Economic Feasibility Analysis and Regulatory Flexibility Determination, in the FEA, for OSHA's regulatory flexibility analysis of NAICS 482110, Rail transportation.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

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In allocating the share of costs to very small entities, OSHA did not have direct information about how many very small entities were engaged in silica-related activities. Instead, OSHA assumed that the affected employees would be distributed among entities of different size according to each entity size class's share of total employment. In other words, if 15 percent of employees in an industry worked in very small entities (those with fewer than 20 employees), then OSHA assumed that 15 percent of affected employees in the industry

would work in very small entities. However, in reality, OSHA anticipates that in industries with foundries, none of the entities with fewer than 20 employees have foundries or, if they do, that the impacts are much smaller than estimated here.

SBREFA Comments on Impacts on General Industry and Maritime

In this section, OSHA reviews comments addressing economic impacts in general industry and maritime that were submitted during the SBREFA process prior to the PEA. OSHA addressed these comments in the PEA that was made available for public comment, but OSHA did not receive comments specifically addressing its responses to the SBREFA recommendations. OSHA is reprinting its responses here for the convenience of the reader.

SERs from foundries stated that there had been a long-run decline in the number of foundries in the United States, with the industry under continued pressure from foreign competitors and the need to meet new domestic regulations. The total expense of the draft standard and inability to meet lower PELs would pressure more U.S. foundries out of business, continuing an historical trend in this industry, SERs said. The variability in the foundry products and small open-area production plants would make meeting lower PELs difficult and costly. Many smaller foundries would be put out of business, the SERs said, and many jobs lost in the industry. ''Twenty percent of profits is a great deal to spend on engineering controls with questionable results . . . . [t]he economics of the foundry industry today are not pretty,'' one SER said. And another: ''The cost of meeting the standard will be very difficult . . . . A PEL of 50 would put us out of business.'' OSHA found in this FEA that costs as percentage of profits for even very small foundries would not rise to a level of 20 percent.

SERs from the brick industry stated that meeting the provisions of the draft proposed standard, particularly with a lower PEL, would be very tough for their competitive, low margin industry. Similarly, a SER from the pre-cast concrete industry said, ''The problem is not putting the company out of business, but that the price of products will increase.'' OSHA found that because bricks face limited foreign competition, a very small change in the price of bricks would not affect the viability of the industry.

Other SERs (industrial sand, molding powders, refractory concrete) noted that the impact of the standard on them, particularly if the PEL is lowered, would entail substantial costs, but indirect effects could be significant as well since their major customers (foundries) could be negatively impacted, too. ''Refractory companies are going out of business with the foundries,'' one SER said. OSHA has concluded that foundries will not, in general go out of business.

e. Regulatory Flexibility Screening Analysis

To determine if the Assistant Secretary of Labor for OSHA can certify that the final silica standard for general industry and maritime will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the final standard on small entities. The minimum threshold effects for this purpose are annualized costs equal to one percent of annual revenues and annualized costs equal to five percent of annual profits applied to each affected industry. (OSHA uses five percent as a threshold for significant impacts on small entities rather than the ten percent used for potentially serious impacts on industries in order to assure that small entity impacts will always receive special attention.) OSHA has applied these screening tests both to small entities and to very small entities. For purposes of certification, the threshold level cannot be exceeded for affected small entities or very small entities in any affected industry. Table VII–19 and Table VII–20 show that, in general industry and maritime, the annualized costs of the final rule exceed one percent of annual revenues for small entities and very small entities in one industry. These tables also show that the annualized costs of the final rule exceed five percent of annual profits for small entities in 15 industries and for very small entities in 25 industries. OSHA is therefore unable to certify that the final rule will not have a significant economic impact on a substantial number of small entities in general industry and maritime and must prepare a Final Regulatory Flexibility Analysis (FRFA). The FRFA is presented in Section VII.I of this preamble.

3. Impacts in Construction

a. Economic Feasibility Screening Analysis: All Establishments

To determine whether the final rule's estimated costs of compliance would threaten the economic viability of affected construction industries, OSHA used the same data sources and methodological approach that were used earlier in this section for general industry and maritime. OSHA first compared, for each affected construction industry, annualized compliance costs to annual revenues and profits per (average) affected establishment. The results for all affected establishments in all affected construction industries are presented in Table VII–21, using annualized costs per establishment for the final PEL of 50 μg/m^3.

The annualized cost of the rule for the average establishment in construction, encompassing all construction industries, is estimated at $1,097 in 2012 dollars. The estimates of the annualized costs per affected establishment range from $4,811 for NAICS 237300 (Highway, Street, and Bridge Construction) and $4,463 for NAICS 237100 (Utility System Construction) to $364 for NAICS 236100 (Residential Building Construction) and $360 for NAICS 221100 (Electric Utilities).

Table VII–21 shows that the annualized costs of the rule do not exceed one percent of annual revenues or 10 percent of annual profits for any affected construction industry. NAICS 238100 (Foundation, Structure, and Building Exterior Contractors) has both the highest cost impact as a percentage of revenues, of 0.12 percent, and the highest cost impact as a percentage of profits, of 3.66 percent. For all affected establishments in construction, the estimated annualized cost of the final rule is, on average, equal to 0.05 percent of annual revenue and 1.52 percent of annual profit. These are well below the minimum threshold levels of 1 percent and 10 percent, respectively.

Therefore, even though the annualized costs of the final rule incurred by the construction industry as a whole are roughly twice the combined annualized costs incurred by general industry and maritime, OSHA concludes, based on its screening analysis, that the annualized costs as a percentage of annual revenues and as a percentage of annual profits are below the threshold level that could threaten the economic viability of any of the construction industries. OSHA therefore finds that the final rule is economically feasible for each of the industries engaged in construction activities. OSHA further notes that while there would be additional costs (not attributable to the final rule) for some employers in construction industries to come into compliance with the preceding silica standard, these costs would not affect the Agency's

determination of the economic feasibility of the final rule.

Below, OSHA provides additional information to further support the Agency's conclusion that the final rule would not threaten the economic viability of any construction industry.

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Table VII-21: Screening Analysis for Establishments in Construction Affected by OSHA's Final Silica Standard

NAICS	Industry	Total Annualized Costs	Affected Establish-ments	Annualized Costs per Affected Establish-	Revenues per Establish-ment ($1,000)	Profit Rate [a]	Profits per Establish-ment	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
221100	Electric Utilities	$3,203,249	4,662	$360	$41,073	0.67%	$275,190	0.00%	0.13%
236100	Residential Building Construction	$54,944,997	151,034	$364	$1,260	2.23%	$28,104	0.03%	1.29%
236200	Nonresidential Building Construction	$52,733,126	41,018	$1,286	$6,843	2.23%	$152,604	0.02%	0.84%
237100	Utility System Construction	$83,397,297	18,686	$4,463	$6,328	3.10%	$196,183	0.07%	2.27%
237200	Land Subdivision	$1,960,835	2,150	$912	$6,479	-1.30%	-$84,222	0.01%	-1.08%
237300	Highway, Street, and Bridge Construction	$48,314,733	10,043	$4,811	$10,023	2.89%	$289,655	0.05%	1.66%
237900	Other Heavy and Civil Engineering Construction	$13,342,117	4,222	$3,160	$5,732	2.89%	$165,660	0.06%	1.91%
238100	Foundation, Structure, and Building Exterior Contractors	$139,227,106	85,801	$1,623	$1,300	3.41%	$44,343	0.12%	3.66%
238200	Building Equipment Contractors	$60,058,912	142,536	$421	$1,788	3.66%	$65,452	0.02%	0.64%
238300	Building Finishing Contractors	$55,340,177	77,330	$716	$858	3.41%	$29,268	0.08%	2.45%
238900	Other Specialty Trade Contractors	$101,830,889	63,214	$1,611	$1,617	3.41%	$55,146	0.10%	2.92%
999200	State governments	$8,620,645	0	N/A	N/A	N/A	N/A	N/A	N/A
999300	Local governments	$35,997,165	0	N/A	N/A	N/A	N/A	N/A	N/A
	Total	**$658,971,248**	**600,695**						

[a] Profit rates were calculated by OSHA, as the average of profit rates for 2000 through 2012, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2015).

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

b. Normal Year-to-Year Variations in Profit Rates

As previously noted, the United States has a dynamic and constantly changing economy in which large year-to-year changes in industry profit rates are commonplace. A recession, a downturn in a particular industry, foreign competition, or the increased competitiveness of producers of close domestic substitutes are all easily capable of causing a decline in profit rates in an industry of well in excess of 10 percent in one year or for several years in succession.

To demonstrate the normal year-to-year variation in profit rates for all the establishments in construction affected by the final rule, OSHA presented data in the FEA on year-to-year profit rates and year-to-year percentage changes in profit rates, by industry, for the years 2000–2012. For the combined affected industries in construction over the 13-year period, the average change in profit rates was 63.09 percent a year. If the three worst years are excluded, there is still substantial variation in profits, far larger than the change in profits that would be necessary if the costs of this rule cannot be passed on.

These data indicate that even if the annualized costs of the final rule for the most significantly affected construction industries were completely absorbed in reduced annual profits, the magnitude of reduced annual profit rates is well within normal year-to-year variations in profit rates in those industries and does not threaten their economic viability. Of course, a permanent loss of profits would present a greater problem than a temporary loss, but it is unlikely that all costs of the final rule would be absorbed in lost profits. Given that, as discussed in Chapter VI of the FEA, the overall price elasticity of demand for the outputs of the construction industry is fairly low and that almost all of the costs estimated in Chapter V of the FEA are variable costs, the data and economic theory suggest that most firms will see small declines in output rather than that any but the most extremely marginal firms would face any real risk of closure. Many parts of the construction industry have already absorbed much more drastic changes in profit without evidence of industry collapse or major change.

Market Structure and Market Impacts in the Construction Industry

At a conceptual level, the market-determined output of the construction industry depends on the intersection of demand and supply curves. Incremental compliance costs of the rule (which are almost entirely variable costs) shift the construction supply curve upward. The net effect is an increase in the price for construction activities and a reduction in the level of activity (with the magnitude of this effect depending on the price elasticity of demand). Lower levels of activity mean less construction work, a reduction in the number of construction establishments, and a concomitant reduction in construction employment. The greater the price elasticity of demand and the greater the increase in marginal costs, the larger will be the reduction in equilibrium output. In terms of prices, the greater the price elasticity of demand, the smaller the increase in prices will be for a given increment to marginal costs, and the larger the reduction in output.

Increasing the cost of construction project activities that generate silica exposures has two effects on the demand for these activities. First, increasing the cost of silica-related jobs relative to the costs of other construction inputs might result in substitution away from this type of work. Architects, building designers, and contractors might be more likely to choose building methods and materials that eliminate or reduce the need to perform silica-related jobs. For example, pre-cast concrete structures that require a relatively high level of concrete finishing work would become more expensive relative to other building technologies. Contractors and others could reduce the cost impact of the standard by switching to other building methods unaffected by the silica rule when the alternative would result in lower cost than would compliance with the rule. The magnitude of these impacts will depend on the feasibility, characteristics, and relative expense of alternative technologies.

Second, some of the increase in the cost of silica-generating activities will increase the marginal cost of construction output and cause the construction supply curve to shift upward, resulting in a higher price for each quantity produced. The magnitude of the impact of the cost increases due to the silica rule on the supply relationship will depend on the size of the cost increases and the importance of silica-generating activities in the overall cost of construction projects. If the silica-generating activities are a small portion of the overall cost of construction then the supply curve shift will be smaller when compared to a shift in the supply curve from silica-generating activity that is a large portion of the overall cost of construction. If, for example, there is a one percent increase in the costs of a silica generating activity and the silica generating activity constitutes only one percent of the costs of a building, then the total increase in the cost of the building will be an almost unobservable 0.01 percent. Magnitude of shifts in derived demand for a service used in making another product are determined by the price change for the final product, not the price change for the service itself.

In practice, if one considers the costs of the final rule relative to the size of construction activity in the United States, it is clear that the price and profit impacts of the final rule on construction industries must be quite limited. The annualized cost of the final rule would be equal to approximately 0.1 percent of the value of annual construction activity in the U.S. Moreover, construction activity in the U.S. is not subject to any disadvantage from foreign competition—any foreign firms performing construction activities in the United States would be subject to OSHA regulations.

c. Impacts by Type of Construction Demand

The demand for construction services originates in three independent sub-sectors: residential building construction, nonresidential building construction, and nonbuilding construction.

Residential Building Construction: Residential building demand is derived from the household demand for housing services. These services are provided by the stock of single and multi-unit residential housing units. Residential housing construction represents changes to the housing stock and includes construction of new units and modifications, renovations, and repairs to existing units. A number of studies have examined the price sensitivity of the demand for housing services. Depending on the data source and estimation methodologies, these studies have estimated the demand for housing services at price elasticity values ranging from -0.40 to -1.0, with the smaller (in absolute value) less elastic values estimated for short-run periods (Glennon, 1989, Document ID 0707; Mayo, 1981, Document ID 0794). In the long run, it is reasonable to expect the demand for the stock of housing to reflect similar levels of price sensitivity.

Many of the silica-generating construction activities affected by the rule are not widely used in single-family construction or renovation. This assessment is consistent with the cost estimates that show relatively low impacts for residential building contractors. (*See* Table VI–9 of the FEA—the costs as a percent of revenues

for Residential Building Construction are estimated to be 0.03 percent and the costs as a percent of profits are estimated to be 1.29 percent). Multi-family residential construction might have more substantial impacts, but, based on Census data, this type of construction represents a relatively small share of net investment in residential buildings.

Nonresidential Building Construction: Nonresidential building construction consists of industrial, commercial, and other nonresidential structures. As such, construction demand is derived from the demand for the output of the industries that use the buildings. For example, the demand for commercial office space is derived from the demand for the output produced by the users of the office space. The price elasticity of demand for this construction category will depend, among other things, on the price elasticity of demand for the final products produced, the importance of the costs of construction in the total cost of the final product, and the elasticity of substitution of other inputs that could substitute for nonresidential building construction. ERG (2007c) found no studies that attempted to quantify these relationships (Document ID 1710). But given the costs of the final rule relative to the size of construction spending in the United States, the resultant price or revenue effects are likely to be quite small as well.

Nonbuilding Construction: Nonbuilding construction includes roads, bridges, and other infrastructure projects. Utility construction (power lines, sewers, water mains, etc.) and a variety of other construction types are also included. A large share of this construction (63.8 percent) is publicly financed (ERG, 2007a, Document ID 1709). For this reason, a large percentage of the decisions regarding the appropriate level of such investments is not made in a private market setting. The relationship between the costs and price of such investments and the level of demand might depend more on political considerations than the factors that determine the demand for privately produced goods and services.

While a number of studies have examined the factors that determine the demand for publicly financed construction projects, these studies have focused on the ability to finance such projects (*e.g.,* tax receipts) and socio-demographic factors (*e.g.,* population growth) to the exclusion of cost or price factors. In the absence of budgetary constraints, the price elasticity of demand for public investment is therefore probably quite low. On the other hand, budget-imposed limits might constrain public construction spending. If the dollar value of public investments were fixed, a price elasticity of demand of 1 would be implied and any percentage increase in construction costs would be offset with an equal percentage reduction in investment (measured in physical units), keeping public construction expenditures constant.

Public utility construction comprises the remainder of nonbuilding construction. This type of construction is subject to the same derived-demand considerations discussed for nonresidential building construction, and for the same reasons, OSHA expects the price and profit impacts to be quite small.

SBREFA Comments on Impacts on the Construction Industry

In this section OSHA reviews comments addressing economic impacts in construction that were submitted during the SBREFA process prior to the PEA. OSHA addressed these comments in the PEA that was made available for public comment, but did not receive comments specifically addressing its responses to the SBREFA recommendations. OSHA is reprinting its responses here for the convenience of the reader.

One commenter believed that OSHA had ignored the range of profitability among businesses, and thus did not adequately recognize that the average percentage reduction in profits could mean bankruptcy for those firms struggling to stay afloat. The Agency's approach to economic feasibility is designed to address the overall health of industries in compliance with legal precedent, which permits OSHA to find a regulation economically feasible even though it may close some marginal firm. In most years, ten percent or more of construction firms exit the industry (See U.S. Census Bureau Business Dynamics Statistics, available at *http://www.census.gov/ces/dataproducts/bds/data_firm.html*). The slight acceleration of the closure of such firms is not the kind of economic impact that would make a regulation economically infeasible.

The commenter also asserted that OSHA ignored the cost of credit and that this also varies across businesses. OSHA believes that the cost of credit is not an important issue in this case because OSHA's analysis demonstrates that, in most cases, upfront costs can usually be met from cash flow. Earlier in this chapter, OSHA noted that its choice of a threshold level of ten percent of annual profits for economic feasibility determinations is low enough that even if, in a hypothetical worst case, all compliance costs were upfront costs, then upfront costs would still equal 88.5 percent of profits and thus would be affordable from profits alone without needing to resort to credit markets. As shown in Table VI–12 of the FEA, all industries' costs are a very small percentage of profits, assuring that even upfront costs can be met from profits without resorting to credit markets. Further, a firm that is having trouble meeting upfront costs can rent the appropriate tools without incurring any upfront capital investment costs.

A SER asserted that the impact of the rule would be ''catastrophic'' for the concrete cutting industry. One SER maintained that the rule would be both economically and technologically infeasible for the specialty trade concrete cutting industry (Document ID 0937, p. 69). The Small Business Advocacy Review (SBAR) Panel recommended that OSHA thoroughly review the economic impacts, and develop a more detailed economic feasibility analysis for certain industries (Document ID 0937, p. 69). OSHA believes that the analyses in this chapter and in Chapter IX of the FEA address the SER's comments and the SBAR Panel recommendations.

Concrete cutting is undertaken for such purposes as grooving for projects such as highways, bridges, and sidewalks along with repairing these structures when they become operationally unsound. These contracts are bid on by firms who will all fall under the final silica rule, so there is no economic disadvantage between firms caused by the silica rule. Because the silica rule only applies in areas subject to OSHA jurisdiction, there is no foreign competition that would not also be subject to the silica standard. The cutting industry also works on runways and parking lots along with homebuilders for smaller projects. The demand for these products are relatively inelastic and not subject to foreign competition, enabling these companies to pass most of the costs of this final rule onto their consumers. Based on these analyses, OSHA disagrees that the rule would be ''catastrophic'' or economically infeasible for the concrete cutting industry.

d. Economic Feasibility Screening Analysis: Small and Very Small Businesses

The preceding discussion focused on the economic viability of the affected construction industries in their entirety. However, even though OSHA found that the silica standard did not threaten the

survival of these construction industries, there is still the possibility that the industries' competitive structures could be significantly altered.

To address this possibility, OSHA examined the annualized costs per affected small and very small entity for each affected construction industry. Table VII–22 and Table VII–23 show that in no construction industries do the annualized costs of the final rule exceed one percent of annual revenues or 10 percent of annual profits either for small entities or for very small entities. Therefore, OSHA concludes, based on its screening analysis, that the annualized costs as a percentage of annual revenues and as a percentage of annual profits are below the threshold level that could threaten the competitive structure of any of the construction industries.

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Table VII-22: Screening Analysis for Small Entities in Construction Affected by OSHA's Final Silica Standard

NAICS	Industry	Total Annualized Costs	Affected Small Entities	Annualized Costs per Affected Entities	Revenues per Entities ($1,000)	Profit Rate [a]	Profits per Entity	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
221100	Electric Utilities	$285,915	624	$458	$27,367	0.67%	$183,358	0.00%	0.25%
236100	Residential Building Construction	$49,798,948	149,765	$333	$935	2.23%	$20,849	0.04%	1.59%
236200	Nonresidential Building Construction	$34,357,970	39,073	$879	$4,030	2.23%	$89,871	0.02%	0.98%
237100	Utility System Construction	$30,262,348	16,757	$1,806	$2,391	3.10%	$74,126	0.08%	2.44%
237200	Land Subdivision	$966,584	2,106	$459	$2,136	-1.30%	-$27,771	0.02%	-1.65%
237300	Highway, Street, and Bridge Construction	$21,399,925	8,737	$2,449	$4,417	2.89%	$127,660	0.06%	1.92%
237900	Other Heavy and Civil Engineering Construction	$5,415,610	3,960	$1,368	$2,104	2.89%	$60,802	0.06%	2.25%
238100	Foundation, Structure, and Building Exterior Contractors	$110,212,308	84,369	$1,306	$1,026	3.41%	$34,974	0.13%	3.74%
238200	Building Equipment Contractors	$41,087,873	139,065	$295	$1,126	3.66%	$41,222	0.03%	0.72%
238300	Building Finishing Contractors	$44,499,467	76,597	$581	$695	3.41%	$23,685	0.08%	2.45%
238900	Other Specialty Trade Contractors	$76,873,828	61,966	$1,241	$1,216	3.41%	$41,474	0.10%	2.99%
999200	State governments	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
999300	Local governments	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Total	**$415,160,777**	**583,018**						

[a] Profit rates were calculated by OSHA, as the average of profit rates for 2000 through 2012, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2015).

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

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Table VII-23: Screening Analysis for Very Small Entities (fewer than 20 employees) in Construction Affected by OSHA's Final Silica Standard

NAICS	Industry	Total Annualized Costs	Affected Entities with <20 Employees	Annualized Costs per Affected Entities	Revenues per Entities	Profit Rate [a]	Profits per Entities	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
221100	Electric Utilities	$22,113	49	$451	$5,314,217	0.67%	$43,054	0.01%	1.05%
236100	Residential Building Construction	$41,292,996	146,304	$282	$100,203,852	2.23%	$15,216	0.04%	1.85%
236200	Nonresidential Building Construction	$18,792,402	34,409	$546	$69,489,248	2.23%	$45,015	0.03%	1.21%
237100	Utility System Construction	$13,802,596	14,297	$965	$16,198,831	3.10%	$35,104	0.09%	2.75%
237200	Land Subdivision	$632,988	1,631	$388	$6,154,243	-1.30%	-$14,246	0.04%	-2.72%
237300	Highway, Street, and Bridge Construction	$7,480,629	6,891	$1,086	$12,773,940	2.89%	$53,526	0.06%	2.03%
237900	Other Heavy and Civil Engineering Construction	$2,813,457	3,541	$795	$3,812,866	2.89%	$31,119	0.07%	2.55%
238100	Foundation, Structure, and Building Exterior Contractors	$64,727,230	78,217	$828	$48,524,264	3.41%	$21,148	0.13%	3.91%
238200	Building Equipment Contractors	$27,233,382	121,895	$223	$94,507,036	3.66%	$22,897	0.04%	0.98%
238300	Building Finishing Contractors	$31,391,077	70,079	$448	$43,353,995	3.41%	$15,369	0.10%	2.91%
238900	Other Specialty Trade Contractors	$47,721,089	57,826	$825	$42,192,221	3.41%	$24,871	0.11%	3.32%
999200	State governments	N/A	49	N/A	N/A	N/A	N/A	N/A	N/A
999300	Local governments	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Total	**$255,909,961**	**535,188**						

[a] Profit rates were calculated by OSHA, as the average of profit rates for 2000 through 2012, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2015).

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

e. Differential Impacts on Small Entities and Very Small Entities

Below, OSHA provides some additional information about differential compliance costs for small and very small entities that might influence the magnitude of differential impacts for these smaller businesses.

The distribution of impacts by size of business is affected by the characteristics of the compliance measures. For silica controls in construction, the dust control measures consist primarily of equipment modifications and additions made to individual tools, rather than large, discrete investments, such as might be applied in a manufacturing setting. As a result, compliance advantages for large firms through economies of scale are limited. It is possible that some large construction firms might derive purchasing power by buying dust control measures in bulk. However, given the simplicity of many control measures, such as the use of wet methods on machines already manufactured to accommodate controls, such differential purchasing power appears to be of limited consequence.

The greater capital resources of large firms will give them some advantage in making the relatively large investments needed for some control measures. For example, cab enclosures on heavy construction equipment or foam-based dust control systems on rock crushers might be particularly expensive for some small entities with an unusual number of heavy equipment pieces. Nevertheless, where differential investment capabilities exist, small construction firms may also have the capability to achieve compliance with lower-cost measures, such as by modifying work practices. In the case of rock crushing, for example, simple water spray systems can be arranged without large-scale investments in the best commercially available systems.

In the program area, large firms might have a slight advantage in the delivery of training or in arranging for health screenings. This phenomenon has been accounted for in the analysis that OSHA provides.

f. Regulatory Flexibility Screening Analysis

To determine if the Assistant Secretary of Labor for OSHA can certify that the final silica standard for construction will not have a significant economic impact on a substantial number of small entities, OSHA applies the same screening analysis to construction as it does for general industry, as discussed earlier in that section for the same reasons: annualized costs equal to one percent of annual revenues and annualized costs equal to five percent of annual profits applied to each affected industry. OSHA has applied these screening tests both to small entities and to very small entities. For purposes of certification, the threshold levels cannot be exceeded for affected small or very small entities in any affected industry.

Table VII–22 and Table VII–23 show that in no construction industries do the annualized costs of the final rule exceed one percent of annual revenues or five percent of annual profits either for small entities or for very small entities. However, as previously noted in this section, OSHA is unable to certify that the final rule will not have a significant economic impact on a substantial number of small entities in general industry and maritime and must prepare a Final Regulatory Flexibility Analysis (FRFA). The FRFA is presented in Section VII.I of this preamble.

4. Employment Impacts on the U.S. Economy

The discussion below on employment impacts of the silica rule on the U.S. economy is divided into three parts: (1) a brief summary of the employment impacts of the proposed silica rule (based on an analysis performed for OSHA by its subcontractor, Inforum, in 2011, Document ID 1701) that the Agency included in the PEA in support of the silica proposal; (2) a review of estimates provided by commenters on the employment effects of the silica proposal; and (3) a summary of a recent analysis of the employment effects of the final silica rule that Inforum performed for OSHA, followed by a critique of the commenters' analysis of employment effects relative to Inforum's analysis.

a. Inforum Analysis of Employment Effects Prepared for Silica Proposal

In October 2011, OSHA directed Inforum [82] to run its macroeconomic model to estimate the employment impacts of the costs [83] of the proposed silica rule. Inforum ran the model for the ten-year period 2014–2023 and reported its annual and cumulative employment and other macroeconomic results. While employment effects varied from year to year and from industry to industry, a key Inforum result was that the proposed silica rule cumulatively would generate an additional 8,625 job-years over the period 2014—2023, or an additional 862.5 job-years annually, on average, over the period.[84] A fuller discussion of Inforum's macroeconomic model and the results of its analysis can be found in Chapter VI of the PEA in support of OSHA's silica proposal and in the Inforum report itself (Inforum, 2011, Document ID 1701).

b. Estimates by Commenters on Employment Effects of the Silica Proposal

Three commenters on the silica proposal—the National Federation of Independent Business (NFIB) with the NFIB Research Foundation; the American Chemistry Council (ACC) with Stuart Sessions of Environomics, Inc.; and the Construction Industry Safety Coalition (CISC) with Environomics, Inc.—provided or reported estimates of the employment effects of the proposed silica rule. These commenter estimates are summarized below.

The NFIB Research Foundation performed a study (Document ID 2210, Attachment 2) to estimate the employment and other macroeconomic effects of OSHA's proposed rule, using the Agency's own estimates of the annualized compliance costs of the proposed rule for affected employers of approximately $637 million in 2009 dollars. The study modeled (a) anticipated employer costs due to the proposed rule, (b) changes to private sector demand, and (c) changes to state and local government spending associated with the proposed rule, and then forecast their effects using NFIB's Business Size Impact Module (BSIM) to run a simulation. The BSIM is a dynamic, multi-region model based on the Regional Economic Models, Inc. (REMI) structural economic forecasting and policy analysis model, which integrates input-output, computable general equilibrium, econometric, and economic geography methodologies. Costs were estimated by five size classes of firms. It was noted that the annualized compliance costs of the proposed rule:

. . . also represent new demand for private sector goods and services for firms who assist businesses affected by the new PEL in

[82] Inforum, which stands for the INterindustry FORecasting at the University of Maryland, is a not-for-profit Maryland corporation. Inforum has over 45 years of experience designing and using macroeconomic models of the United States (and other countries). Details of Inforum's macroeconomic model are presented later in this section.

[83] The estimated cost at the time was approximately $650 million in 2009 dollars using a 3 percent discount rate.

[84] A ''job-year'' is the term of art used to reflect the fact that an additional person is employed for a year, not that a new job has necessarily been permanently created.

complying with the proposed rule. In the BSIM, this new demand for goods and services provided by the private sector acts as a countervailing force to any negative impact on employers the new annualized compliance costs may have (Document ID 2210, Attachment 2, p. 8).

The summary findings of the NFIB Research Foundation study included an overall loss of 27,000 jobs and lost output of over $72 billion in the long run, with at least half the loss expected to occur in the small business sector.

The American Chemistry Council (ACC) (Document ID 4209–A1) reported on Mr. Sessions's post-hearing brief (Document ID 4231), which provided estimates of the economic and employment impacts of the general industry costs to comply with the proposed silica rule and, in addition, criticized Inforum's estimates of the employment effects of the proposed silica rule (Inforum, 2011, Document ID 1701).

Mr. Sessions estimated economic impacts based on the URS Corporation estimates of $6.131 billion as the cost of the proposed silica rule on 19 general industry sectors (Document ID 4209–1, pp. 102–103). (Note that the analysis does not include the construction sector and is more than 50 times higher than OSHA's general industry cost estimate in the proposal). The economic impacts were estimated in two analytical steps: (1) estimate the impact of the proposed regulation's compliance costs on the value of output of the affected industries; and (2) estimate how the expected changes in output will reverberate throughout the economy, using IMPLAN—a well-known input-output model of the U.S. economy.

The first step was achieved by estimating the amount of cost pass-through of the compliance costs, using a supply elasticity of 1.0, and then estimating the demand response to this price increase assuming a demand elasticity of -1.5. This results in a decline in industry revenue equal to about 20 percent of annualized compliance costs, which—given URS's estimates of compliance costs—is equal to $1.23 billion per year. Again using the IMPLAN model, the corresponding estimated employment effect is 18,000 lost jobs annually (5,400 direct effect; 5,000 indirect effect; and 7,500 induced effect) and a loss in economic output/GDP of more than $1.6 billion per year.

Additionally, Mr. Sessions reviewed Inforum's analysis of the employment impacts of the proposed rule. He asserted that OSHA had supplied Inforum with year-by-year compliance costs that were only 53 percent of the annualized costs that OSHA had estimated in the PEA so that Inforum's projections of employment effects would be seriously underestimated:

> OSHA estimates the cost of the Proposed Standard to be $658 million per year in 2009 dollars on an annualized basis, excluding the hydraulic fracturing industry. Assuming a 7%/year discount rate, this annual cost, *continuing forever* as OSHA estimates it will, is equivalent to a present value cost of $9.4 billion dollars in the initial year of compliance. For comparison with this figure, I calculate (also assuming a 7% discount rate) that the present value in the first year for the ten-year schedule of compliance costs shown in Inforum's Table 1 is only $5.0 billion [italics added] (Document ID 4231).

In reviewing the above procedures, OSHA concludes that Mr. Sessions has misinterpreted his own calculations. The annualized value of an infinite series of costs (*i.e.,* continuing forever) discounted at 7 percent is equal to 0.07 (the annualization factor) x the present value (PV). Hence, the annualized cost of Mr. Session's present value of $9.4 billion should equal $658 million. Now, OSHA provided a stream of costs for 10 years, not forever. The annualization factor for annualized costs incurred over ten years using a 7 percent discount rate is equal to 0.1424. Therefore, the PV of OSHA's costs given to Inforum should be $658 million/0.1424, or about $4.6 billion. Mr. Sessions only confused issues by using first-year costs (which is irrelevant to his exercise) rather than annualized costs. So, there is nothing in Mr. Sessions's calculations that would suggest that OSHA had provided Inforum with seriously incomplete costs. However, just to make sure, OSHA and ERG also reviewed the year-by-year proposal cost data given to Inforum (for Inforum, 2011, Document ID 1701) and found nothing amiss.

The Construction Industry Safety Coalition, submitted a late comment on the silica proposal (CISC, 2015), which contains estimates prepared by Environomics, Inc. (Environomics, 2015) of the employment impacts of the proposed silica rule on the construction sector (Document ID 4242). This late comment, including the contained Environomics study, has been excluded from OSHA decision-making consideration, but is presented here for informational purposes only.

The employment effects estimated by Environomics (2015) reflect annual costs to construction industries of $4.9 billion, which includes almost $3.9 billion of direct compliance costs to construction employers and another $1.05 billion of costs passed through from general industry (as a result of the silica rule for general industry) to the construction industry (Document ID 4242). Environomics used the IMPLAN model to translate the estimated $4.9 billion annual cost of the silica rule into more than 52,700 lost jobs related to the construction industry. These job losses would consist of about 20,800 in construction; 12,180 additional jobs lost in industries that supply materials, products, and services to the construction industry; and nearly 20,000 further jobs lost when those who lose their jobs in construction and supplier industries no longer have earnings to spend (*i.e.*, ''induced'' jobs). Furthermore, Environomics argued that ''(t)hese job figures are expressed on a full-time equivalent basis. Given the number of part-time and seasonal jobs in construction, the number of actual workers and actual jobs affected will be much more than 52,700'' (Environomics, 2015, Document ID 4242, p. 2).

c. Inforum Analysis of Employment Effects of the Final Silica Rule

In December 2015, OSHA directed Inforum to run its macroeconomic model to estimate the industry and aggregate employment impacts on the U.S. economy of the cost of OSHA's final silica rule.[85] The Agency believes that the specific model of the U.S. economy that Inforum uses—called the LIFT (Long-term Interindustry Forecasting Tool) model—is particularly suitable for this work because it combines the industry detail of a pure input-output model (which shows, in matrix form, how the output of each industry serves as inputs in other industries) with macroeconomic modeling of demand, investment, and other macroeconomic parameters.[86] The Inforum model can thus both trace changes in particular industries through their effect on other industries and also

[85] The estimated cost of the final rule that OSHA provided Inforum was about $962 in annualized terms in December 2015. The final cost presented in the FEA is about $1,030 million in annualized terms, or about 7 percent ($68 million) higher than the costs used by Inforum to estimate the employment effects of the final rule. OSHA believes that if the most recent cost estimates had been used, they would have had a minor effect on Inforum's estimate of the employment impact of the final rule.

[86] The LIFT model combines a dynamic input-output (I–O) core for 110 productive sectors with a full macroeconomic model with more than 1,200 macroeconomic variables that are consistent with the National Income and Product Accounts (NIPA) and other published data. LIFT employs a ''bottom-up'' regression approach to macroeconomic modeling (so that aggregate investment, employment, and exports, for example, are the sum of investment and employment by industry and exports by commodity). Unlike some simpler forecasting models, price effects are embedded in the model and the results are time-dependent (that is, they are not static or steady-state, but present year-by-year estimates of impacts consistent with economic conditions at the time).

examine the effects of these changes on aggregate demand, imports, exports, and investment, and in turn determine net changes to Gross Domestic Product (GDP), employment, prices, etc.

Using industry-by-industry compliance cost estimates provided by OSHA,[87] Inforum employed the LIFT model of the U.S. economy to compute the industry-level and macroeconomic impacts expected to follow implementation of the silica standard. The general methodology was to embed the compliance costs into the industry price functions of the LIFT model, solve the equations of the model with the additional costs included in the calculations, and then compare the simulation to a baseline scenario which did not include the additional costs. Enforcement of the rule was assumed to start in 2017 in construction and in 2018 in general industry and maritime (with enforcement of engineering control requirements for hydraulic fracturing activities beginning in 2021). The timing of the compliance costs reflected the phased-in enforcement of the rule, and the LIFT model results were calculated over a ten-year horizon, that is, through 2026.

The most significant Inforum result is that the final silica rule cumulatively generates an additional 9,500 job-years over the period 2017–2026, or an additional 950 job-years annually, on average, over the period (Inforum, 2016). It should be noted, however, that these results vary significantly from year to year. For example, in 2017, the first year in which the silica final rule would be in effect and when most capital costs for control equipment would be incurred, an additional 21,100 job-years would be generated as a result of the silica rule. Then, through 2026, the change in job-years relative to the baseline ranges from a high of 19,600 (in 2019) to a low of −17,300 (in 2020).[88]

Inforum emphasized that all of these estimated job-year impacts of the silica rule, both positive and negative, should be viewed as negligible—relative to total U.S. employment of between 157 and 168 million workers during the time period under consideration and not statistically different from an estimate of 0 job-years (that is, that the silica rule would have no job impact).

The employment impacts of the silica rule would also vary significantly from industry to industry and from sector to sector. For example, for the period 2017–2026, the construction industry would, on average, gain 4,260 job-years annually while the rest of the U.S. economy would, on average, lose 3,310 job-years annually. Again, relative to total employment in the construction sector of about 10 million workers and employment in the rest of the U.S. economy of about 150 million workers over the 10-year period, these employment impacts should be considered negligible. For a fuller discussion of OSHA's estimate of the employment and other macroeconomic impacts of the silica rule, see Inforum (2016).

One obvious question is why the employment impacts of the silica rule would be positive in construction and negative elsewhere. There seem to be two major reasons. One is that, as reflected in the Inforum model, there is little foreign competition in U.S. construction and the price elasticity of demand in construction is extremely low relative to demand for products in most other industries. Hence, output and employment would be expected to decline minimally in response to any price increase if employers in construction pass on the costs of the silica rule. Second, and probably more important, in OSHA's view, compliance with many of the provisions in the silica rule is relatively labor-intensive, often requiring the application of additional labor in the regulated firms themselves. Examples would include time spent for training, medical surveillance, and activities to meet the PEL (such as setting up and using control equipment and performing housekeeping tasks). The increased labor required to produce a unit of output in regulated firms would tend to increase employment in those industries (holding output constant). This is particularly true in construction, where compliance with the PEL would be much more labor-intensive—both because engineering controls in construction are typically mobile and require more worker activity and because housekeeping and other worker actions are expected to play a larger role in achieving compliance with the PEL. By comparison, engineering control equipment in general industry/maritime is usually in a fixed location (eliminating the need for workers to move the equipment) and worker actions would play a smaller role in achieving compliance with the PEL.

Finally, OSHA turns to a critique of the commenters' analysis of employment effects of the proposed silica rule relative to Inforum's analysis of employment effects of the final silica rule. This critique reflects comments provided in the Inforum report (Inforum, 2016).

The NFIB Research Foundation Analysis: Although the NFIB Research Foundation study (Document ID 2210, Attachment 2) reported that careful attention was given to the analysis of costs and their attribution by firm size, it doesn't offer much information on how the BSIM model works or how the results were obtained. ''From what is generally known about the REMI model upon which it is based, the general mechanism is probably the sequence of (1) increased costs leading to (2) increased output price leading to (3) reduced demand and therefore jobs'' (Inforum, 2016, p. 8). The study does acknowledge that the costs also represent new private sector demand for firms that assist affected employers in complying with the new PEL, but the purported positive impacts of this private sector demand are not visible in the study. Presumably the reported impacts are net effects that combine the negative effects from the increased prices and reduced demand of the affected sectors with the stimulus from spending on the supplying sectors; however, that is not clear, and the stimulus is not quantified. In Inforum's analysis (Inforum, 2016), these effects are explicitly considered, both for intermediate goods and services as well as investment.

Another important difference from Inforum's analysis is that the NFIB study did not attempt to quantify the additional jobs created in the affected industries. In Inforum's LIFT model, these were captured as changes in labor productivity. For several industries, especially construction, although the industry does experience increased costs, it must also hire more workers to comply with the silica rule. The additional jobs required in the affected industries are not discussed or apparently modeled in the NFIB study. In summary, it seems that the

[87] OSHA contractor ERG provided silica-rule compliance cost data for 13 segments of the construction sector plus construction activity by state and local governments, and for 102 industrial sectors. The costs were specified in 2012 dollars and covered a 10 year horizon, beginning with the implementation of the rule. The data covered eight cost types and were classified as intermediate, capital, and direct labor costs. In order to integrate the compliance costs within the LIFT model framework, Inforum established a mapping between the OSHA NAICS-based industries and the LIFT production sectors. *See* Inforum (2016) for a discussion of these and other transformations of OSHA's cost estimates to conform to the specifications of the LIFT model.

[88] The fluctuations in employment from year to year as a result of the proposed rule reflect how the Inforum model works. The model has large short-term multipliers (from the initial increase in compliance expenditures) but long-term stabilizers to return to an equilibrium output and employment level. Hence, the short-term multipliers may cause output and employment to overshoot in one year and adjust in the other direction in the next year or two as the model (and the real-world economy) equilibrates.

counteracting influences due to intermediate and investment related purchases from other industries, and the job-creating expenditures in the affected industries were not, in fact, captured in the study.

The CISC and ACC Studies: These two studies are being critiqued together because they both rely on costs many times higher than OSHA's estimates and because they both made projections using the IMPLAN model.

What accounts for the difference between LIFT simulations and the CISC and ACC estimates? There are several factors at play:

Probably most importantly, CISC's estimate starts with annual compliance costs for the construction industry that are nearly 7 times larger than OSHA's estimates for the construction industry (only) ($4.1 billion vs. an average of over $600 million, both in 2012 dollars). Meanwhile, the ACC study estimates costs for general industry that are more than 16 times larger than OSHA's estimates for the final rule ($6.1 billion in 2009 dollars versus $359 million in 2012 dollars. Moreover, the CISC and ACC studies assumes that the same annualized cost estimates are imposed each year, whereas the OSHA cost estimates vary over the 10 year time period, with peak costs occurring in the first year.

Neither the CISC nor the ACC application of the IMPLAN model accounted for the increase in demand for capital equipment and intermediate goods and services needed to comply with the proposed silica rule. Thus, the employment and income boosting impacts of these expenditures are not captured in their analysis. In contrast, Inforum's methodology uses an explicit price function where annual compliance costs by industry change commodity prices in proportion to their share of total annual gross costs. In turn, price changes affect production and employment through a dynamic general equilibrium framework. Demand and supply price elasticities in the LIFT model are composites of several sets of empirically estimated functions for final demand, exports, imports, and price mark-ups. Furthermore, the parameters of these functions vary by type of product according to the econometric estimation.

At OSHA's request, Inforum made a separate run using the LIFT model in the absence of the final silica rule for the construction industry but with the final silica rule for general industry and maritime. The purpose of this run was to calculate the indirect effects (only) of the final silica rule for general industry and maritime on prices and employment in the construction industry (Inforum, 2016). This LIFT simulation estimated that the final silica rule for general industry and maritime indirectly increased prices in the construction industry by an average of .005 percent. The direction, if not the magnitude of this effect, is consistent with the CISC/Environomics results (Environomics, 2015, Document ID 4242). This led to a modest decline in construction output and construction jobs. As shown in Table 9 of the Inforum report (Inforum, 2016), the decline in jobs varied from +290 to −940 a year over the period 2017 to 2026, with a cumulative job impact of −4.8 thousand jobs over the 10-year period. Again, it should be emphasized that this separate run was made in the absence of the final silica rule for the construction industry.[89]

The IMPLAN model is static and cannot compute employment and output impacts over time, and it cannot show how the economy evolves to cope with changes in costs. In order to extrapolate over ten years, the authors simply multiply the first year effects by 10. The results are implausible for a dynamic economy as the full static one-year impact is unlikely to be the average impact over the course of several years. At least theoretically, the economy contains powerful forces pushing it towards full employment equilibrium. Therefore, most changes to output and employment due to cost or demand shocks tend to be neutralized through time. That is, most impacts, negative or positive, will approach zero over the long term. Indeed, Inforum's LIFT model produces dynamic results that vary from year to year, which is consistent with fluctuations in the state of the economy and with short and long term expenditure effects. It shows how the employment is reallocated among industries and how the economy eventually will return to the baseline, or potential, level of employment.

While the IMPLAN study places the regulatory analysis within the context of the overall economy, it does not take full advantage of the framework. For instance, given data for gross output in the base year it is possible to compute the industry price effect so that the revenue shocks can be judged relative to a price elasticity of demand. Instead, the study employs an unrealistically large construct of a 5 to 1 compliance cost to revenue loss. Finally, the IMPLAN model's inability to model the long-term properties of the economy severely undermines the study's conclusion of long term cost to the economy.

[89] As shown in Table 6 of the Inforum report, the cumulative effect of the final rule for general industry, maritime, and construction is to increase construction employment by 42,600 job years over the 10-year time period, or about 4,260 jobs a year, on average. Hence, the cumulative effect of the final rule for construction alone is to increase construction employment by about 47,400 (42,600 + 4,800) jobs, or about 4,740 jobs a year, to the extent that the two components are additive.

G. Benefits and Net Benefits

In this section, OSHA discusses the benefits and net benefits of the final silica rule. To set out an approach to estimate the benefits, the Agency will, in the following sections, estimate the number of silica-related diseases prevented as a result of the rule, estimate the timing of the potentially avoided diseases, monetize their economic value, and discount them. Taking into account the estimated costs of the final rule, presented in Chapter V of the FEA, OSHA will then estimate the net benefits and incremental benefits of the rule. Finally, the Agency will assess the sensitivity of the estimates to changes in various cost and benefit parameters.

This section presents OSHA's quantitative estimates of what rule-induced benefits would be under certain assumptions. OSHA acknowledges that these estimates are heavily influenced by the underlying assumptions, and also that the long time frame of this analysis (60 years) is a source of uncertainty. The assumptions underlying these estimates of deaths and morbidity avoided will be discussed in detail as they appear in the remainder of this chapter, but the major ones are as follows:

- The exposure profile and other industrial profile data presented in Chapter III of the FEA reflect both current conditions and future conditions (extending over the next sixty years);
- To separate the effects of this new rule from the effects of compliance with existing standards, it is assumed that any workers currently exposed above the preceding PEL are exposed to levels of silica that exactly meet the preceding PEL;
- The rule will result in workers being exposed at the new PEL but will never reduce exposures below the new PEL;
- Workers have identical exposure tenures (45 years, except where otherwise noted);
- The effects of baseline respirator use on risk are ignored; and
- The assumptions inherent in developing the exposure-response functions discussed in Section VI, presented in Table VI–1 of this preamble, are reasonable throughout the exposure ranges relevant to this benefits

analysis. (The reasonableness of these assumptions is discussed in Section VI.)

The first two assumptions are also the basis for the cost analysis in Chapter V of the FEA. The basis for the last assumption is discussed in greater detail in Section VI of this preamble and will be briefly reviewed in this section. It bears emphasis, however, that the sources of data for OSHA's benefits analysis are the same as those used in the Quantitative Risk Assessment (Section VI of this preamble) and the technological feasibility analysis in Chapter IV of the FEA.

While OSHA did not quantify the benefits of the ancillary provisions, consistent with the statute (29 U.S.C. 655(b)(7), section 6(b)(7)), the Agency finds that these provisions are beneficial and necessary in order for the standard to be fully and correctly implemented and for the full benefits of the rule to be realized. On the whole, OSHA intends the requirements for training on control measures, housekeeping, and other ancillary provisions of the rule to apply where those measures are used to limit exposures. Without effective training on use of engineering controls, for example, it is unreasonable to expect that such controls will be used properly and consistently. The ancillary provisions found in the rule are generally standard and common throughout OSHA regulations.

The provision requiring exposure assessment in general industry is integral to determining the engineering controls and work practices needed to control employee exposure to the new PEL, to evaluate the effectiveness of the required engineering and work practice controls, and to determine whether additional controls must be instituted. In addition, monitoring is necessary to determine which respirator, if any, must be used by the employee, and it is also necessary for compliance purposes.

The requirement for regulated areas in general industry and maritime serves several important purposes including alerting employees to the presence of respirable crystalline silica at levels above the PEL, restricting the number of people potentially exposed to respirable crystalline silica at levels above the PEL, and ensuring that those who must be exposed are properly protected. Similarly, the competent person requirement in the construction standard will protect bystanders by restricting access to work areas only when necessary, benefiting those bystanders through reduced exposures.

Written exposure control plans provide a systematic approach for ensuring proper function of engineering controls and effective work practices that can prevent overexposures from occurring. OSHA expects a written exposure control plan will be instrumental in ensuring that employers comprehensively and consistently protect their employees.

The medical surveillance provisions have the potential to protect workers through the early detection of silica-related illnesses and will enable employees to take actions in response to information about their health status gleaned from medical surveillance. Additionally, by requiring medical surveillance to general industry and maritime workers exposed at or above the action level, OSHA provides an incentive for employers to further reduce exposures, where possible, to avoid incurring the costs of medical surveillance.

1. Estimates of the Number of Avoided Cases of Silica-Related Disease

For reasons described in detail in this preamble, OSHA has adopted a PEL of 50 μg/m^3 in its silica standards covering general industry, maritime, and construction, along with an alternative method of compliance (Table 1) in construction. Analogous to the estimates in the PEA, OSHA has calculated estimates of the benefits associated with the PEL of 50 μg/m^3 for respirable crystalline silica, and corresponding Table 1 in construction, by applying the dose-response relationships developed in OSHA's quantitative risk assessment (QRA) to exposures at or below the preceding PELs.

a. Exposure Profiles

OSHA determined exposure levels at or below the preceding PELs by first developing an exposure profile of current exposures for industries with workers exposed to respirable crystalline silica, using OSHA inspection and site-visit data, and then applying this exposure profile to the total current worker population. The industry-by-industry exposure profile is presented in Chapter III of the FEA.

Because OSHA relied solely on measurement of airborne exposures, respirator use may result in lower baseline exposures inside the respirator than would be indicated by the airborne exposures measurements. The extent to which this affects OSHA's benefits calculations depends on the extent to which there was baseline respirator use in the risk assessment studies OSHA relied on and how these studies accounted for respirator use, if they did so at all. OSHA reviewed the risk assessment studies it is relying on as well as earlier studies that described the source of exposure data for each cohort and how exposures were estimated for cohort members to determine whether respirator use was accounted for. OSHA found that the overwhelming majority of studies did not mention either respirator use or how they accounted for respirator use, even though many took place in time periods and at exposures levels where some respirator use could have been expected. Some studies accounted for use of ''dust controls'' but did not state whether these ''dust controls'' included respirator use. Two studies (Rando *et al.* 2001, Document ID 0415), whose exposure estimates for North American industrial sand workers were used by Hughes *et al.* (2001, Document ID 1060), and Dosemeci *et al.* (1993), whose exposure estimates for Chinese mine and pottery workers were modified and used by Chen *et al.* (2001, Document ID 0332; 2005, Document ID 0985), mention adjusting exposure estimates to account for respirator use, but did not discuss in detail how these adjustments were calculated. Most studies OSHA relied on, directly or indirectly, cover long periods of time, over which respirator use varied. Most cover some time after OSHA set a general industry PEL of approximately 100 μg/m^3 and required the use of a respirator if that exposure level was exceeded. In summary, OSHA does not know the extent of respirator use in the risk assessment studies relied on for the benefits analysis, nor how they might differ from current respirator use. As a result, OSHA is unable to accurately adjust its estimates to account for baseline respirator use.

OSHA also is not able to quantify the effectiveness of respirator use. (OSHA regulations provide for assigned protection factors, but these are based on ideal conditions rather than real world conditions.) It is thus difficult to know how to correct for possible respirator use. As will be discussed below, OSHA estimates benefits relative to a baseline characterized by compliance with the preceding PEL. The preceding PEL in construction and maritime is approximately 250 μg/m^3. If respirators have a protection factor of five, then they would be equivalent to the new PEL of 50 μg/m^3 if fully effective at 250 μg/m^3. In general industry there is a preceding PEL of approximately 100 μg/m^3. If respirators have a protection factor of two, then they would be equivalent to the new PEL of 50 μg/m^3, if fully effective. Beyond this, OSHA does not have the data to quantify the effects of respirator use because it is well known that in actual practice in work settings, respirators are not always as protective

as the assigned protection factors would indicate. For the purpose of estimating the health benefits of the final rule, exposures above the relevant preceding PELs were set at the relevant preceding PEL; for purposes of comparing the effects of the preceding and the new standards, the analysis thus assumes full compliance with both, without taking baseline respirator use into account.

By applying the dose-response relationships from the literature to estimates of exposures at or below the preceding PELs across industries, it is possible to estimate the number of cases of the following diseases expected to occur in the worker population given exposures at or below the preceding PELs (the ''baseline''):

- fatal cases of lung cancer,
- fatal cases of non-malignant respiratory disease (NMRD) (including silicosis),
- fatal cases of end-stage renal disease, and
- cases of silicosis morbidity.

Non-fatal cases of lung cancer, NMRD and end-stage renal disease were not estimated. In that respect, the estimates of the benefits are understated. However, OSHA's benefits calculations do not, for example, factor in any impact on the rule's implementation of the following aspect of the Agency's enforcement approach: As a general matter, where compliance with a standard's requirement clearly creates a new hazard, employers can raise a defense that compliance with the requirement is not feasible, and OSHA would work with the employer to implement an alternative means of protection that does not create a serious hazard.[90]

In a comment suggesting that some reductions in exposures (and thus some benefits) were not included in OSHA's analysis, Dr. Ruth Ruttenberg noted that ''OSHA/ERG did not consider stomach cancer, autoimmune disease, and other cancer and non-cancer health effects of silica exposure'' (Document ID 2256, Attachment 4, p. 11). These potential benefits were not quantified, for the PEA or FEA, because the Agency does not, at this time, have sufficient exposure-response data to perform a quantitative risk assessment for these illnesses. The Health Effects and Significance of Risk section of this preamble contain a more detailed discussion of these potential silica-related health effects that were not quantified.

b. OSHA's Method for Using Risk Models and Exposure Profile To Estimate Cases Avoided as a Result of the Rule

The core of OSHA's methodology for benefits analysis is to calculate the number of estimated premature deaths and illness cases avoided as a result of the new rule. To do this, OSHA estimates the expected number of mortality and morbidity cases expected to occur under the assumption that the preceding PEL is being met (*i.e.*, those workplaces where the preceding PEL is currently exceeded are set equal to the preceding PEL), and then subtract the expected number of mortality and morbidity cases estimated to occur with the new rule in place. OSHA then estimates the numbers of disease cases and deaths that would result after the new standard goes into effect (*i.e.*, assuming full compliance in that no worker will be exposed in excess of the new PEL). For this purpose, OSHA assumes all exposures above the new PEL are reduced to the new PEL of 50 $\mu g/m^3$. The difference between these estimates represents the numbers of disease cases and deaths that the Agency estimates would be avoided as a result of issuing the new standard. That is, this approach focuses on calculating estimates derived from eliminating those exposures between the preceding PEL and the new PEL. As explained later, these estimated mortality and morbidity cases avoided are then monetized to comprise the benefits (in dollar terms) of the rule.

By focusing on exposures between the preceding PEL (even for workers exposed above the preceding PEL) and the new PEL exclusively, and ignoring the possibility that workers' exposures are reduced below the new PEL, OSHA's calculations will have a tendency toward underestimation. Some exposures may be reduced to below the new PEL of 50 $\mu g/m^3$ as a result of engineering controls that do more than needed. Also, some exposures below the new PEL of 50 $\mu g/m^3$ may be reduced further due to ''bystander effects,'' by which those already exposed below the new PEL but working near other exposed workers would have their exposures reduced further.

In order to estimate the number of deaths prevented, OSHA uses a lifetime risk model, which is a mathematical framework that explicitly follows workers from the beginning of their work lives until retirement. Workers are assumed to start work at age 20 and work continuously until age 65, resulting in a 45-year work life, and then assumed to live another 15 years post-retirement, or until age 80. This estimate is useful because the OSH Act requires OSHA to examine exposures for an entire working life. Shorter job tenures will be discussed further below.

Using this model, OSHA calculates the workers' cumulative workplace exposures to silica, and estimates the probability of their dying each year from silica-related diseases. The model also establishes the background probability of the workers' dying from non-silica-related causes. The increase in the workers' probability of dying due to cumulative silica exposure in the workplace is added to this background probability. As will be explained in more detail later, the difference in these probabilities is used to form the basis for estimating the number of illnesses and deaths due to silica exposures as they currently exist and the estimated number of illnesses and deaths that would be avoided when the standard is fully in effect, assuming full compliance.

The background, age-specific survival probabilities are based on the current (2011) U.S. (male) population, the latest year for which age-specific all-cause mortality statistics are available.[91] The

[90] In FEA Chapter IV, OSHA responds to commenters who have stated that safety hazards would increase in the presence of the rule (due to, for instance, use of wet methods on roofs) by suggesting technologically feasible alternatives, including using wet methods or exhaust ventilation on the ground or on platforms or scaffolds. Other commenters also described how fall protection on roofs was already being used where wet methods are employed.

[91] Overall, approximately 3 percent of all construction workers are women. (BLS, 2014—Labor Force Statistics from the Current Population Survey, available at *http://www.bls.gov/cps/cpsaat11.pdf*). There is no comparable breakdown for manufacturing occupations as a whole but, for selected occupations for which data are available, women are always fewer than 15 percent of the relevant manufacturing workforce. OSHA used background mortality rates for the U.S. male population because the cohorts in the key studies used in the Agency's quantitative risk assessment were composed overwhelmingly of male workers. OSHA used the exposure-response models from these studies in a life table analysis to estimate excess risk of disease mortality from exposure to respirable crystalline silica after accounting for competing causes of death due to background causes. Because, in most key studies, the exposure-response models were built using data from male workers only, it is unknown how these models would change for female workers, or for mixed-gender populations, as it is not clear that females would react to the silica exposure in the same exact way as males. There is no such model data available for these cohorts. Furthermore, OSHA believes that use of all-cause mortality data for the U.S. population as a whole is not appropriate since the working populations studied in the cohort studies, as well as the present population of workers covered by the rule, are overwhelmingly male and do not reflect the nearly equal proportion of males and females represented by the all-cause mortality data for the U.S. population as a whole. If one were to assume that the exposure-response model for female workers was the same as that for male workers, then the resulting relative risk (RR, the ratio of the risk of disease mortality occurring in the exposed to the risk of disease mortality occurring

exposure-response functions for different diseases, which relate cumulative silica exposure and increased probabilities of respective disease endpoints, are drawn from specific studies discussed in this preamble, Section VI—Final Quantitative Risk Assessment and Significance of Risk.[92] Estimates of the number of cases of silicosis prevented by the new standard were also based on cumulative risk models taken from several morbidity studies, but were not used in life table analyses as was done for mortality (*see* Section VI of this preamble, Final Quantitative Risk Assessment and Significance of Risk). The exposure levels used in the model cover the U.S. exposure profile as presented in Table III–9 in Chapter III Industry Profile of the FEA. OSHA's exposure profiles for general industry and maritime and for construction contain the estimated numbers of employees exposed within specific bands of exposure levels: below 25 μg/m^3, 25 to 50 μg/m^3, and above 50 μg/m^3 (in bands of 50 μg/m^3 to 100 μg/m^3, 100 μg/m^3 to 250 μg/m^3, and above 250 μg/m^3, whenever any of these bands are above the preceding PEL, OSHA lowered the estimate for the band to the preceding PEL).

The results in Table III–9 in the FEA represent average daily exposures in the risk model for general industry and maritime. In construction, occupational exposure is commonly intermittent (*i.e.*, not occurring every workday), necessitating an adjustment to accurately estimate these workers' cumulative exposure and risk. Workers in the construction sector perform a multitude of tasks, only some of which involve silica exposure. OSHA's estimated exposure levels represent the 8-hour time-weighted average of exposure on days when workers perform tasks involving silica exposures. However, to account for the fact that, in most affected construction occupations, workers do not do such tasks every day, the cumulative exposure estimate for these workers needed to be adjusted. To account for this intermittent exposure, the risk model uses an adjustment factor which estimates the percentage of days in which a worker will typically perform tasks that generate silica exposures. These adjustment factors are generally based on the proportion of time workers perform silica-generating activities along with associated work crew sizes.[93] So, for example, if, on average, a group of workers is estimated to spend 20 percent of its time performing tasks involving silica exposure, the model multiplies the base exposure level—the exposure that the group of workers is estimated to have based on the exposure profile—by this 20 percent. In the Agency's model, this adjustment factor is calculated as the total number of full time equivalent days that affected employees spend on silica-related tasks divided by total affected employment as shown in Chapter III of the FEA. For all construction occupations other than hole drillers using hand-held drills, OSHA calculated an FTE adjustment factor of 28 percent that was derived from the exposure profile. Hole drillers using hand-held drills have a large number of employees and an extremely low adjustment factor as compared to all other occupations. Because the risk models are nonlinear, averaging such disparate groups together provides unrepresentative results and therefore, this occupation has its risk calculated separately. For hole drillers using hand-held drills, OSHA calculated an adjustment factor of 3.5 percent.

In order to calculate the number of expected and avoided cases for each health outcome, OSHA assumes that all workers whose exposures fall within a band are exposed the same and assigns the average of all individual exposure observations within the relevant band (*i.e.,* the mean exposure) as the single point estimate within each band.[94] This point estimate of exposure is then used with the associated risk estimate for each health outcome, which is multiplied by the estimated number of workers exposed within the exposure band to calculate the number of workers who experience that health outcome in the absence of the new rule. For workers currently exposed above the new PEL, OSHA assumes that their post-rule exposures will be lowered to the new PEL of 50 μg/m^3. This reflects the fact that the Agency is taking no benefits for reducing exposure above the previous PELs to the previous PELs. The analysis starts from a baseline of the previous PELs. A similar calculation is then performed at these new exposure levels for these currently overexposed workers: The numbers of workers exposed within each exposure band of the post-rule exposure profile is then multiplied by the associated risk estimates for each health outcome to yield estimates of the numbers of disease cases and fatalities that will occur after the standard is implemented. Finally, subtracting this post-implementation number of deaths and disease cases from those estimated under baseline (pre-rule) conditions yields an estimate of the number of deaths and illness cases averted due to the standard.

As an example, Table VII–23–1 presents the summary calculations for a risk model that produces one estimate of the number of lung cancer deaths avoided by the revised standard for workers in general industry if they were all exposed to silica for 45 years (this uses the ToxaChemica 2004 risk model of lung cancer deaths avoided).

in the unexposed) for a particular cumulative exposure would be the same. Because the risk of disease mortality in the exposed population is calculated by multiplying the RR by the background risk in the unexposed population, the risk of mortality in the exposed population would be different between females and males and would depend upon the background gender-specific disease risks. Because the background cause-specific (*e.g.*, lung cancer or NMRD) mortality for females is generally lower than that for males, the Agency would expect that the predicted risk of mortality to exposed females may be slightly lower than that for exposed males. On the other hand, this effect may be offset by female workers' greater likelihood of surviving to the advanced age groups in which silica-related diseases most typically appear in severe forms and become a cause of death. Given the absence of exposure-response models for female workers, which are required to estimate a proper RR of disease for females, it is impossible to make any sound conclusion on how the risk estimates would change for female workers.

[92] Specifically the low estimate for lung cancer uses estimates from ToxaChemica (2004, Document ID 0469), the high estimate for lung cancer uses Attfield and Costello (2004, Document ID 0543), the renal disease estimate uses Steenland, Attfield, and Mannetje (2002) (Document ID 1089), the morbidity estimate for silicosis uses Buchanan, Miller, and Soutar (2003, Document ID 0306), and the mortality estimate for silicosis uses Mannetje, *et. al.* (2002, Document ID 1089). *See* Section VI—Final Quantitative Risk Assessment and Significance of Risk in this preamble for more discussion.

[93] Detailed methodology and estimates for each occupation are discussed in the construction engineering control cost section in Chapter V of the FEA, in the subsection entitled ''Aggregate 'Key' and 'Secondary' Labor Costs for Representative Projects.''

[94] Individual exposure data are presented within various sections of Chapter IV, Technological Feasibility, of the FEA. All individual observations are presented in *Technical and Analytical Support for OSHA's Final Economic Analysis for the Final Respirable Crystalline Silica Standard: Excel Spreadsheets Supporting the FEA*, available in Docket OSHA–2010–0034 at *www.regulations.gov*.

Table VII-23-1 Lung Cancer Benefits Model

For an Illustrative Scenario in Which Workers Are Uniformly Exposed to Silica for 45 Years
Exposure Profile - General Industry (PEL 50 µg/m3)

	Total	<25 µg/m³	25-50 µg/m³	50-100 µg/m³	100-250 µg/m³	>250 µg/m³
Number of Workers at risk	291,019	142,071	51,377	40,831	28,297	28,443
Modeled Exposure Level- Baseline*		14	36	70	100	100
Model Exposure Level- PEL 50 µg/m3		14	36	50	50	50
Baseline						
Excess Death Rate Per 1,000 Workers**		14.7	17.9	20.1	21.1	21.1
Excess Number of Deaths**	5,021	2,084	921	819	597	600
PEL 50						
Excess Death Rate Per 1,000 Workers**		14.7	17.9	19.0	19.0	19.0
Excess Number of Deaths**	4,858	2,084	921	776	538	540
Difference Baseline - PEL 50						
Differential Death Rate per 1,000 Workers		0.0	0.0	1.1	2.1	2.1
Lung Cancer Deaths Averted	**163**	0.0	0.0	43	60	60
Annual Lung Cancer Deaths Averted	**4**					

*From the current exposure profile except that exposures above 100 µg/m³ are set to 100 µg/m³
**Relative to lung cancer mortality among the U.S. male population as a whole
Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis and Office of Technological Feasibility

In Table VII–23–1, the total General Industry population at risk for excess lung cancer is 291,019. There are 142,071 workers in the range of silica exposure of below 25 µg/m³, 51,377 workers exposed between 25 and 50 µg/m³, etc. The ''Model Exposure Level-Baseline'' row provides the mean exposure level within each range, which is the point estimate of exposure for which the associated lifetime risk estimate is used to estimate the number of lung cancer deaths that occur among workers exposed within each exposure range. For example, from the exposure profile, the mean exposure for workers in General Industry who are exposed below 25 µg/m³ is 14 µg/m³, and the risk of lung cancer for all workers in this exposure band is calculated from this average exposure of 14 µg/m³. Though the exposure profile includes 28,297 workers exposed in the range of 100–250 µg/m³ and 28,443 workers exposed above 250 µg/m³, to estimate the number of baseline lung cancer deaths, those workers' exposure levels are set at

the preceding PEL of 100 μg/m³. In this example, estimated benefits due to the new PEL do not include any benefits to workers for their exposures being reduced to the preceding PEL; only those benefits associated with the exposure levels being reduced from the preceding PEL or lower to the new PEL are included in the estimates. The row labeled ''Model Exposure Level-50 PEL'' shows the expected exposures among workers that result after the standard is promulgated. Exposures of workers exposed below 50 μg/m³ are expected to remain unchanged while the exposures of all workers who are currently exposed above 50 μg/m³ are expected to be reduced to the new PEL of 50 μg/m³.[95]

Table VII–23–1 also presents the estimated excess risk of lung cancer per 1,000 workers for each exposure band and the number of lung cancer deaths that would occur among workers exposed within each exposure band for 45 years. For example, among workers exposed within the lowest exposure band, the lifetime risk model estimates an increased risk of lung cancer above the background mortality risk of 14.7 deaths per 1,000 workers at a constant exposure to 14 μg/m³ silica for 45 years. Multiplying this risk estimate by the number of workers at risk in that exposure band (142,071) yields an estimated 2,084 lung cancer deaths. Doing the same across the various baseline exposure level bands results in an estimated baseline total of 5,021 lung cancer deaths due to exposure to silica for the population of workers at risk. The table shows similar estimated lung cancer risks and estimated numbers of deaths in the post-standard scenario. For all workers whose baseline 45-year exposures are at or above 50 μg/m³, the estimated risk of lung cancer associated with exposure at the new PEL of 50 μg/m³ is 19.0 per 1,000 workers. Multiplying this risk by the number of workers exposed to silica at levels between 50 and 100 μg/m³ (41,596), for example, yields an estimated 776 deaths occurring in this group for the post-standard scenario. Doing the same for each exposure band for the post-standard scenario and summing across all exposure bands, the number of estimated excess lung cancer deaths post-standard is 4,858. The next two rows show the difference between the baseline and the post-standard scenarios, both for lung cancer death risks (''differential lung cancer death rate'') and numbers of deaths (''lung cancer deaths averted''). The final total number of lung cancer deaths averted is 163. Dividing by the analytic time horizon of 45 years results in about 4 annual deaths averted.

The preceding example assumes a constant exposure level each year for 45 years. Elsewhere in this chapter, OSHA examines what would happen if the day-to-day exposure remains the same but job tenure is shorter. In order to have a valid comparison, OSHA compares each scenario to what is estimated to happen over 45 years. All job tasks, and hence cumulative exposure, do not change with decreased job tenure; they are just spread over more workers. Thus, if OSHA were to examine a job tenure of 25 years, almost twice as many workers would be exposed for almost half as long as for the 45-year assumption. With a strictly proportional (linear) risk function the benefits of having half the exposure for twice the number of workers would exactly offset each other and final benefits would be the same. Hence the net effect of such changes is directly related to non-linearities in the various lifetime risk models.

c. Results for Cases Avoided

OSHA received a number of comments concerning the Agency's preliminary risk assessment and discussion of the health effects of silica in this preamble to the proposed rule. Those comments are discussed in detail in Sections V (Health Effects) and VI (Final Quantitative Risk Assessment and Significance of Risk) of this preamble to the final rule.

OSHA examined the various lung cancer risk models presented in its QRA to estimate the benefits of lowering the PEL. As can be inferred from Table VI–1 of the Final QRA, the ToxaChemica, Inc. (2004, Document ID 0469) log-linear model estimated the lowest estimate of lung cancer cases avoided from lowering the PEL to 50 or 100 μg/m³, whereas the Attfield and Costello (2004, Document ID 0543) model estimated the highest number of lung cancer cases avoided. The remainder of the studies indicated an intermediate reduction in risk. OSHA used the ToxaChemica 2004 (log-linear model) and Attfield and Costello studies to characterize a range of estimated lung cancer reduction, acknowledging that neither of these estimates captures the full range of uncertainty associated with the models and data used.

Table VII–24 shows the range of modeled estimates for the number of avoided fatal lung cancers for PELs of 50 μg/m³ and 100 μg/m³ for the scenario in which workers are uniformly exposed to silica for 45 years. At the final PEL of 50 μg/m³, the modeling approach yields estimates of 2,921 to 8,246 lung cancers prevented over the lifetime of the worker population, with a midpoint estimate of 5,584 fatal lung cancers prevented. This is the equivalent of between 65 and 183 cases avoided annually, with a midpoint estimate of 124 cases avoided annually, given a 45-year working life of exposure.

Following Park (2002, Document ID 0405), as discussed in the Agency's QRA, OSHA's estimation model suggests that the final PEL of 50 μg/m³ would, in the scenario in which workers are uniformly exposed to silica for 45 years, prevent 14,606 fatalities over the lifetime of the worker population from non-malignant respiratory diseases arising from silica exposure.[96] This is equivalent to 325 fatal cases prevented annually. Some of these fatalities would be classified as silicosis, but most would be classified as other pneumoconiosis and chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis and emphysema. That is one reason why we would expect this estimate to exceed the count based solely on death certificates (for instance, in 2013, CDC's count based on state-provided vital records is 111 deaths annually from silicosis in the United States).

Certain commenters argued that the recent CDC count of silicosis mortality from death certificates is evidence that OSHA's benefits were overestimated.

Some commenters, such as the American Chemistry Council and Faten Sabry, Ph.D., representing the Chamber of Commerce, argued—based on the numbers of silicosis-related deaths recorded in recent years reported in mortality surveillance data—that OSHA overestimated the estimated benefits of the standard (Document ID 2263, p. 57; 3729, p. 1; 2288, Appendix 6; 4209, pp. 3–4). Dr. Sabry stated that the 52 deaths reported by the CDC in 2010 where silicosis was identified as an underlying cause of death were considerably fewer than the number of silicosis-related deaths that OSHA claimed would be avoided once the proposed standard becomes fully implemented. Dr. Sabry concluded, ''[s]o, by OSHA's calculation, reducing the PEL to 50 μg/m³ will prevent more silicosis-related deaths than actually occur in the United States today—which suggests that OSHA's risk assessment is faulty'' (Document ID 2288, Appendix 6). The

[95] For the purposes of estimating costs and benefits, OSHA assumes full compliance with all applicable OSHA standards.

[96] Park *et al.* (2002, Document ID 0405) also found that silica exposure was responsible for a significant number of deaths that had been attributed to diseases other than silicosis.

National Utility Contractors Association (NUCA) made the same argument when it asserted: ''OSHA predicts that this proposed rule will prevent approximately 600 silica related deaths per year, but the CDC is recording less than 100 deaths per year'' (Document ID 3729, p. 1). The National Federation of Independent Business also argued that OSHA estimated 375 prevented cases of silicosis that would have led to deaths, but the CDC reported only about 150 deaths per year where silicosis was the underlying cause or a contributing factor, causing OSHA to overestimate lives saved due to the standard by about 150 percent (Document 2210, Attachment 1, p. 3).

OSHA disagrees that the silicosis mortality surveillance data alone provides evidence that OSHA has overstated the quantitative benefits of the rule. OSHA derived its benefits estimates from exposure data presented in the Industry Profile chapter of the FEA and from its quantitative risk assessment, which is based on epidemiological data that quantify relationships between exposure and disease risk. OSHA relied on these estimates to estimate the number of silicosis-related deaths and illnesses that would occur absent a revised standard and the number of deaths that would be avoided by promulgation of such a standard. From this analysis, OSHA estimated that 325 deaths from silicosis and other non-malignant lung disease and 918 silicosis morbidity cases are estimated to be avoided annually once the full effects of the standards are realized. The 52 deaths cited by Dr. Sabry appears to refer to only the number of deaths with silicosis coded as the ''underlying'' cause of death on death certificates, and does not include deaths coded with silicosis as a ''contributing'' cause. Combined with the deaths where silicosis is coded as a ''contributing'' cause, in this case 49, CDC/NIOSH reported a total of 101 deaths where silicosis was either an underlying cause of death or a contributing cause of death.

OSHA's model does not only count fatalities related to silicosis. OSHA's estimate of the impact of exposure to respirable crystalline silica includes deaths from other diseases (lung cancer, non-malignant respiratory disease such as chronic bronchitis and emphysema, and end-stage renal disease) that, according to scientific evidence, can be caused by exposure to respirable crystalline silica (Document ID 1711; 2175, p. 2). OSHA also estimated, based on the Park study discussed previously, that 325 cases of fatal non-malignant respiratory diseases associated with exposure to silica, including, but not limited to silicosis, that would be prevented annually due to the final standard. Thus, OSHA's estimates of the numbers of deaths prevented that are due to non-malignant respiratory disease are not comparable to surveillance statistics that only capture silicosis as a cause of death. Furthermore, Dr. Sabry's comments are primarily focused on the hydraulic fracturing industry, which only recently became a major source of silica exposure, where most of the effects of current exposures will likely not be seen for a number of years, underlining why this analysis of past trends is not instructive for epidemiological estimates.

In response to NUCA's comparison of OSHA's estimate of 679 deaths avoided to the estimate of fewer than 100 deaths from the surveillance data, the Agency again points out that the model accounts for causes of death other than those resulting from silicosis and therefore reported to CDC/NIOSH in the surveillance data. Therefore, NUCA's comparison is faulty because focusing exclusively on silicosis mortality fails to capture silicosis morbidity, as well as mortality and morbidity resulting from other diseases related to silica exposure, including lung cancer, other non-malignant respiratory disease such as chronic bronchitis and emphysema, and renal disease (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk, Table VI–1).

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Table VII-24
Estimated Number of Avoided Fatal & Nonfatal Illnesses Resulting from a Reduction in Crystalline Silica Exposure of At-Risk Workers over 45 Years Due to Final PEL of 50 µg/m^3 and Alternative PEL of 100 µg/m^3[**]**

	Total Number of Avoided Cases						Annual Number of Avoided Cases					
	50 µg/m^3			100 µg/m^3			50 µg/m^3			100 µg/m^3		
	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Lung Cancers												
Attfield and Costello 2004 (higher estimate) [a]	8,246	6,360	1,886	4,454	4,264	190	183	141	42	99	95	4
Midpoint	5,584	4,554	1,029	2,792	2,695	97	124	101	23	62	60	2
ToxaChemica 2004 (lower estimate) [b]	2,921	2,749	172	1,129	1,125	4	65	61	4	25	25	0
Silicosis & Other Non-Malignant Respiratory Diseases	14,606	12,052	2,554	7,669	7,591	78	325	268	57	170	169	2
End Stage Renal Disease	8,689	7,902	787	3,746	3,720	26	193	176	17	83	83	1
Total Number of Fatal Illnesses Prevented												
Attfield and Costello 2004 (higher estimate) [a]	31,541	26,314	5,228	15,869	15,575	293	701	585	116	353	346	7
Midpoint	28,879	24,508	4,370	14,206	14,006	200	642	545	97	316	311	4
ToxaChemica 2004 (lower estimate) [b]	26,216	22,703	3,513	12,544	12,437	107	583	505	78	279	276	2
Total Number of Silicosis Morbidity Cases Prevented*	41,293	23,863	17,429	21,481	20,245	1,236	918	530	387	477	450	27

*Assessed at 2/1 or higher X-ray, following ILO criteria

**OSHA estimates are based on point estimates. The sensitivity analysis and the probabilistic uncertainty analysis incorporate standard errors

[a] Document ID 0543; [b] Document ID 0469

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

George Kennedy of the National Utilities Contractor's Association makes a similar ''apples and oranges'' error in his comment:

> OSHA predicts that this rule will prevent approximately 600 silica-related deaths per year. But how is this possible if the CDC is reporting less than 100? (Document ID 3583, p. 2240)

Mr. Kennedy's comment is based on comparing CDC counts of documented silicosis fatality cases, but this count is not a report on *all* silica-related deaths. The Agency's articulated need for the standard, however, is based on the finding that silica exposure results in an array of adverse, mutually independent health endpoints. In contrast, the CDC estimate deals with a small part of the overall health risk from silica exposure.

As also discussed in the Agency's QRA, OSHA finds that workers with higher cumulative exposures to silica are at elevated risk of lung cancer, end-stage renal disease, and non-malignant respiratory diseases. Based on the midpoint of the lower high-end estimate (Attfield and Costello, 2004, Document ID 0543) and a higher low-end estimate (ToxaChemica log-linear model, Document ID 0469), OSHA's estimation model estimates that the new PEL of 50 $\mu g/m^3$ would, in the scenario in which workers are uniformly exposed to silica for 45 years prevent 5,584 cases of lung cancer, or about 124 cases annually upon reaching ''steady state'' (*see* later discussion of this concept) in 60 years. Based on Steenland, Attfield, and Mannetje (2002, Document ID 1089), OSHA's estimation model estimates that the final PEL would prevent 8,689 cases of end-stage renal disease, or about 193 cases annually in steady state. And based on Park (2002, Document ID 0405), OSHA's estimation model estimates that the new PEL would prevent 14,606 cases of non-malignant respiratory diseases (including silicosis) over the lifetime of 45 cohorts' worth of worker population, or about 325 cases annually in steady state, of which 2,970 (66 annually) are attributable to diagnosed cases of silicosis, based on Mannetje (2002, Document ID 1089).

Combining the three major fatal health endpoints—lung cancer, non-malignant respiratory diseases, and end-stage renal disease—OSHA's modeling approach yields estimates that the new PEL would prevent between 26,216 and 31,541 premature fatalities over the lifetime of the current worker population, with a midpoint estimate of 28,879 fatalities prevented. This is the equivalent of between 583 and 701 premature fatalities avoided annually, with a midpoint estimate of 642 premature fatalities avoided annually, given a 45-year working life of exposure.

In addition, the final silica rule is estimated to prevent a large number of cases of silicosis morbidity. Table VII–25 is designed to compare available estimates of actual silicosis cases to the estimates generated by OSHA exposure profile and models. The first set of rows compares present estimates of 2/1 and the second set of rows estimates of 1/0 cases of silicosis generated by various risk models using OSHA's exposure profile. Going across, the first columns are for a tenure length of 45 years, the second set for a tenure length of 13 years. Then below in the second panel, the final set of rows is based on Rosenman, *et al.* (2003, Document ID 1166) estimates of actual silicosis cases, generated with an alternative modeling approach. To be consistent with OSHA's jurisdiction, OSHA revised Rosenman's estimate to remove workers not in OSHA's jurisdiction, such as miners. The lower panel, based on Rosenman, *et al.* (Document ID 1166), shows, assuming 45 years of exposure, that between 2,700 and 5,475 new cases of silicosis, at an ILO x-ray rating of 1/0 or higher, are estimated to occur annually at current exposure levels as a result of silica exposure at establishments within OSHA's jurisdiction (*i.e.,* excluding miners).[97] The various models OSHA used yield estimates of between 836 and 8,011 cases, assuming 45 years of exposure and between 393 and 10,107 cases assuming 13 years of exposure at an ILO x-ray rating of 1/0 or higher. OSHA's risk models for morbidity using OSHA's exposure profile are thus somewhat consistent with epidemiologically based estimates of silicosis cases though some are a bit over the epidemiological estimates. When a job tenure of 13 years is assumed, the table shows that for most models, as compared to the 45 year job tenure analysis, the results are a lower numbers of cases, while other models yield estimates of cases within the range estimated by Rosenman for U.S. workers other than miners (who are outside OSHA's jurisdiction.) There are, however, exceptions. The estimated number of cases for some models falls below Rosenman's estimates. On the other hand, two models show an increased number of cases which are above the range of Rosenman's estimates. This is a result of very high rates of cases expected to occur in persons exposed at levels above the preceding PELs. Since OSHA does not estimate benefits to workers exposed at levels above the preceding PELs, any estimated increase in cases among such workers will not affect OSHA's benefits analysis.

[97] Rosenman indicated that the underlying cases of silicosis morbidity have changed little over time, testifying that data from the National Intake Survey indicated that the nationwide number of hospitalizations where silicosis was one of the discharge diagnoses has remained constant, with 2,028 hospitalizations reported in 1993 and 2,082 in 2011 (Document ID 3425, p. 2).

Table VII-25

Estimates of Annual Number of Silicosis Cases Currently and Annual Number of Silicosis Cases Prevented According to Various Risk Models For the Illustrative Scenario in Which Workers Are Uniformly Exposed to Silica for 45 Years, or Alternatively, 13 Years□Risk

		45 Years		13 Years	
		OSHA Estimated Number of Cases Based on Relevant Study		OSHA Estimated Number of Cases Based on Relevant Study	
ILO rating	Study	At Current Exposures *	Under Theoretical Compliance with Preceding PELs	At Current Exposures*	Under Theoretical Compliance with Preceding PELs
2/1+	Miller (1998)	5,498	2,008	5,206	3,556
	Buchanan (2003)** [a]	5,588	1,642	3,164	1,592
1/0+	Chen (2005) pottery worker	836	214	393	39
	Chen (2005) tungsten miner	1,977	283	489	39
	Chen (2005) tin miner	5,337	2,600	4,942	2,296
	Buchanan (2003) [a]	8,011	5,433	10,107	5,380
	Chen (2001)	6,531	3,967	7,172	1,875
	Hnizdo and Sluis-Cremer (1993)	6,148	3,508	3,981	103

		Estimate of Current Cases	
		Low	High
1/0+	Rosenman [b]	3,600	7,300
	Rosenman, estimated portion in OSHA jurisdiction***[b]	2,700	5,475

*as indicated in exposure profile in FEA Chapter III, Table III-9

**estimation of *all* silicosis morbidity cases, including ones that may ultimately be fatal

***excluding 25%, based on portion of death certificates listing mining as occupation

[a] Document ID 0306, Document ID 1166

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

A number of commenters took issue with the general idea that silicosis is an occupational health problem for workers whose exposures to silica did not exceed the preceding PELs. These commenters typically pointed to the significant decline in the number of silicosis deaths reported by the CDC in the last few decades.

OSHA does not find these comments persuasive. As explained in depth in the Health Effects and Risk Assessment sections of this preamble, while the Agency welcomes any apparent decline in silicosis cases, the Agency has substantial evidence that significant risk remains at preceding PELs. The commenters do not account for the undercounting of silicosis deaths from death certificates, as demonstrated by Rosenman (Document ID 1166] and others; nor do they address other health endpoints beyond fatal silicosis. Although the decline in reported cases may indicate the Agency's success up to this point in reducing the incidence of silicosis, it cannot be taken as an absolute measure of how many silica-related disease cases currently exist in the population. Most silicosis cases are not fatal—given that the total cases of silicosis have apparently remained largely constant, fewer silicosis fatalities may mean that more individuals are living with silicosis for longer periods while ultimately dying of other causes.[98]

While OSHA has estimated morbidity from silicosis, it has not attempted to estimate the number of morbidity cases

[98] As indicated previously, Rosenman found that the underlying cases of silicosis morbidity have changed little over time, remaining constant, even while reported fatalities have declined (Document ID 3425, p. 2).

from these other health endpoints. Including these other endpoints would increase estimates of the number of overall cases avoided.

As summarized in Table VII–25, OSHA expects that, in the scenario in which workers are uniformly exposed to silica for 45 years, the silica rule will eliminate the majority of 1/0, 1/1, and 1/2 silicosis cases. However, the Agency has not included the elimination of these less severe silicosis cases in its estimates of the monetized benefits and net benefits of the final rule. Instead, as shown above in Table VII–24, OSHA focused its morbidity-only benefits and related net benefits analysis exclusively on the number of silicosis cases reaching the more severe levels of 2/1 and above (moderate-to-severe silicosis, using the ILO method for assessing severity). As discussed in the Agency's QRA, OSHA estimates that the new PEL of 50 μg/m^3 for the current worker population would, in the scenario in which workers are uniformly exposed to silica for 45 years, prevent 41,293 cases of moderate-to-severe silicosis (2/1 or more) over a working life, or about 918 cases prevented annually.[99]

As previously discussed, OSHA based its estimates of reductions in the number of silica-related diseases using estimates that reflect a working life of constant exposure for workers who are employed in a respirable crystalline silica-exposed occupation for their entire working lives, from ages 20 to 65.[100] In other words, these estimates reflect an assumption that workers do not enter or exit jobs with silica exposure mid-career or switch to other exposure groups during their working lives. While the Agency is legally obligated to examine the effect of exposures from a 45-year working lifetime of exposure,[101] for purely informational purposes, the Agency also alternatively examined the effect of assuming that workers are exposed to silica for three other tenure lengths: 25, 13, and 6.6 working years (*see* Table VII–26a through Table VII–26c for number of cases and Table VII–28a through Table VII–28d for monetary benefits for all four tenure levels).

Table VII–26a presents cases for a worker exposed for 25 years. While each individual worker is estimated to have less cumulative exposure under the 25-years-of-exposure assumption, in fact 56 percent (25/45) as much, the effective exposed population over time is proportionately increased (due to the turnover of workforce for a constant number of jobs, and hence total exposure), over the same time period. A comparison of Table VII–26a to Table VII–24, reflecting exposures over 25 working years versus 45 working years, shows variations in the number of estimated prevented cases by health outcome. Estimated prevented cases of fatal end-stage renal disease are higher in the 25-year model, whereas cases of fatal non-malignant respiratory disease and silicosis morbidity are lower. In the case of lung cancer, the effect varies by model, with a decrease in the Attfield and Costello, 2004 higher estimate (Document ID 0543) and an increase in the ToxaChemica, 2004 lower estimate (Document ID 0469). Looking at overall totals, the midpoint estimate of the number of avoided fatalities under the new PEL of 50 μg/m^3 is 642 for 45 years, increasing to 772 for 25 years. For total morbidity, there instead is a decrease: from 918 cases avoided for 45 years down to 443 cases avoided for 25 years, Table VII–26b presents results for 13 years of exposure. For a 13 year job tenure, the midpoint for the number of fatalities avoided is 982 while the total number morbidity cases avoided is 246. Finally, Table VII–26c presents the results for 6.6 years of exposure. In this scenario, the midpoint for the number of fatalities avoided is 1,382 and the total number of morbidity cases avoided is 194. Looking across the tenure results shows that midpoint mortality significantly increases with lower tenure, while total morbidity has a large decrease with lower tenure.

A commenter, Joseph Liss, objected to the Agency's approach of simultaneously increasing the estimated exposed population—not because it was technically incorrect, but because it makes it harder to see the difference in risk to a particular exposed population (Document ID 1950, pp. 16–19).

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[99] The unfiltered count of morbidity cases is reported only in Table VII–25. The Agency believes the actual number of morbidity-only cases prevented by the standard in the scenario in which workers are uniformly exposed for 45 years is somewhere between 918 and 984 cases annually, using Mannetje (2002) (Document ID 1089) to estimate the number of prevented silicosis fatalities (66) and excluding these fatalities from the estimated ''morbidity-only'' cases. While the Agency received no comment on its methodology for counting morbidity cases, in preparing the FEA OSHA discovered that the simultaneous accounting for morbidity in Buchanan's study of coal miners (2003, Document ID 0306) and pre-mortality morbidity in Park (2002) (Document ID 0405) could result in a potential double-counting of morbidity valuation (discussed later in this chapter), as some of the Buchanan's cases diagnosed with 2/0+ silicosis at retirement could ultimately proceed to death. A precise estimate of the morbidity-only cases is not possible, as Buchanan also excluded a number of cases where the workers had already died, possibly from silicosis, so that Buchanan was, in turn, likely underestimating the total lifetime morbidity risk from silicosis. By relying on Mannetje, OSHA avoids any potential double counting of benefits.

[100] In construction, the analysis assumes that while workers gain additional exposure annually, they are not necessarily exposed to silica constantly, depending upon the demands of the job.

[101] Section 6(b)(5) of the OSH Act states: ''The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' Given that OSHA must analyze significant risk over a working life, the Agency estimated benefits for the affected population over the same period.

Table VII-26a

Estimated Number of Avoided Fatal & Nonfatal Illnesses Resulting from a Reduction in Crystalline Silica Exposure of At-Risk Workers over 25 Years Due to Final PEL of 50 μg/m^3 and Alternative PEL of 100 μg/m^3**

	Total Number of Avoided Cases						Annual Number of Avoided Cases					
	50 μg/m^3			100 μg/m^3			50 μg/m^3			100 μg/m^3		
	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Lung Cancers												
Attfield and Costello 2004 (higher estimate) [a]	7,349	5,787	1,562	3,897	3,776	121	163	129	35	87	84	3
Midpoint	6,301	5,344	957	2,981	2,916	65	140	119	21	66	65	1
ToxaChemica 2004 (lower estimate) [b]	5,253	4,900	352	2,064	2,056	8	117	109	8	46	46	0
Silicosis & Other Non-Malignant Respiratory Diseases	14,964	12,233	2,731	7,888	7,736	152	333	272	61	175	172	3
End Stage Renal Disease	13,458	12,235	1,223	3,760	3,720	40	299	272	27	84	83	1
Total Number of Fatal Illnesses Prevented												
Attfield and Costello 2004 (higher estimate) [a]	35,771	30,255	5,516	15,545	15,232	313	795	672	123	345	338	7
Midpoint	34,723	29,812	4,912	14,629	14,372	257	772	662	109	325	319	6
ToxaChemica 2004 (lower estimate) [b]	33,675	29,368	4,307	13,713	13,512	200	748	653	96	305	300	4
Total Number of Silicosis Morbidity Cases Prevented*	19,931	12,701	7,230	11,190	9,625	1,565	443	282	161	249	214	35

*Assessed at 2/1 or higher X-ray, following ILO criteria

** Results are estimates based on assumptions outlined in the benefits analysis.

[a] Document ID 0543, Document ID 0469

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Table VII-26b

Estimated Number of Avoided Fatal & Nonfatal Illnesses Resulting from a Reduction in Crystalline Silica Exposure of At-Risk Workers over 13 Years Due to Proposed PEL of 50 µg/m³ and Alternative PEL of 100 µg/m³**

	Total Number of Avoided Cases						Annual Number of Avoided Cases					
	50 µg/m³			100 µg/m³			50 µg/m³			100 µg/m³		
	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Lung Cancers												
Attfield and Costello 2004 (higher estimate) [a]	10,353	9,016	1,337	3,998	3,906	91	230	200	30	89	87	2
Midpoint	8,265	7,260	1,005	3,786	3,732	54	184	161	22	84	83	1
ToxaChemica 2004 (lower estimate) [b]	6,177	5,503	674	3,575	3,558	17	137	122	15	79	79	0
Silicosis & Other Non-Malignant Respiratory Diseases	14,091	11,411	2,680	7,523	7,370	152	313	254	60	167	164	3
End Stage Renal Disease	21,853	19,859	1,995	9,441	9,376	65	486	441	44	210	208	1
Total Number of Fatal Illnesses Prevented												
Attfield and Costello 2004 (higher estimate) [a]	46,297	40,285	6,011	20,961	20,653	309	1,029	895	134	466	459	7
Midpoint	44,209	38,529	5,680	20,750	20,478	272	982	856	126	461	455	6
ToxaChemica 2004 (lower estimate) [b]	42,121	36,772	5,348	20,539	20,304	235	936	817	119	456	451	5
Total Number of Silicosis Morbidity Cases Prevented*	11,069	8,379	2,690	6,333	5,878	455	246	186	60	141	131	10

*Assessed at 2/1 or higher X-ray, following ILO criteria

** Results are estimates based on assumptions outlined in the benefits analysis.

[a] Document ID 0543; [b] Document ID 0469

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Table VII-26c

Estimated Number of Avoided Fatal & Nonfatal Illnesses Resulting from a Reduction in Crystalline Silica Exposure of At-Risk Workers over 6.6 Years Due to Proposed PEL of 50 µg/m³ and Alternative PEL of 100 µg/m³**

	Total Number of Avoided Cases						Annual Number of Avoided Cases					
	50 µg/m³			100 µg/m³			50 µg/m³			100 µg/m³		
	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Lung Cancers												
Attfield and Costello 2004 (higher estimate) [a]	17,707	16,394	1,314	7,306	7,227	79	393	364	29	162	161	2
Midpoint	12,107	10,819	1,288	5,377	5,320	57	269	240	29	119	118	1
ToxaChemica 2004 (lower estimate) [b]	6,507	5,244	1,263	3,449	3,413	35	145	117	28	77	76	1
Silicosis & Other Non-Malignant Respiratory Diseases	14,031	11,319	2,712	7,422	7,266	156	312	252	60	165	161	3
End Stage Renal Disease	36,031	32,727	3,304	15,587	15,479	108	801	727	73	346	344	2
Total Number of Fatal Illnesses Prevented												
Attfield and Costello 2004 (higher estimate) [a]	67,769	60,439	7,330	30,316	29,972	344	1,506	1,343	163	674	666	8
Midpoint	62,169	54,865	7,304	28,387	28,065	322	1,382	1,219	162	631	624	7
ToxaChemica 2004 (lower estimate) [b]	56,569	49,290	7,279	26,458	26,158	300	1,257	1,095	162	588	581	7
Total Number of Silicosis Morbidity Cases Prevented*	8,733	6,782	1,951	9,480	6,782	2,699	194	151	43	424	151	60

*Assessed at 2/1 or higher X-ray, following ILO criteria

Results are estimates based on assumptions outlined in the benefits analysis.

[a] Document ID 0543; [b] Document ID 0469

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

TABLE VII-27

Estimated Annualized Undiscounted Monetized Benefits of the Silica Rule for Morbidity and Mortality For the Scenario in Which Workers Are Uniformly Exposed to Silica for 45 Years *

PEL	50 µg/m³			100 µg/m³		
	Valuation			Valuation		
	Low	Midpoint	High	Low	Midpoint	High
Cases						
Fatalities - Total						
ToxaChemica 2004 (lower estimate) [b]	$7,207,460,195	$7,207,460,195	$7,207,460,195	$3,473,656,028	$3,473,656,028	$3,473,656,028
Midpoint	$7,718,678,442	$7,718,678,442	$7,718,678,442	$3,792,868,857	$3,792,868,857	$3,792,868,857
Attfield and Costello 2004 (higher estimate) [a]	$8,229,896,689	$8,229,896,689	$8,229,896,689	$4,112,081,687	$4,112,081,687	$4,112,081,687
Morbidity Preceding Mortality						
ToxaChemica 2004 (lower estimate) [b]	$45,177,585	$1,857,928,191	$3,346,609,761	$21,604,397	$888,480,816	$1,755,357,235
Midpoint	$48,812,915	$2,007,431,128	$3,966,049,340	$23,874,355	$981,832,835	$1,939,791,315
Attfield and Costello 2004 (higher estimate) [a]	$52,448,245	$2,156,934,064	$4,261,419,883	$26,144,313	$1,075,184,853	$2,124,225,394
Morbidity Not Preceding Mortality						
Total	$83,781,052	$3,445,495,765	$6,807,210,478	$43,583,880	$1,792,387,046	$3,541,190,213
TOTAL						
ToxaChemica 2004 (lower estimate) [b]	$7,336,418,832	$12,510,884,151	$17,361,280,434	$3,538,844,305	$6,154,523,891	$8,770,203,477
Midpoint	$7,851,272,409	$13,317,472,941	$18,491,938,260	$3,860,327,092	$6,658,170,799	$9,273,850,385
Attfield and Costello 2004 (higher estimate) [a]	$8,366,125,986	$13,832,326,518	$19,298,527,050	$4,181,809,879	$6,979,653,586	$9,777,497,293

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

* Results are estimates based on the assumption outlined throughout this chapter.

[a] Document ID 0543; [b] Document ID 0469

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OSHA reported in the PEA that in the construction industry, which has an unusually high rate of job turnover compared to other industries, BLS data show that the mean job tenure with one's current employer is 6.6 years (BLS, 2010a, Document ID 1620), and the median age of construction workers

in the U.S. is 41.6 years (BLS, 2010b, Document ID 1672). OSHA further noted that BLS does not have data on occupational tenure within an industry, but that the Agency would expect that job tenure in the construction occupations as a whole would be substantially greater than the job tenure with a worker's current employer. None of the commenters disagreed. Furthermore, many workers may return to the construction industry after unemployment or work in another industry. Job tenure with the current employer, however, is longer in the other industries affected by the silica rule (BLS, 2010a, Document ID 1620).

Dr. Ronald Bird, submitting a comment on behalf of the U.S. Chamber of Commerce—as well as an unaffiliated commenter, Joseph Liss—suggested that OSHA's estimates of disease cases prevented from 45 years of silica exposure is unrepresentative of the typical tenure of workers affected by the standard, particularly in construction (Document ID 2368, p. 18; Document ID 1950, pp. 15–19). Dr. Bird suggested that workers will routinely change occupations in the course of their lifetime. From a probabilistic standpoint, he calculated that workers would, on average, likely work in an occupation for less than six years. The comments directly from the Chamber of Commerce go further, to say that ''[n]o such 45-year career silica exposures exist in today's working world . . .'' (Document ID 2288, p. 11).

The article (Rytina, 1983, Document ID 2368) that Dr. Bird cited for his data on occupational turnover provides data that refute the assumptions of Dr. Bird's model. While Dr. Bird assumes that occupational turnover is constant without regard to age or length of occupational experience, the Rytina article states:

> Not surprisingly, occupational mobility rates declined sharply with age . . . The rate for workers age 35–44 was less than one fourth as high as that for workers 18 and 19 years of age. * * * [O]ccupational change among older workers occurs less frequently because of attachments to a particular occupation or the risks of losing income, job security, and pension rights, which might accompany an occupational shift (Rytina, 1983, Document ID 2368, p. 5).

Furthermore, the Rytina article shows that among workers 45 to 54 years of age, 16.5 percent of workers have been in the same occupation for 25 years or more, and among workers 55 and older, 32.9 percent have been in the same occupation for 25 years or more. By comparison, Dr. Bird's model suggests that, regardless of age, no more than 13 percent of workers will remain in a given occupation for more than 20 years.

Two commenters also provided evidence of the average tenures of their workers that is contrary to Dr. Bird's estimates. The National Industrial Sand Association (NISA) noted, ''many NISA member company employees work at their workplaces for all or much of their worklives. In 2004, a study calculated the mean tenure for NISA member company employees fitting the definition of the study's cohort to be 19.7 years'' (Document ID 2195, p. 19). Southern Company, an electric utility, noted that it ''has approximately 8000 employees in job titles performing activities with potential exposures to silica-containing materials. The average tenure for these employees is 17 years; 37% of these employees have over 20 years work experience'' (Document ID 2185, p. 3).

Other commenters provided evidence to refute the Chamber of Commerce claim that that 45-year career silica exposures no longer exist in today's working world (Document ID 2288, p. 11). During the public hearing, participants on a panel comprised of members of the International Union of Bricklayers and Allied Craftworkers (BAC) were asked if they had colleagues who had worked longer than forty years in their trade. All six of the participants affirmed that they did (Document ID 3585, Tr. 3053). Further, several labor groups submitted evidence of lengthy worker tenure. The BAC noted that:

> A review of our International Pension Fund records documented 116 individuals who have worked for 40 years or more. We consider this figure to understate the work lives of Fund participants because many of these individuals had previous work experience in the construction industry before being represented by BAC. In additional, we believe this figure understates the number of participants with work lives of 45 years, because the Fund was established in 1972 and it was not until roughly a decade later that even half of BAC affiliates had commenced participation in the Fund (Document ID 4053, Attachment 1, p. 2).

Similarly, The United Association of Plumbers, Fitters, Welders, and HVAC Service Techs, submitted that ''a review of membership records documented 35,649 active members who have worked 45 years or more while they have been a member of the union.'' They also concur with the BAC statement that the number may be understated given previous work experience (Document ID 4073, Attachment 3, p. 1). And the International Union of Operating Engineers' Central Pension Fund found the average operating engineer has over 20 years of service in the trade with a range up to 49.93 years (Document ID 4025, Attachment 1, pp. 6–7).

Dr. Bird also objected to OSHA's approach of using a single representative exposure to measure lifetime exposure. He states: ''If exposures are variable over the course of a year, the lifetime exposure pattern is contrary to OSHA's assumption and the benefits from the proposed reduction in the PEL would be considerably less'' (Document ID 2368, p. 19). Dr. Bird apparently faults the Agency for not considering the possibility that future exposures may be lower than those observed on a given day. However, it is equally plausible that a worker's future exposures may be higher than on the day they were observed by OSHA. The single-day exposure data is the best available data in the record for those workers, and the Agency does not find any persuasive evidence in this record to suggest an obvious bias to characterizing exposure from a single day rather over the course of consecutive days.

Paragraph (i)(2)(v) of the general industry and maritime standard and paragraph (h)(2)(v) of the construction standard also contain specific provisions for diagnosing latent tuberculosis (TB) in the silica-exposed population and thereby reducing the risk of TB being spread to the population at large. OSHA currently lacks good methods for quantifying these benefits. Nor has the Agency attempted to assess benefits directly stemming from enhanced medical surveillance in terms of reducing the severity of symptoms from the illnesses that do result from present or future exposure to silica. Dr. Ruth Ruttenberg, an economist representing the AFL–CIO, noted this as a source of the underestimation of the benefits in her comments (Document ID 2256, Attachment 4, pp. 9–12). However, no commenters suggested how to quantify these effects.

OSHA's risk estimates are based on application of exposure-response models derived from several individual epidemiological studies as well as the pooled cohort studies of Steenland *et al.* (2001, Document ID 0492) and Mannetje *et al.* (2002, Document ID 1089). OSHA recognizes that there is uncertainty around any of the point estimates of risk derived from any single study. In its preliminary risk assessment (summarized in Section VI of this preamble), OSHA has made efforts to characterize some of the more important sources of uncertainty to the extent that available data permit. This specifically includes characterizing statistical

uncertainty by reporting the confidence intervals around each of the risk estimates (presented in the Preliminary Quantitative Risk Assessment, Document ID 1711); by quantitatively evaluating the impact of uncertainties in underlying exposure data used in the cohort studies; and by exploring the use of alternative exposure-response model forms. OSHA finds that these efforts reflect much, but not necessarily all, of the uncertainties associated with the approaches taken by investigators in their respective risk analyses. However, for reasons explained in Section VI of this preamble, OSHA concludes that characterizing the risks and benefits as a range of estimates derived from the full set of available studies, rather than relying on any single study as the basis for its estimates, better reflects the uncertainties in the estimates and more fairly captures the range of risks likely to exist across a wide range of industries and exposure situations.

Section VI of this preamble provides a more complete discussion of the source of uncertainty in the risk assessment functions used in this benefits analysis. The sources of uncertainty include the degree to which OSHA's risk estimates reflect the risk of disease among workers with widely varying exposure patterns. Some workers are exposed to fairly high concentrations of crystalline silica only intermittently, while others experience more regular and constant exposure. Risk models employed in the quantitative assessment are based on a cumulative exposure metric, which is the product of average daily silica concentration and duration of worker exposure for a specific task. Consequently, these models assume the same risk for a given cumulative exposure regardless of the pattern of exposure, reflecting a worker's long-term average exposure without regard to intermittencies or other variances in exposure. That is, the use of the cumulative exposure metric in these models assumes that there are no significant dose-rate effects in the relationship between silica exposure and risk.

Possible dose-rate effects in the silica exposure-response relationships, particularly for silicosis. OSHA's reliance on a cumulative exposure metric to assess the risks of respirable crystalline silica is discussed in Section V of this preamble. Uncertainty with respect to the form of the statistical models used to characterize the relationship between exposure level and risk of adverse health outcomes is discussed in Section VI.

In its quantitative risk assessment, OSHA used the exposure-response models from the best available evidence (*i.e.*, the key studies discussed at length in Section V, Health Effects and Section VI, Final Quantitative Risk Assessment and Significance of Risk) to estimate risks for 45 years of exposure to the previous PELs, revised PEL, and the action level. When examining the risk estimates specifically for silicosis mortality and morbidity in Table VI, one interesting observation is the apparent difference in the exposure-response relationship for these two endpoints. For example, for 45 years of exposure to the action level (25 μg/m^3), there would be an estimated 4 deaths from silicosis and 21 cases of silicosis (with chest X-ray ILO category of 2/1 or greater) per 1,000 workers; at the previous PEL (100 μg/m^3), there would be an estimated 11 deaths from silicosis and 301 cases of silicosis per 1,000 workers. In other words, nearly 20 percent of silicosis cases are estimated to be fatal at the relatively low exposure of 25 μg/m^3 but only about 4 percent are estimated to be fatal at the relatively high exposure of 100 μg/m^3.[102] Moreover, as noted previously, morbidity and mortality estimates change in opposite directions in response to varying the assumption about workers' total length of exposure. Although this issue was not explicitly raised in the rulemaking record, OSHA notes and addresses it here.

OSHA attributes this apparent difference in the exposure-response relationships for silicosis mortality and morbidity to several factors. First, the silicosis mortality study (ToxaChemica, 2004, Document ID 0469) defined deaths using death certificate data, in which silicosis or unspecified pneumoconiosis was recorded as the underlying cause of death. In contrast, the silicosis morbidity study (Buchanan *et al.*, 2003, Document ID 0306) defined silicosis cases using data from chest x-rays showing radiographic opacities. These radiographic signs of silicosis represent an early endpoint that is very different from silicosis death as the underlying cause of death. Such disparate endpoints are alone one reason why OSHA does not believe that the exposure-response curves should necessarily be proportional.

In addition, as discussed in Section V.E, Comments and Responses Concerning Surveillance Data on Silicosis Morbidity and Mortality, silicosis is well-known to be underreported on death certificates in that deaths due to silicosis could have been reported as tuberculosis or chronic obstructive pulmonary disease (Document ID 1089, pp. 724–725; 1030; 3425, p. 2; 3577, Tr. 855, 867; 4204, p. 17; 2175, p. 3; 3577, Tr. 772). Also, silica-exposed workers are at risk for other silica-related diseases, including lung cancer and renal disease, as well as other non-exposure-related causes of death such that many workers who contract silicosis will not ultimately die from silicosis. Therefore the reported silicosis deaths at any level are the lowest possible number of such deaths. Workers with higher cumulative exposures are also likely to be older, and therefore may have a higher rate of other conditions that could have been listed on death certificates. Furthermore, as discussed in Section VI, OSHA's risk assessment required some degree of extrapolation at high doses (*e.g.*, 45 years of exposure to 250 and 500 μg/m^3 respirable crystalline silica) that result in cumulative exposures not experienced by many of the cohort members studied. Thus, OSHA attributes the apparent non-proportionality in the exposure-response curves for silicosis mortality and morbidity to these factors. It is possible nonetheless, that future research may shed additional light on this topic.

d. Estimating a Stream of Benefits Over Time

Risk assessments in the occupational environment are generally designed to estimate the risk of an occupationally related illness over the course of an individual worker's lifetime. As previously discussed, the current occupational exposure profile for a particular substance for the current cohort of workers can be matched up against the expected profile after the final standard takes effect, creating a ''steady state'' estimate of benefits. However, in order to annualize the benefits for the period of time after the silica rule takes effect, it is necessary to create a timeline of benefits for an entire active workforce over that period.

There are various approaches for modeling the workforce. As explained below, OSHA uses a model that considers the effect of lowering exposures for the entire working population. At one extreme, however, one could assume that all of the relevant silica exposures will occur after the

[102] Even if one subtracts off the Table VI–1 estimates of other silica-attributable diseases (*e.g.,* lung cancer) from the 100 μg/m^3 denominator, on the assumption that those diseases cause mortality before silicosis has a chance to do so, the ratio of fatal silicosis cases to the remaining silicosis diagnoses is still no more than 6.6 percent at 100 μg/m^3, as opposed to the ratio of nearly 20 percent at 25 μg/m^3.

standard goes into effect and none of the benefits occurs until after the worker retires, or at least 45 years in the future. In the case of lung cancer, that period would effectively be 60 years, since the 45 years of exposure must be added to a 15-year latency period during which it is assumed that lung cancer does not develop.[103] At the other extreme, one could assume that the benefits occur immediately, or at least immediately after a designated lag. Neither extreme reflects the reality that silica-related diseases that this standard aims to reduce significantly occur at various times during and after the working lives of these populations of workers, with the majority of cases occurring sometime after the typical worker is middle aged. Indeed, based on the various risk models (as detailed in model life tables in Appendix A to the QRA), which reflect real-world experience with development of disease over an extended period of time; it appears that the actual pattern occurs at some point between these two extremes.

The model OSHA uses, therefore, is one that considers the effect of lowering exposures for the entire working population. This population-based approach does not simply follow the pattern of the risk assessments, which are based in part on life tables, and observe that typically the risk of the illness grows gradually over the course of a working life and into retirement. While this would be a good working model for an individual exposed over a working life, it is not very descriptive of the exposed population as a whole. In the latter case, in order to estimate the benefits of the standard over time, OSHA considers that workers currently being exposed to silica are going to vary considerably in age. Since the health risks from crystalline silica exposure depend on a worker's cumulative exposure over a working lifetime, the overall benefits of the final standard will phase in over several decades, as the cumulative exposure gradually falls for all age groups, until those now entering the workforce reach retirement and the annual stream of silica-related illnesses reaches a new, significantly lowered ''steady state.'' However, the beneficial effects of the rule begin in the near term and increase over time until that ''steady state'' is reached; and, for a given level of cumulative exposure, the near-term impact of the final rule will be greater for workers who are now middle-aged or older, compared to younger workers with similar current levels of cumulative exposure. This conclusion follows from the structure of the relative risk models used in this analysis and the fact that the background mortality rates for diseases such as lung cancer, chronic obstructive pulmonary disease and renal disease increase with age.

In order to characterize the magnitude of benefits before the steady state is reached, OSHA created a linear phase-in model to reflect the potential timing of benefits. Specifically, OSHA estimated that, for all non-cancer cases, while the number of cases of silica-related disease would gradually decline as a result of the final rule, they would not reach the steady-state level until 45 years had passed. The reduction in cases in any given year in the future was estimated to be equal to the steady-state reduction (the number of cases in the baseline minus the number of cases in the new steady state) times the ratio of the number of years since the standard was implemented and a working life of 45 years; in other words, the number of non-malignant silica-relates cases of disease avoided is assumed to increase in direct proportion to the number of years the standard is in effect until year 45, at which point the numbers hold steady. This formulation also assumes that the number of workers is constant over the entire time frame. Expressed mathematically:

$N_t = (C - S) \times (t/45)$,

where N_t is the number of non-malignant silica-related diseases avoided in year t; C is the current annual number of non-malignant silica-related diseases; S is the steady-state annual number of non-malignant silica-related diseases; and t represents the number of years after the final standard takes effect, with $t \leq 45$.

In the case of lung cancer, the function representing the decline in the number of cases as a result of the final rule is similar, but there would be a 15-year lag before any reduction in cancer cases would be achieved. Expressed mathematically, for lung cancer:

$L_t = (C_m - S_m) \times ((t\text{-}15)/45)$,

where $15 \leq t \leq 60$ and L_t is the number of lung cancer cases avoided in year t as a result of the final rule; C_m is the current annual number of silica-related lung cancers; and S_m is the steady-state annual number of silica-related lung cancers.

This model was extended to 60 years for all the health effects previously discussed in order to incorporate the 15-year lag, in the case of lung cancer, and a 45-year working life. OSHA also has estimated the benefits using other job tenures. For this purpose, OSHA examined scenarios for the same number of years—60 years—but with the work force restarting exposure whenever the first job tenure cycle was complete.

OSHA also has estimated the benefits using other job tenures. For this purpose, OSHA examined scenarios for the same number of years—60 years—but with the work force restarting exposure whenever the first job tenure cycle was complete.

In order to compare costs to benefits, OSHA assumes that economic conditions remain constant and that annualized costs will continue for the entire 60-year time horizon used for the benefits analysis (as discussed in Chapter V of the FEA). OSHA invited comments on this assumption in the PEA, for both the benefit and cost analysis. OSHA was particularly interested in what assumptions and time horizon should be used instead and why. The Agency did not receive any comments on this point.

2. Monetizing the Benefits

OSHA also estimates the monetary value of health and longevity improvements of the type associated with the final silica rule. These estimates are for informational purposes only because OSHA cannot use benefit-cost analysis as a basis for determining the PEL for a health standard. The Agency's methodology for monetizing benefits is based on both the relevant academic literature and on the approaches OSHA and other regulatory agencies have taken in the past for similar regulatory actions.

In explaining OSHA's methodology for monetizing health and longevity improvements, OSHA relied on a 45 year occupational tenure. Later, OSHA discusses monetization under alternative occupational tenures of 25, 13 and 6.6 years.

a. Placing a Monetary Value on Individual Silica-Related Fatalities Avoided

To estimate the monetary value of the reductions in the number of silica-related fatalities, OSHA relied, as OMB recommends in its Circular A–4, on estimates developed from the willingness of affected individuals to pay to avoid a marginal increase in the risk of fatality. While a willingness-to-pay (WTP) approach clearly has theoretical merit, it should be noted that an individual's willingness to pay to reduce the risk of fatality would tend to underestimate the total willingness to pay, which would include the willingness of others—particularly the

[103] This assumption is consistent with the 15-year lag incorporated in the lung cancer risk models used in OSHA's QRA.

immediate family—to pay to reduce that individual's risk of fatality.[104]

For estimates using the willingness-to-pay concept, OSHA relies on existing studies of the imputed value of fatalities avoided based on the theory of compensating wage differentials in the labor market. These studies rely on certain critical assumptions for their estimates, particularly that workers understand the risks to which they are exposed and that workers have legitimate choices between high- and low-risk jobs. Actual labor markets only imperfectly reflect these assumptions. A number of academic studies, as summarized in Viscusi and Aldy (2003, Document ID 1220), have shown a correlation between higher job risk and higher wages, suggesting that employees demand monetary compensation in return for a greater risk of injury or fatality. The estimated trade-off between lower wages and marginal reductions in fatal occupational risk—that is, workers' willingness to pay for marginal reductions in such risk—yields an imputed value of an avoided fatality: the willingness-to-pay amount for a reduction in risk divided by the reduction in risk.

OSHA has used this approach in many recent proposed and final rules (see 69 FR 59305 (Oct. 4, 2004) and 71 FR 10099 (Feb. 28, 2006), the preambles for the proposed and final hexavalent chromium rule). Limitations to this approach (see Hintermann, Alberini and Markandya, (2010, Document ID 0739)), have been examined in a recent WTP analysis, by Kniesner et al. (2012, Document ID 3819), using panel data to examine the trade-off between fatal job risks and wages. This article addressed many of the earlier econometric criticisms by controlling for measurement error, endogeneity, and heterogeneity. Accordingly, OSHA views this analysis as buttressing the estimates in Viscusi and Aldy (2003, Document ID 1220), which the Agency is continuing to rely on for the FEA.[105]

OSHA received several comments on the use of willingness-to-pay measures and estimates based on compensating wage differentials. For example, Peter Dorman, Professor of Economics, Evergreen State College, Eric Frumin of Change to Win, and Dr. Ruth Ruttenberg, representing the AFL–CIO, in addition to critiquing the academic studies used to develop the willingness-to-pay measure, cited the absence of effective labor markets for capturing a wage differential for hazardous work (Document ID 2260, Attachment 1; 2372, Attachment 1, pp. 4–15; 2256, Attachment 4, p. 9). OSHA acknowledges that there has been an absence of a wage premium for risk in certain labor markets, and cites this absence in Chapter II of the FEA as an example of market failure. Nonetheless, while the Agency agrees that the absence of a wage premium for risk demonstrates the need for regulatory intervention in the labor market, it does not, in itself, invalidate the use of the willingness-to-pay approach for the informational purposes for which OSHA calculates benefits, so long as there are some reasonably well-functioning parts of the labor market that can be used to estimate the willingness to pay for some subset of workers. OSHA finds that there are such sections of the labor market.

Several studies indicate that there are enough functional parts of the labor market to allow for some quantification of the risk, typically expressed as the value of a statistical life (VSL), a possible measure of willingness to pay. For example, Viscusi and Aldy (2003) conducted a meta-analysis of studies in the economics literature that use a willingness-to-pay methodology to estimate the imputed value of life-saving programs and found that each fatality avoided was valued at approximately $7 million in 2000 dollars. For the PEA, the Agency used the GDP Deflator (U.S. BEA, 2010) to convert this estimate to $8.7 million in 2009 dollars for each fatality avoided. For the FEA, the base year has been further updated to 2012 using the GDP Deflator (U.S. BEA, 2013), yielding an estimate of $9.0 million per fatality avoided.[106]

There are a number of factors that could influence the value of a statistical life (VSL) calculation in different labor markets, but for the purpose of its analysis OSHA has identified methods for normalizing the risk between markets. For example, in Kniesner, Viscusi, and Ziliak (2010, Document ID 0767), the authors addressed the issue of the heterogeneity of the VSL approach among various labor markets by developing analytical tools (quantile regressions) for differentiating by income. For the purpose of quantifying the effects of income growth over time on the value of a statistical life, OSHA relies on their data, which generally show that VSL increases with increased worker income (as banded by quartile). Despite potential weaknesses in the VSL approach, Executive Order 12866 recommends monetization of regulatory benefits (including increases in longevity), and the Agency concludes this constitutes the best available method for this purpose.

b. Placing a Monetary Value on Individual Non-Fatal Silica-Related Diseases Avoided

In addition to the benefits that are based on the imputed value of fatalities avoided, workers also place a value on occupational injuries or illnesses avoided, which reflect their willingness to pay to avoid monetary costs (for medical expenses and lost wages) and quality-of-life losses as a result of occupational illness. Silicosis, lung cancer, and renal disease can be totally disabling and adversely affect individuals for years or even decades in non-fatal cases, or before ultimately proving fatal. Because monetary measures of the willingness to pay for avoiding these illnesses are rare and difficult to find OSHA has included a range based on a variety of estimation methods.

Consistent with Buchanan *et al.* (2003), OSHA estimated the total number of moderate to severe silicosis cases prevented by the final rule, as measured by 2/1 or more severe x-rays (based on the ILO rating system). However, while radiological evidence of moderate to severe silicosis is evidence of significant material impairment of health, placing a precise monetary value on this condition is difficult, in part because the severity of symptoms may vary significantly among individuals.

[104] *See*, for example, Thaler and Rosen (1976), (Document ID 1520, pp. 265–266); Sunstein (2004) (Document ID 1523, p. 433); or Viscusi, Magat and Forrest (1988), the last of whom write that benefits from improvement in public health ''consist of two components, the private valuation consumers attach to their own health, plus the altruistic valuation other members of society place on their health.'' That paper uses contingent valuation methods to suggest that the effect of altruism could significantly alter willingness-to-pay estimates for some kinds of health improvement. There are, however, many questions concerning how to measure the altruistic component and the conditions under which it might matter.

[105] For example, if workers are willing to pay $50 each for a 1/100,000 reduction in the probability of dying on the job, then the imputed value of an avoided fatality would be $50 divided by 1/100,000, or $5,000,000. Another way to consider this result would be to assume that 100,000 workers made this trade-off. On average, one life would be saved at a cost of $5,000,000.

[106] An alternative approach to valuing an avoided fatality is to monetize, for each year that a life is extended, an estimate from the economics literature of the value of that statistical life-year (VSLY). *See*, for instance, Aldy and Viscusi (2007) (Document ID 1522) for discussion of VSLY theory and FDA (2003, Document ID 1618, pp. 41488–9), for an application of VSLY in rulemaking. OSHA has not investigated this approach which was not recommended by any commenter in the record. It acknowledges, however, that such an approach would have the effect of lowering estimated benefits because silica-related health outcomes largely affect older workers and retirees as they approach actuarially expected life expectancies.

For that reason, in the PEA, as well as in the FEA, the Agency has employed a broad range of valuation, which should encompass the range of severity these individuals may encounter. Using the willingness-to-pay approach, discussed in the context of the imputed value of fatalities avoided, OSHA has estimated a range in valuations (updated and reported in 2012 dollars) that runs from approximately $64,000 per case—which reflects estimates developed by Viscusi and Aldy (2003, Document ID 1220), based on a series of studies primarily describing simple accidents—to upwards of $5.2 million per case—which reflects estimates developed by Magat, Viscusi, and Huber (1996, Document ID 0791) for non-fatal cancer. The latter number is based on an approach that applies a willingness-to-pay value to avoid serious illness that is calibrated relative to the value of an avoided fatality. OSHA (2006, Document ID 0941) previously used this approach in the FEA supporting its hexavalent chromium final rule, and EPA (2003, Document ID 0657) used this approach in its Stage 2 Disinfection and Disinfection Byproducts Rule concerning regulation of primary drinking water. EPA used the study by Magat, Viscusi & Huber (1996, Document ID 0791) on the willingness to pay to avoid nonfatal lymphoma and chronic bronchitis as a basis for valuing a case of nonfatal cancer at 58.3 percent of the value of a fatal cancer. OSHA's estimate of $5.2 million in 2012 dollars for an avoided case of non-fatal cancer is based on this 58.3 percent figure.

There are several benchmarks for valuation of health impairment due to silica exposure, using a variety of techniques, which provide a number of mid-range estimates between OSHA's high and low estimates of $5.2 million and $64,000. For example, EPA (2008) recently estimated a cost of approximately $460,000, in 2008 dollars, per case of chronic bronchitis, which OSHA (2009) used as the basis for comparison with less severe lung impairments from diacetyl exposure. Another approach is to employ a cost-of-injury model. Combining estimates of productivity losses (*i.e.*, lost wages, fringe benefits, and household production), medical costs (including hospitalizations), and loss of quality-of-life components, Miller (2005), using an enhanced cost-of-injury model, estimated the average silicosis disease cost the equivalent of $335,000 in 2012 dollars).[107]

Miller (2005) also estimated the morbidity costs of several different pneumoconioses other than silicosis and found the other cases to be even more costly to society than silicosis. While the full costs of renal disease are less well known, the medical costs alone of dealing with end-stage renal disease run over $64,000 annually per patient (Winkelmayer, 2002). This suggests that a more comprehensive analysis of the direct costs of renal disease, as well as for the various lung impairments, would produce an estimate well above the $64,000 estimate of injuries in Viscusi and Aldy (2003). Moreover, several studies (*e.g.*, Alberini and Krupnick, 2000) have found that the cost of injury approach tends to significantly underestimate the true economic cost of an injury or illness, relative to the willingness to pay approach, which includes quality of life impacts and psychic costs as well as medical costs and lost income. In this way, looking only at specific elements of this valuation, such as a workers compensation payouts (to the extent they can be linked to a specific employer in a timely manner), would dramatically underestimate the cost of the illness to society.

Thus, the various studies presented in Chapter VII of the FEA suggest that the imputed value of avoided morbidity associated with silica exposure, both for cases preceding death and for non-fatal cases, ranges between $64,000 and $5.2 million, depending in part on the model used to compute the value and in part on the severity and duration of the case. OSHA considers this wide range of estimates is descriptive of the value of preventing morbidity associated with moderate-to-severe silicosis, as well as the morbidity preceding mortality due to other causes enumerated here—lung cancer, lung diseases other than cancer, and renal disease. OSHA is therefore applying these values to monetize cases of avoided silica-related morbidity.[108]

OSHA has included these estimates of silicosis morbidity throughout the analysis. For mortality, OSHA has included the midpoints of $64,000 and $5.2 million ($2.63 million) for all mortality cases. The high and low estimates in the remainder of this document for mortality not only reflect different point estimates, but different levels for the morbidity effect.

Public Comment on Valuing Non-Fatal Cases of Silicosis

OSHA requested public input on the issue of valuing the cost to society of non-fatal cases of moderate-to-severe silicosis, as well as the morbidity associated with other related diseases of the lung, and with renal disease. A number of commenters did not directly provide quantitative estimates of the cost of silicosis or other silica-related health effects, but provided qualitative descriptions of the heavy burden to health, work, and family life incurred by having silicosis.

For example, Alan White, of the United Steelworkers Local Union 593, who developed silicosis after working in a foundry for 16 years as a general helper, described the practical implications of developing silicosis:

> First of all, for me, there was the growing problem of being out of breath sooner than I used to. That's a difficult situation for a competitor, especially since I didn't know why. Then, I received a big surprise during the conversation with the first doctor when I found out that I have silicosis and that I will lose my job. He and the other doctors all agreed that the diagnosis is silicosis. Watching your wife and other loved ones cry as they figure out what silicosis is was a big hit and then, shortly afterward, there was the radical pay cut from a transfer out of the foundry to a department where I knew nothing because I chose my health over money . . . There are also difficulties outside of work and issues for me to look forward to in the future. Walking while talking on a cell phone is very exhaustive, as well as walking up the stairs from my basement to my second floor apartment. I have increasing difficulty on my current job. Certain irritants like air fresheners, potpourri and cleaners make home life increasingly difficult and I was told that it's downhill from here for both work and home life (Document ID 3477, p. 2).

Mr. White also described how the foundry went to considerable expense to hire people to do the job he previously had done, including the costs to the foundry for mistakes made by the trainees replacing him. Such personnel costs to the employer would not be

[107] Miller (2005) estimated the cost of a silicosis case, using an enhanced direct cost approach—including a quality-adjusted-life-years component—to be $265,808 in 2002 dollars.

[108] For the purpose of simplifying the estimation of the monetized benefits of avoided illness and death, OSHA simply added the monetized benefits of morbidity preceding mortality to the monetized benefits of mortality at the time of death, and both would be discounted at that point. In theory, however, the monetized benefits of morbidity should be recognized (and discounted) at the onset of morbidity, as this is what a worker's willingness to pay is presumed to measure—that is, the risk of *immediate* death or an *immediate* period of illness that a worker is willing to pay to avoid—a practice that would increase the present value of discounted morbidity benefits. A parallel tendency toward underestimation occurs with regard to morbidity not preceding mortality, since it implicitly assumes that the benefits occur at retirement, as per the Buchanan model, but many, if not most, of the 2/0 or higher silicosis cases will have begun years before (with those classifications, in turn, preceded by a 1/0 classification). As a practical matter, however, the Agency lacks sufficient data at this time to refine the analysis in this way.

captured by either the willingness-to-pay approach or cost-of-injury approach.

In addition to questioning the underlying willingness to pay approach, at least one commenter indicated various ways in which the approach employed by OSHA would tend to underestimate the economic benefits of the rulemaking. Dr. Ruttenberg argued that the WTP approach does not include costs to third parties of silica-related illnesses and injuries, starting with a number of government programs:

> In its *Preliminary Economic Analysis*, OSHA says that it wants public input on the issue of valuing the cost to society of non-fatal cases of moderate-to severe silicosis, as well as the morbidity associated with other related diseases of the lung, and with renal disease. (PEA, p. VII–15) This is a key request because adding such societal costs can double the benefits of preventing these diseases. In an article by a lawyer and two economists looking at the social cost of dangerous products, Shapiro, Ruttenberg, and Leigh argue that a large economic burden is borne by private insurance, government programs, the business community and the victims and their families. Those affected by occupational exposures, such as silica, may become eligible for a range of cash or in-kind assistance. Such programs may include unemployment compensation, food stamps, Medicaid, Medicare, State Children's Health Insurance Program (SCHIP), Temporary Assistance for Needy Families (TANF), Social Security Disability, and Old Age, Survivors and Disability Insurance. There are also costs for use of military hospitals and clinics (Document ID 2256, Attachment 4, pp. 9–10) (citations omitted).

Part of the cost of the injury or fatality may be borne in substantial part by the victim's family:

> There is another group of costs that can easily double, or even triple, the direct and indirect totals. These are social and economic impacts that are also caused by an incident. They often involve third-party payments, or stress on the victim or his/her family members. The financial pressures on a family can include the need for a caregiver, need for additional income from children or spouse to fill the gap between previous earnings and workers compensation, or psychotherapy for family members to cope with harsh new realities. When children lose their chance at college and higher future earnings, the impact can be hundreds of thousands of dollars (Document ID 2256, Attachment 4).

Dr. Ruttenberg pointed to an existing Department of Transportation study, which suggested that only a fraction of the economic cost of motor vehicle accidents was actually borne by the victim, with the remainder of the costs split between governmental bodies, insurers, and other parties (Document ID 2256, Attachment 4, p. 11).[109]

The Center for Progressive Reform argued that there is value to reducing economic inequities created by occupational illnesses related to silica exposure:

> The proposal's implications for fair treatment of workers also deserve more attention. The proposed standards would benefit a population comprising mostly construction workers (more than 85% of the total affected population). This is an industry that is a bastion for middle class workers and those striving to attain middle class status. It is also an industry that employs a significant number of foreign-born and non-union workers, groups who typically have limited power to negotiate improved working conditions. Ensuring that these workers' health is better protected against the hazards of silica exposure is an important step toward reducing socioeconomic inequality, given the linkages between individual health and social mobility. Other federal agencies, including the National Highway Traffic Safety Administration (NHTSA) and Department of Justice (DOJ), have gone so far as to argue that equity and other non-monetizable benefits are sufficient to justify rules for which the monetized costs far outweigh the monetized benefits. (As with the OSH Act, the authorizing statutes under which NHTSA and DOJ were acting do not require cost-benefit analysis, much less require the agencies to produce rules with monetized benefits that outweigh monetized costs) (Document ID 2351, p. 7) (citations omitted).

The Agency recognizes that, as with third party effects, there are aspects of economic equity issues related to occupational injury, illness, and mortality that merit attention for policy making. As noted previously, however, the OSH Act requires that OSHA policy for toxic substances be ultimately determined by issues of risk and feasibility, as opposed to cost-benefit criteria.

The Agency requested public input on the issue of valuing the cost to society of non-fatal cases of moderate to severe silicosis, as well as the morbidity associated with other related diseases of the lung, and with renal disease. The final benefits analysis summarized below and discussed in greater detail in the FEA incorporates OSHA's response to public comment.

c. Adjusting Monetized Benefits To Reflect Rising Future Value

In the PEA, OSHA suggested, provided estimates, and requested comment on adjusting future values of illness and mortality prevention to account for changes in real income over time. Ronald White of the Center for Effective Government favored integrating this element into the monetized benefits analysis (Document ID 2341, p. 3).[110] No commenters argued against it. For the reasons provided in the PEA and described below, the Agency is adopting this approach and has used it to develop its primary benefits estimates.

OSHA's estimates of the monetized benefits of the final rule are based on the imputed value of each avoided fatality and each avoided silica-related disease. As previously discussed, these, in turn, are derived from a worker's willingness-to-pay to avoid a fatality (with an imputed value per fatality avoided of $9.0 million in 2012 dollars) and to avoid a silica-related disease (with an imputed value per disease avoided of between $64,000 and $5.3 million in 2012 dollars). Two related factors suggest that these values will tend to increase over time and help to better identify the amount that a worker would be willing to pay to avoid a fatality.

First, economic theory and empirical evidence from the relevant studies indicate that the value of reducing life-threatening and health-threatening risks—and correspondingly the willingness of individuals to pay to reduce these risks—will increase as real per capita income increases.[111] With increased income, an individual's health and life becomes more valuable relative to other goods because, unlike other goods, they are without close substitutes. Expressed differently, as income increases, consumption will increase but the marginal utility of consumption will decrease. In contrast, added years of life (in good health) are, in the model of Hall and Jones (2007, Document ID 0720), not subject to the same type of diminishing returns and, indeed, may be viewed as the ultimate good.

Second, real per capita income has broadly been increasing throughout U.S. history, including during recent

[109] The Agency acknowledges this is a likely and potentially substantial source of underestimation of morbidity costs and is currently investigating ways to capture this currently unquantified dimension of benefits for potential use in future rulemakings.

[110] The estimates of monetized benefits to reflect changes in real income over time developed in the PEA contained an error in the formulas (an inconsistent discount rate was used) that resulted in underestimated benefits. That error has been corrected in the estimates presented in the FEA.

[111] Simple modeling can show this directly. For example, Rosen (1988) (Document ID 1165) demonstrates that the value of life can be expressed as the marginal rate of substitution between wealth and the probability of survival. An increase in wealth or income will therefore increase an individual's willingness to pay.

periods.[112] For example, for the period 1950 through 2000, real per capita income grew at an average rate of 2.31 percent a year (Hall and Jones, 2007, Document ID 0720),[113] although real per capita income for the recent 25 year period 1983 through 2008 grew at an average rate of only 1.3 percent a year (U.S. Census Bureau, 2010, Document ID 1621). More important is the fact that real U.S. per capita income is estimated to grow significantly in future years. The Annual Energy Outlook (AEO) estimates, prepared by the Energy Information Administration (EIA) in the Department of Energy (DOE), estimates an average annual growth rate of per capita income in the United States of 2.7 percent for the period 2011–2035.[114] The U.S. Environmental Protection Agency prepared its economic analysis of the Clean Air Act using the AEO estimates. OSHA concludes that it is reasonable to use the same AEO estimates employed by DOE and EPA, and correspondingly estimates that per capita income in the United States will increase by 2.7 percent per year over the 60-year period in the analysis for this silica rule. OSHA, as discussed below, will not use this value combined with the best estimate of income elasticity. Instead OSHA derives a lower combined measure of the adjustment that combines income elasticity and rate of economic growth. Further, OSHA analyzes the sensitivity of the results to this assumption later in this chapter.

On the basis of the predicted increase in real per capita income in the United States over time and the expected resulting increase in the value of avoided fatalities and diseases, OSHA has adjusted its estimates of the benefits of the final rule to reflect the anticipated increase in their value over time. This type of adjustment has been supported by EPA's Science Advisory Board (EPA, 2000b, Document ID 0652) [115] and applied by EPA.[116] OSHA accomplished this adjustment by modifying benefits in year i from $[B_i]$ to $[B_i * (1 + k)^i]$, where ''k'' is the estimated annual increase in the magnitude of the benefits of the final rule.[117]

What remains is to estimate a value for ''k'' with which to increase benefits annually in response to annual increases in real per capita income, where ''k'' is equal to $(1 + g) * (\eta)$, ''g'' is the expected annual percentage increase in real per capita income, and ''η'' is the income elasticity of the value of a statistical life. Probably the most direct evidence of the value of ''k'' comes from the work of Costa and Kahn (2003, 2004). They estimate repeated labor market compensating wage differentials from cross-sectional hedonic regressions using census and fatality data from the Bureau of Labor Statistics for 1940, 1950, 1960, 1970, and 1980. In addition, with the imputed income elasticity of the value of life on per capita GNP of 1.7 derived from the 1940–1980 data, they then predict the value of an avoided fatality in 1900, 1920, and 2000. Given the change in the value of an avoided fatality over time, it is possible to estimate a value of ''k'' of 3.4 percent a year from 1900–2000; of 4.3 percent a year from 1940–1980; and of 2.5 percent a year from 1980–2000.[118]

Other, more indirect evidence comes from estimates in the economics literature on the income elasticity of the value of a statistical life. Viscusi and Aldy (2003, Document ID 1220) performed a meta-analysis on 49 wage-risk studies and concluded that the confidence interval upper bound on the income elasticity did not exceed 1.0 and that the point estimates across a variety of model specifications ranged between 0.5 and 0.6.[119] Applied to a long-term increase in per capita income of about 2.7 percent a year, this would suggest a value of ''k'' of about 1.5 percent a year.

More recently, Kniesner, Viscusi, and Ziliak (2010, Document ID 0767), using panel data quintile regressions, developed an estimate of the overall income elasticity of the value of a statistical life of 1.44. Applied to a long-term increase in per capita income of about 2.7 percent a year, this would suggest a value of ''k'' of about 3.9 percent a year.

Based on the preceding discussion of these three approaches for estimating the annual increase in the value of the benefits of the final rule and the fact that the estimated increase in real per capita income in the United States has flattened in recent years and could remain so, OSHA has selected a conservative value for ''k'' of approximately 2 percent a year over the next 60 years.

Thus, based on the best current thinking and data on willingness to pay and its relationship to income elasticity as income increases, OSHA concludes that a 2 percent increase in benefits per year, as measured by a corresponding anticipated increase in VSL, is a reasonable, mid-range estimate. However, OSHA recognizes the uncertainties surrounding these estimates and has subjected them to sensitivity analysis, as discussed below.

Accordingly, OSHA concludes that the rising value, over time, of health benefits is a real phenomenon that should be taken into account in estimating the annualized benefits of the final rule. Table VII–4, in the following section, and the monetized benefits estimates that follow it, show estimates of the monetized benefits of the silica rule with this adjustment integrated into the valuation. OSHA provides a sensitivity analysis of the effects of this approach later in this chapter.

d. The Monetized Benefits of the Final Rule

Table VII–27 presents the estimated annualized (over 60 years, using a 0 percent discount rate) benefits from each of these components of the valuation, and the range of estimates, based on risk model uncertainty (notably in the case of lung cancer), and the range of uncertainty regarding valuation of morbidity. As shown, the full range of monetized benefits, undiscounted, for the final PEL of 50 μg/m^3 runs from $7.3 billion annually, in the case of the lowest estimate of lung cancer risk and the lowest valuation for morbidity, up to $19.3 billion annually, for the highest of both. Note that the value of total benefits is more sensitive to the valuation of morbidity (ranging from $7.9 billion to $18.5 billion, given estimates at the midpoint of the lung cancer models) than to the lung cancer model used (ranging from $12.5 to $13.8

[112] In addition, as Costa (1998) and Costa and Kahn (2004) (Document ID 0609) point out, elderly health, longevity, and well-being in the United States have historically been improving, which also has the effect of increasing the imputed value of life. Of course, improvements in elderly health, longevity, and well-being are not independent of increases in per capita income over the same period.

[113] The results are similar if the historical period includes a major economic downturn (such as the United States has recently experienced). From 1929 through 2003, a period in U.S. history that includes the Great Depression, real per capita income still grew at an average rate of 2.22 percent a year (Gomme and Rupert, 2004) (Document ID 0710).

[114] The EIA used DOE's National Energy Modeling System (NEMS) to produce the Annual Energy Outlook (AEO) estimates (EIA, 2011) (Document ID 1573). Future per capita GDP was calculated by dividing the projected real gross domestic product each year by the estimates U.S. population for that year.

[115] Supplementary evidence in support for this type of adjustment comes from EPA (2010) (Document ID 1713) and U.S. Department of Transportation (2014) guidelines.

[116] *See*, for example, EPA (2003) (Document ID 0657) and EPA (2008) (Document ID 0661).

[117] This precise methodology was suggested in Ashford and Caldart (1996) (Document ID 0538).

[118] These estimates for ''k'' were not reported in Costa and Kahn (2003 Document ID 0610, 2004, Document ID 0609) but were derived by OSHA from the data presented. The changes in the value of ''k'' for the different time periods mainly reflect different growth rates of per capita income during those periods.

[119] These results conflict with the more recent work by Hall and Jones (2007) (Document ID 0720), which concludes that the income elasticity of the value of life should be larger than 1.

billion, given estimates at the midpoint of the morbidity valuation).[120]

[120] As previously indicated, these valuations include all the various estimated health endpoints. In the case of mortality this includes lung cancer, non-malignant respiratory disease and end-stage renal disease. The Agency highlighted lung cancers in this discussion due to the model uncertainty. In calculating the monetized benefits, the Agency is typically referring to the midpoint of the high and low ends of potential valuation—in this case, the undiscounted midpoint of $7.7 billion and $19.5 billion.

This result comports with the very wide range of valuation for morbidity. At the low end of the valuation range, the total value of benefits is dominated by mortality ($7.7 billion out of $7.9 billion at the case frequency midpoint), whereas at the high end the majority of the benefits are related to morbidity ($11.2 billion out of $18.7 billion at the case frequency midpoint). Also, the analysis illustrates that most of the morbidity benefits are related to silicosis cases that are not ultimately fatal. At the valuation and case frequency midpoint of $13.3 billion, $7.7 billion in benefits are related to mortality, $2.0 billion are related to morbidity preceding mortality, and $3.5 billion are related to morbidity not preceding mortality.

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TABLE VII-27

Estimated Annualized Undiscounted Monetized Benefits of the Silica Rule for Morbidity and Mortality For the Scenario in Which Workers Are Uniformly Exposed to Silica for 45 Years *

PEL	50 µg/m³			100 µg/m³		
	Valuation			Valuation		
	Low	Midpoint	High	Low	Midpoint	High
Cases						
Fatalities - Total						
ToxaChemica 2004 (lower estimate) [b]	$7,207,460,195	$7,207,460,195	$7,207,460,195	$3,473,656,028	$3,473,656,028	$3,473,656,028
Midpoint	$7,718,678,442	$7,718,678,442	$7,718,678,442	$3,792,868,857	$3,792,868,857	$3,792,868,857
Attfield and Costello 2004 (higher estimate) [a]	$8,229,896,689	$8,229,896,689	$8,229,896,689	$4,112,081,687	$4,112,081,687	$4,112,081,687
Morbidity Preceding Mortality						
ToxaChemica 2004 (lower estimate) [b]	$45,177,585	$1,857,928,191	$3,346,609,761	$21,604,397	$888,480,816	$1,755,357,235
Midpoint	$48,812,915	$2,007,431,128	$3,966,049,340	$23,874,355	$981,832,835	$1,939,791,315
Attfield and Costello 2004 (higher estimate) [a]	$52,448,245	$2,156,934,064	$4,261,419,883	$26,144,313	$1,075,184,853	$2,124,225,394
Morbidity Not Preceding Mortality						
Total	$83,781,052	$3,445,495,765	$6,807,210,478	$43,583,880	$1,792,387,046	$3,541,190,213
TOTAL						
ToxaChemica 2004 (lower estimate) [b]	$7,336,418,832	$12,510,884,151	$17,361,280,434	$3,538,844,305	$6,154,523,891	$8,770,203,477
Midpoint	$7,851,272,409	$13,317,472,941	$18,491,938,260	$3,860,327,092	$6,658,170,799	$9,273,850,385
Attfield and Costello 2004 (higher estimate) [a]	$8,366,125,986	$13,832,326,518	$19,298,527,050	$4,181,809,879	$6,979,653,586	$9,777,497,293

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

* Results are estimates based on the assumption outlined throughout this chapter.

[a] Document ID 0543; [b] Document ID 0469

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3. Discounting of Monetized Benefits

As previously noted, the estimated stream of benefits arising from the final silica rule is not constant from year to year, both because of the 45-year delay after the rule takes effect until all active workers obtain reduced silica exposure over their entire working lives and because of, in the case of lung cancer, a 15-year latency period between reduced exposure and a reduction in the probability of disease. An appropriate discount rate [121] is needed to reflect the timing of benefits over the 60-year period after the rule takes effect and to

[121] Here and elsewhere throughout this section, unless otherwise noted, the term ''discount rate'' always refers to the real discount rate—that is, the discount rate net of any inflationary effects.

allow conversion to an equivalent steady stream of annualized benefits.[122]

a. Alternative Discount Rates for Annualizing Benefits

Following OMB (2003) guidelines (Document ID 1493], OSHA has estimated the annualized benefits of the final rule using separate discount rates of 3 percent and 7 percent. Consistent with the Agency's own practices in recent final and final rules, OSHA has also estimated, for benchmarking purposes, undiscounted benefits—that is, benefits using a zero percent discount rate.

The ''appropriate'' or ''preferred'' discount rate to use to monetize health benefits is a controversial topic, which has been the source of scholarly economic debate for several decades.[123] However, in simplest terms, the basic choices involve a social opportunity cost of capital approach or social rate of time preference approach. OSHA analyzes the benefits of this rule under both approaches.

The social opportunity cost of capital approach reflects the fact that private funds spent to comply with government regulations have an opportunity cost in terms of foregone private investments that could otherwise have been made. The relevant discount rate in this case is the pre-tax rate of return on the foregone investments (Lind, 1982b, pp. 24–32) (Document ID 1622).

The rate of time preference approach is intended to measure the tradeoff between current consumption and future consumption, or in the context of the final rule, between current benefits and future benefits. The *individual* rate of time preference is influenced by uncertainty about the availability of the benefits at a future date and whether the individual will be alive to enjoy the delayed benefits. By comparison, the *social* rate of time preference takes a broader view over a longer time horizon—ignoring individual mortality and the riskiness of individual investments (which can be accounted for separately).[124]

A usual method for estimating the social rate of time preference is to calculate the post-tax real rate of return on long-term, risk-free assets, such as U.S. Treasury securities (OMB, 2003, Document ID 1493). A variety of studies have estimated these rates of return over time and reported them to be in the range of approximately 1–4 percent.

OMB Circular A–4 (2003) recommends using discount rates of 3 percent (representing the social rate of time preference) and 7 percent (a rate estimated using the social cost of capital approach) to estimate benefits and net benefits (Document ID 1493). Ronald White of the Center for Effective Government endorsed the use of a 3 percent discount rate—since it ''appropriately reflects a social rate of time preference approach consistent with recommendations for benefits evaluation by the U.S. Environmental Protection Agency'' (Document ID 2341, pp. 3–4). Charles Gordon argued for a 0 percent discount rate:

> The economic literature indicates that the social discount rate should be 2 percent or 3 percent. But I believe the social discount rate should be zero, because if you were asked the question, do you want yourself saved from crystalline silica exposure . . . or do you want your son to be saved from crystalline silica death 20 years from now, you could not answer that question. You could not give a preference (Document ID 3588, Tr. 3789–90).

In acknowledgement of OMB Circular A–4 (2003, Document ID 1493), OSHA presents benefits and net benefits estimates using discount rates of 3 percent (representing the social rate of time preference) and 7 percent (a rate estimated using the social cost of capital approach). The weight of the evidence favors using a discount rate of 3 percent or less, and that 3 percent is one of the options permitted by OMB, the Agency is using a 3 percent discount rate to display its primary estimates of benefits under the social rate of time preference method.

b. Summary of Annualized Benefits Under Alternative Discount Rates

Table VII–28a through Table VII–28d presents OSHA's estimates of the sum of the annualized benefits of the final rule, under various occupational tenure assumptions, using alternative discount rates of 0, 3, and 7 percent, with a breakout between construction and general industry/maritime, with each table presenting these results for a different tenure level. All of these benefits calculations reflect willingness-to-pay values that, as previously discussed, increase in real value at 2 percent a year.

Given that the stream of benefits extends out 60 years, the value of future benefits is highly sensitive to the choice of discount rate. As previously established in Table VII–27, the undiscounted benefits (*i.e.,* using the 0 percent discount rate) for the scenario in which workers are uniformly exposed to silica for 45 years range from $7.3 billion to $19.3 billion annually. In Table VII–28a, for 45 years tenure, using a 3 percent discount rate, the annualized benefits range from $4.8 billion to $12.6 billion. Using a 7 percent discount rate, the annualized benefits range from $2.7 billion to $6.9 billion. As can be seen, going from undiscounted benefits (with a midpoint of $13.3 billion) to benefits calculated at a 7 percent discount rate (with a midpoint of $4.8 billion) has the effect of cutting the annualized benefits of the final rule by 64 percent.

Comparing across tenure levels for representative benefits, Table VII–28a for 45 years tenure has total benefits at the midpoint estimate of $8.7 billion at a 3 percent discount rate and $4.8 billion at 7 percent discount rate. Table VII–28b for 25 years tenure has total benefits at the midpoint estimate of $10.0 billion at a 3 percent discount rate and $5.5 billion at 7 percent discount rate. Table VII–28c for 13 years tenure has total benefits at the midpoint estimate of $12.3 billion at a 3 percent discount rate and $6.8 billion at 7 percent discount rate. Finally, Table VII–28d for 6.6 years tenure has total benefits at the midpoint estimate of $16.1 billion at a 3 percent discount rate and $9.0 billion at 7 percent discount rate.

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[122] This essential point was missed in a comment by Dr. Ruttenberg, which claimed that OSHA's estimates of the benefits of an avoided fatality were forty percent below the VSL estimate of $8.7 million (in 2009 dollars) that the Agency was using (Document ID 2256, Attachment 4, p. 9). The difference is due to the fact that the avoided fatalities occurred over a 60 year period and had to be discounted.

[123] For a more detailed discussion of the major issues, see, for example, Lind (1982a, 1982b, and 1990, Document ID1622); EPA (2000a, Document ID 1327, Chapter 6); and OMB (2003, Document ID 1493, pp. 31–37).

[124] It is not always possible to explicitly model all forms of uncertainty that are relevant to a regulatory cost-benefit analysis (*e.g.,* medical innovations that allow for more successful treatment of illnesses or changes in industrial practices or locations that in turn change the exposure profile of workers subject to a regulation). Because these uncertainties tend to increase as the time horizon being analyzed lengthens, application of a discount rate provides a reduced-form approach to less heavily weighting the least-certain estimated benefits and costs.

Table VII-28a

Estimated Annual Monetized Benefits Resulting from a Reduction in Exposure to Crystalline Silica

Due to PEL of 50 μg/m^3 and Alternative PEL of 100 μg/m^3

For the Scenario in Which Workers Are Uniformly Exposed to Silica for 45 Years

($Billions)*

PEL		50			100		
Discount Rate	Range	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Undiscounted (0%)	ToxaChemica 2004 (lower estimate) [b]	$7.3	$6.3	$1.0	$3.5	$3.5	$0.0
	Midpoint	$13.3	$10.4	$2.9	$6.7	$6.5	$0.2
	Attfield and Costello 2004 (higher estimate) [a]	$19.3	$14.5	$4.8	$9.8	$9.5	$0.3
Discounted at 3%	ToxaChemica 2004 (lower estimate) [b]	$4.8	$4.1	$0.7	$2.3	$2.3	$0.0
	Midpoint	$8.7	$6.8	$1.9	$4.3	$4.2	$0.1
	Attfield and Costello 2004 (higher estimate) [a]	$12.6	$9.4	$3.1	$6.4	$6.2	$0.2
Discounted at 7%	ToxaChemica 2004 (lower estimate) [b]	$2.7	$2.3	$0.4	$1.3	$1.3	$0.0
	Midpoint	$4.8	$3.7	$1.1	$2.4	$2.3	$0.1
	Attfield and Costello 2004 (higher estimate) [a]	$6.9	$5.2	$1.7	$3.5	$3.4	$0.1

[a] Document ID 0543; [b] Document ID 0469

Results are estimates based on the assumption outlined throughout this chapter.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Table VII-28b

Estimated Annual Monetized Benefits Resulting from a Reduction in Exposure to Crystalline Silica

Due to PEL of 50 μg/m^3 and Alternative PEL of 100 μg/m^3

For the Scenario in Which Workers are Uniformly Exposed to Silica for 25 Years

($Billions)*

PEL		50			100		
Discount Rate	Range	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Undiscounted (0%)	ToxaChemica 2004 (lower estimate) [b]	$9.0	$7.8	$1.2	$4.3	$4.2	$0.1
	Midpoint	$15.2	$12.0	$3.2	$6.5	$6.3	$0.2
	Attfield and Costello 2004 (higher estimate) [a]	$21.4	$16.3	$5.2	$8.7	$8.3	$0.4
Discounted at 3%	ToxaChemica 2004 (lower estimate) [b]	$5.9	$5.1	$0.8	$2.8	$2.7	$0.0
	Midpoint	$10.0	$7.9	$2.1	$4.2	$4.1	$0.1
	Attfield and Costello 2004 (higher estimate) [a]	$14.0	$10.6	$3.4	$5.6	$5.4	$0.2
Discounted at 7%	ToxaChemica 2004 (lower estimate) [b]	$3.3	$2.8	$0.4	$1.6	$1.5	$0.0
	Midpoint	$5.5	$4.4	$1.2	$2.3	$2.3	$0.1
	Attfield and Costello 2004 (higher estimate) [a]	$7.8	$5.9	$1.9	$3.1	$3.0	$0.1

[a] Document ID 0543; [b] Document ID 0469

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Table VII-28c

Estimated Annual Monetized Benefits Resulting from a Reduction in Exposure to Crystalline Silica

Due to PEL of 50 µg/m³ and Alternative PEL of 100 µg/m³

For the Scenario in Which Workers are Uniformly Exposed to Silica for 13 Years

($Billions)*

PEL		50			100		
Discount Rate	Range	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Undiscounted (0%)	ToxaChemica 2004 (lower estimate) [b]	$12.3	$10.8	$1.5	$5.6	$5.6	$0.1
	Midpoint	$18.8	$15.2	$3.5	$7.7	$7.6	$0.1
	Attfield and Costello 2004 (higher estimate) [a]	$25.2	$19.6	$5.6	$9.8	$9.6	$0.2
Discounted at 3%	ToxaChemica 2004 (lower estimate) [b]	$8.0	$7.0	$1.0	$3.7	$3.6	$0.0
	Midpoint	$12.3	$9.9	$2.3	$5.0	$4.9	$0.1
	Attfield and Costello 2004 (higher estimate) [a]	$16.5	$12.9	$3.7	$6.4	$6.3	$0.1
Discounted at 7%	ToxaChemica 2004 (lower estimate) [b]	$4.4	$3.8	$0.6	$2.0	$2.0	$0.0
	Midpoint	$6.8	$5.5	$1.3	$2.8	$2.7	$0.0
	Attfield and Costello 2004 (higher estimate) [a]	$9.2	$7.2	$2.1	$3.5	$3.5	$0.1

[a] Document ID 0543; [b] Document ID 0469

Results are estimates based on the assumption outlined throughout this chapter.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Table VII-28d

Estimated Annual Monetized Benefits Resulting from a Reduction in Exposure to Crystalline Silica

Due to PEL of 50 µg/m³ and Alternative PEL of 100 µg/m³

For the Scenario in Which Workers are Uniformly Exposed to Silica for 6.6 Years

($Billions)*

PEL		50			100		
Discount Rate	Range	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Undiscounted (0%)	ToxaChemica 2004 (lower estimate) [b]	$17.9	$15.9	$2.0	$8.0	$7.9	$0.1
	Midpoint	$24.7	$20.6	$4.1	$10.1	$10.0	$0.1
	Attfield and Costello 2004 (higher estimate) [a]	$31.6	$25.3	$6.3	$12.2	$12.0	$0.2
Discounted at 3%	ToxaChemica 2004 (lower estimate)	$11.5	$10.2	$1.3	$5.2	$5.1	$0.1
	Midpoint	$16.1	$13.4	$2.7	$6.6	$6.5	$0.1
	Attfield and Costello 2004 (higher estimate) [a]	$20.8	$16.6	$4.1	$8.0	$7.9	$0.1
Discounted at 7%	ToxaChemica 2004 (lower estimate) [b]	$6.3	$5.5	$0.7	$2.8	$2.8	$0.0
	Midpoint	$9.0	$7.4	$1.5	$3.6	$3.6	$0.0
	Attfield and Costello 2004 (higher estimate) [a]	$11.7	$9.3	$2.3	$4.5	$4.4	$0.1

[a] Document ID 0543; [b] Document ID 0469

Results are estimates based on the assumptions outlined throughout this chapter.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

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4. Estimates of Net Benefits of the Final Rule

OSHA has estimated as shown in Table VII–29, the monetized and annualized net benefits of the final rule (with a PEL of 50 μg/m³ in general industry/maritime and construction and Table 1 governing almost all controls in Construction), based on the benefits model and costs previously presented in this chapter and in Chapter V of the FEA. Net benefits are the difference between benefits and costs.

Table VII–29 shows net benefits using alternative discount rates of 0, 3, and 7 percent for benefits and costs, including the previously discussed adjustment to monetized benefits to reflect increases in real per capita income over time.

As previously noted, the OSH Act requires the Agency to set standards based on eliminating significant risk to the extent feasible. An alternative criterion of maximizing net (monetized) benefits may result in very different regulatory outcomes. Thus, this analysis of estimated net benefits has not been used by OSHA as the basis for its decision concerning the choice of a PEL or of ancillary requirements for the final silica rule. Instead, it is provided pursuant to Executive Orders 12866 and 13563. OSHA has used the 45 year occupational tenure in its main analysis. OSHA has also examined other possible tenures and provided the results. The occupational tenure results are such the benefits are higher the shorter the occupational tenure. Examination of shorter tenure would actually increase the net benefits because more workers are exposed to silica, albeit for a shorter time each.

Table VII–29 also shows results of estimates of annualized net benefits for an alternative PEL of 100 μg/m³. Under this regulatory alternative, the PEL would be changed from 50 μg/m³ to 100 μg/m³ for all industries covered by the final rule, and the action level would be changed from 25 μg/m³ to 50 μg/m³ (thereby keeping the action level at one-half of the PEL). The ancillary provisions of the standard, such as the medical surveillance provisions, would remain the same in this alternative as in this final rule, but would be impacted by factors such as changes in respirator use and effects on other provisions such as medical surveillance. For example, in the construction sector where medical surveillance requirements are triggered by respirator use, a reduction in respirator use would result in a decrease in the costs associated with medical surveillance. Under this alternative, OSHA determined in the PEA that Table 1 requirements for respirator use would be eliminated and that only abrasive blasters and some underground construction workers, which are not included in Table 1, would be required to wear respirators. However, the number of mortalities and morbidities would rise if workers were exposed to higher levels of silica. OSHA did not receive comment on its analysis of this alternative.

As previously noted in this summary, the choice of discount rate for annualizing benefits has a significant effect on annualized benefits. The same is true for net benefits. For example, the net benefits using a 7 percent discount rate for benefits are considerably smaller than the net benefits using a 0 percent discount rate, declining by more than half to two-thirds under all scenarios. (Conversely, as noted in Chapter V of the FEA, the choice of discount rate for annualizing costs has only a very minor effect on annualized costs.)

Table VII-29
Estimated Monetized Net Benefits Resulting from a Reduction in Exposure to Crystalline Silica Due to the Final PEL of 50 µg/m^3 and Alternative PEL of 100 µg/m^3
($Billions)**

PEL		50	100*
Discount Rate	**Range**		
Undiscounted (0%)	ToxaChemica 2004 (lower estimate) [b]	$6.3	$2.9
	Midpoint	$12.3	$6.0
	Attfield and Costello 2004 (higher estimate) [a]	$18.3	$9.2
3%	ToxaChemica 2004 (lower estimate) [b]	$3.8	$1.7
	Midpoint	$7.7	$3.7
	Attfield and Costello 2004 (higher estimate) [a]	$11.6	$5.7
7%	ToxaChemica 2004 (lower estimate) [b]	$1.7	$0.7
	Midpoint	$3.8	$1.8
	Attfield and Costello 2004 (higher estimate) [a]	$5.9	$2.8

[a] Document ID 0543; [b] Document ID 0469
Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis
*No benefits related to achieving the preceding general industry PEL of 100 µg/m^3 are included in these estimates.

The estimates of net benefits in Table VII–29 show that:

- While the net benefits of the final rule vary considerably—depending on the choice of discount rate used to annualize benefits and on whether the calculated benefits are in the high, midpoint, or low range—benefits exceed costs for the 50 µg/m^3 PEL in all scenarios that OSHA considered (*i.e.,* the highest estimate for costs is lower than the lowest estimate for benefits).
- The Agency's best estimate of the net annualized benefits of the final rule—using a uniform discount rate for both benefits and costs of 3 percent—and cognizant of the uncertainties inherent in the analysis, is between $3.8 billion and $11.6 billion, with a midpoint value of $7.7 billion.

• The alternative of a 100 μg/m³ PEL has lower net benefits under all assumptions, relative to the 50 μg/m³ PEL. However, for this alternative PEL, benefits were also found to exceed costs in all scenarios that OSHA considered.

One commenter, the Mercatus Institute, argued that the benefits for the proposed rule were overestimated due to OSHA's assumption of full compliance, and that this simultaneously underestimated costs, since the cost of complying with existing rules is assumed away. This commenter stated that the Agency should not assume that firms will necessarily comply with the Agency's rules and the benefits estimates should therefore be lower (Document ID 1819, p. 9). OSHA makes three points in response. First, the argument is logically inconsistent—if the Agency did not assume full compliance with the previous PELs and assumes compliance with the new PEL, as Mercatus advocates, it is true that the estimated costs would increase, but so would the estimated benefits. Second, the logic for the Mercatus Institute's argument seems to be undercut by the Mercatus Institute's own observation that the Agency has had success in reducing silicosis, which suggests that in the long run, at least, firms actually do comply with OSHA rules (Document ID 1819, pp. 4–5). Finally, as discussed in the engineering controls section of Chapter V of the FEA, the Agency has determined that the best way for it to calculate costs and benefits is to estimate the incremental costs and benefits of the standard by assuming full compliance. OSHA also emphasizes that the compliance assumption applies to both costs and benefits so that the comparison of one to the other is not necessarily unduly weighted in either direction (an exception would be the counterfactual scenario in which extremely high non-compliance by a few employers changed benefits estimates substantially but cost estimates only slightly).[125]

Estimates of Incremental Benefits of the Final Rule

Incremental costs and benefits are those that are associated with increasing the stringency of the standard. A comparison of incremental benefits and costs provides an indication of the relative efficiency of the final PEL and the alternative PEL. Again, OSHA has conducted these calculations for informational purposes only and has not used this information as the basis for selecting the PEL for the final rule.

Tables VII–30A and VII–30B show result of estimates of the costs and benefits of reducing exposure levels from the preceding PELs of approximately 250 μg/m³ (for construction and maritime) and 100 μg/m³ (for general industry) to the final rule PEL of 50 μg/m³ and to the alternative PEL of 100 μg/m³, using the alternative discount rates of 3 and 7 percent. These tables also introduce a second alternative PEL. Under this second alternative standard, addressed in Tables VII–30A and VII–30B, the PEL would be lowered from 50 μg/m³ to 25 μg/m³ for all industries covered by the final rule, while the action level would remain at 25 μg/m³ (because of difficulties in accurately measuring exposure levels below 25 μg/m³). For the construction sector under this second alternative, Table 1 requirements would also be modified to include respiratory protection for all workers covered under Table 1 (because all exposures for Table 1 activities are assumed to be above 25 μg/m³), and all these covered workers would be subject to the medical surveillance provision.[126]

Table VII–30A breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table VII–30B breaks out costs and benefits by major industry sector or construction task sector. As Table VII–30A shows, at a discount rate of 3 percent, a PEL of 50 μg/m³, relative to a PEL of 100 μg/m³, imposes incremental costs of $381 million per year; incremental benefits of $4.3 billion per year, and additional net benefits of $3.9 billion per year. The final PEL of 50 μg/m³ also has higher net benefits than 100 μg/m³ either at a 3 percent or 7 percent discount rate.

Table VII–30B continues this incremental analysis but with breakdowns between construction and general industry/maritime. As shown, both sectors show strong positive net benefits, which are greater for the final PEL of 50 μg/m³ than the alternative of 100 μg/m³.

The estimates in Tables VII–30A and VII–30B indicate that, across all discount rates, there are net benefits to be achieved by lowering exposures from the preceding PEL (250 μg/m³ or 100 μg/m³) to 100 μg/m³ and then, in turn, lowering them further to 50 μg/m³ and then to 25 μg/m³, and the lower the PEL, the greater the net benefits.[127] Net benefits decline across all incremental changes in PELs as the discount rate for annualizing benefits increases. The incremental net benefit of reducing the PEL from 100 μg/m³ to 50 μg/m³ is greater than the incremental net benefit of reducing the PEL from 50 μg/m³ to 25 μg/m³ under both the 3 percent discount rate and the 7 percent discount rate.

However, the majority of the benefits and costs that OSHA estimates for the final rule (PEL of 50 μg/m³) are from the initial effort to lower exposures from the preceding PEL of 250 μg/m³ in both construction and maritime to 100 μg/m³, as shown in the 100 μg/m³ column and the Incremental Costs/Benefits column between the 100 μg/m³ column and the 50 μg/m³ column in Table VII–30A. The majority of the costs and benefits attributable to lowering exposures to 100 μg/m³ are in the construction industry. OSHA did not estimate any costs or benefits for general industry employers lowering exposures to an alternative of 100 μg/m³ because the preceding PEL was already 100 μg/m³, but a relatively small amount of costs and benefits would be attributed to maritime employers lowering exposures to the alternative of 100 μg/m³ from the preceding PEL of 250 μg/m³. Because a single standard would cover both general industry and maritime employers, those costs and benefits are grouped together in Table VII–30A and VII–30B.

In addition to examining alternative PELs, OSHA also examined alternatives to other provisions of the standard. These alternatives are discussed in the following Chapter VIII of the FEA: Regulatory Alternatives.

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[125] If this rulemaking has the potential to increase compliance with existing regulations, it would be appropriate for the analysis conducted under Executive Order 12866 and 13563 to include both cost and benefits estimates that reflect the new compliance. This is not, however, a legal requirement of the OSH Act. OSHA knows of no way to make such estimates and lacks any persuasive evidence in this rulemaking record that this rulemaking would affect compliance with the preceding PEL.

[126] As with general industry and maritime employees, the limited number of construction workers not covered by Table 1 and estimated to exceed 25 μg/m³ currently, such as abrasive blasters, are assumed to need respiratory protection under this alternative.

[127] The lowest PEL considered as an alternative was 25 μg/m³. In addition, the costs exceed the benefits using the 7 percent discount rate for the 100 μg/m³ alternative, since quantified benefits for the FEA are based entirely on the various quantitative risk assessments, and the PEL for general industry is already set at 100 μg/m³. (There would, however, be net benefits for construction.) As noted previously, the Agency is claiming no quantified benefits for the various ancillary provisions, such as medical surveillance.

Table VII-30A: Estimated Annualized Costs, Benefits and Incremental Benefits of OSHA's Final PEL of 50 µg/m³ and Alternatives of 25 µg/m³ and 100 µg/m³

Millions ($2012)

	25 µg/m³			Incremental Costs/Benefits Between 50 and 25 µg/m³			50 µg/m³			Incremental Costs/Benefits Between 100 and 50 µg/m³s			100 µg/m³		
Discount Rate		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**
Annualized Costs															
Engineering Controls		$661	$674		$0	$0		$661	$674		$241	$261		$421	$413
Respirators		$82	$82		$49	$49		$33	$33		$32	$32		$1	$1
Exposure Assessment		$141	$142		$45	$45		$96	$98		$32	$32		$64	$65
Medical Surveillance		$485	$492		$388	$392		$96	$100		$73	$75		$24	$24
Familiarization and Training		$96	$102		$0	$0		$96	$102		$0	$2		$96	$100
Regulated Area		$12	$12		$9	$9		$3	$3		$3	$3		$0	$0
Written Control Plan		$44	$47		$0	$0		$44	$47		$0	$1		$44	$47
Total Annualized Costs (point estimate)		**$1,521**	**$1,552**		**$491**	**$496**		**$1,030**	**$1,056**		**$381**	**$406**		**$649**	**$650**
Annual Benefits: Number of Cases Prevented**	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)**	178			54			124			62			62		
Fatal Silicosis & other Non-Malignant Respiratory Diseases**	438			113			325			154			170		
Fatal Renal Disease**	321			128			193			110			83		
Silica-Related Mortality**	937	9,340	5,119	295	**$2,942**	**$1,612**	642	$6,398	$3,507	326	$3,248	$1,783	316	$3,151	$1,724
Silicosis Morbidity**	1,040	2,593	1,478	122	**$304**	**$173**	918	$2,289	$1,305	440	$1,098	$626	477	$1,191	$679
Monetized Annual Benefits (midpoint estimate)**		**$11,933**	**$6,598**		**$3,246**	**$1,786**		**$8,687**	**$4,812**		**$4,346**	**$2,409**		**$4,341**	**$2,403**
Net Benefits**		**$10,412**	**$5,046**		**$2,755**	**$1,290**		**$7,657**	**$3,756**		**$3,965**	**$2,003**		**$3,692**	**$1,753**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

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Table VII-30B: Estimated Annualized Costs, Benefits and Incremental Benefits of OSHA's Final PEL of 50 µg/m³ and Alternatives of 25 µg/m³ and 100 µg/m³, by Major Industry Sector*

Millions ($2012)

	25 µg/m³			Incremental Costs/Benefits Between 50 and 25 µg/m³			50 µg/m³			Incremental Costs/Benefits Between 100 and 50 µg/m³			100 µg/m³**		
Discount Rate		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**
Annualized Costs															
Construction		$1,046	$1,059		$387	$387		$659	$673		$104	$120		$555	$553
General Industry/Maritime		$475	$492		$104	$109		$371	$384		$276	$286		$95	$97
Total Annualized Costs		**$1,521**	**$1,552**		**$491**	**$496**		**$1,030**	**$1,056**		**$381**	**$406**		**$649**	**$650**
Annual Benefits: Number of Cases Prevented	**Cases**			**Cases**			**Cases**			**Cases**			**Cases**		
Silica-Related Mortality															
Construction***	754	$7,514	$4,119	209	$2,085	$1,143	545	$5,430	$2,976	233	$2,324	$1,276	311	$3,106	$1,700
General Industry/Maritime***	183	$1,826	$1,001	86	$857	$470	97	$968	$531	93	$924	$506	4	$44	$24
Total***	937	$9,340	$5,119	295	$2,942	$1,612	642	$6,398	$3,507	326	$3,248	$1,783	316	$3,151	$1,724
Silicosis Morbidity															
Construction***	573	$1,430	$815	43	$107	$61	530	$1,323	$754	80	$201	$114	450	$1,122	$640
General Industry/Maritime***	466	$1,163	$663	79	$197	$112	387	$966	$551	360	$898	$512	27	$69	$39
Total***	1,040	$2,593	$1,478	122	$304	$173	918	$2,289	$1,305	440	$1,098	$626	477	$1,191	$679
Monetized Annual Benefits (midpoint estimate)															
Construction***		$8,945	$4,934		$2,192	$1,204		$6,753	$3,730		$2,475	$1,391		$4,228	$2,340
General Industry/Maritime***		$2,988	$1,664		$1,054	$582		$1,934	$1,081		$1,797	$1,018		$113	$63
Total***		**$11,933**	**$6,598**		**$3,246**	**$1,786**		**$8,687**	**$4,812**		**$4,346**	**$2,409**		**$4,341**	**$2,403**
Net Benefits															
Construction***		$7,898	$3,875		$1,805	$817		$6,094	$3,058		$2,420	$1,271		$3,674	$1,787
General Industry/Maritime***		$2,513	$1,171		$950	$473		$1,564	$698		$1,545	$732		$18	($34)
Total***		**$10,412**	**$5,046**		**$2,755**	**$1,290**		**$7,657**	**$3,756**		**$3,965**	**$2,003**		**$3,692**	**$1,753**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant except that the value of VSLs increase with income. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

**No benefits or costs related to achieving the preceding general industry PEL of 100 µg/m³ are included in these estimates.

5. Sensitivity Analysis

In this section, OSHA presents the results of two different types of sensitivity analysis. In the first type of sensitivity analysis, OSHA made a series of isolated changes to individual cost and benefit input parameters in order to determine their effects on the Agency's estimates of annualized costs, annualized benefits, and annualized net benefits. In the second type of sensitivity analysis—a so-called ''break-even'' analysis—OSHA also investigated isolated changes to individual cost and benefit input parameters, but with the objective of determining how much they would have to change for annualized costs to equal annualized benefits.

Again, the Agency has conducted these calculations for informational purposes only and has not used these results as the basis for selecting the PEL for the final rule.

a. Analysis of Isolated Changes to Inputs

The methodology and calculations underlying the estimation of the costs and benefits associated with this rulemaking are generally linear and additive in nature. Thus, the sensitivity of the results and conclusions of the analysis will generally be proportional to isolated variations a particular input parameter. For example, if the estimated time that employees need to travel to (and from) medical screenings is doubled, the corresponding labor costs double as well.

OSHA evaluated a series of such changes in input parameters to test whether and to what extent the general conclusions of the economic analysis held up. OSHA first considered changes to input parameters that affected only costs and then changes to input parameters that affected only benefits. Each of the sensitivity tests on cost parameters had only a very minor effect on total costs or net costs. Much larger effects were observed when the benefits parameters were modified; however, in all cases, net benefits remained significantly positive. On the whole, OSHA found that the conclusions of the analysis are reasonably robust, as changes in any of the cost or benefit input parameters still show significant net benefits for the final rule. The results of the individual sensitivity tests are summarized in Table VII–31A and B and are described in more detail below.

OSHA has tailored the sensitivity analysis to examine issues raised by commenters, particularly with respect to costs. (For more detail, *see* Chapter V of the FEA.) For each alternative, the estimated cost increase is equivalent to the estimated decrease in net benefits (except for minor rounding discrepancies). For instance, in the first example of sensitivity testing, when OSHA doubled the estimated portion of the affected self-employed population from 25 to 50 percent, and estimates of other input parameters remained unchanged, Table VII–31A shows that the estimated total costs of the final rule increased by $17.9 million annually, or by about 1.7 percent, while estimated net benefits also declined by $17.9 million, from $7,657 million to $7,639 million annually.

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Table VII-31A

Sensitivity Tests-Costs

Impact Variable	OSHA's Best Estimate	Sensitivity Test	Impact on Annualized Costs	Percentage Impact on Costs	Adjusted Annualized Costs	Adjusted Estimated Annualized Net Benefit*
Cost						
OSHA's Best Estimate of (a) Annualized Total Cost and (b) Annualized Net Benefits					***(a)*** *$1,029,781,777*	***(b)*** *$7,657,131,438*
Affected self-employed population	25.0%	Double	$17,885,843	1.7%	$1,047,667,621	$7,639,245,595
Familiarization	4 to 40 hours depending on establishment size	Double	$15,936,313	1.5%	$1,045,718,091	$7,641,195,125
Housekeeping	10 mins per worker per day	Double	$12,487,297	1.2%	$1,042,269,074	$7,644,644,141
Thorough cleaning	Initial cleaning only	Annual cleaning	$17,191,599	1.7%	$1,046,973,377	$7,639,939,839
	Initial cleaning only	Cleaning every 5 years	$1,963,372	0.2%	$1,031,745,150	$7,655,168,066
Respirator use in General Industry	10% of workers otherwise exposed above the PEL**	Double	$20,004,553	1.9%	$1,049,786,330	$7,637,126,886
Productivity in construction	Range from 3 to 5%	50% increase	$99,612,982	9.7%	$129,394,760	$7,557,518,456
		50% decrease	-$99,612,982	-9.7%	$930,168,795	$7,756,744,420

Table VII-31B Sensitivity Tests-Benefits**

Impact Variable	OSHA's Best Estimate	Sensitivity Test	Impact on Estimated Annualized Benefits	Percentage Impact on Estimated Benefits	Adjusted Annualized Estimated Benefits	Adjusted Annualized Estimated Net Benefit
Cost						
OSHA's Best Estimate of (c) Annualized Total Benefits and (b) Annualized Net Benefits					*(c) $8,686,913,216*	*(b) $7,657,131,438*
Monetized Benefits (High Morbidity Valuation/High Mortality Case Estimate)	Midpoint	Attfield and Costello 2004 [a] (higher estimate)	$3,872,364,448	45%	$12,559,277,664	$11,529,495,886
Monetized Benefits (Low Morbidity Valuation/Low Mortality Case Estimate)	Midpoint	ToxaChemica 2004 [b] (lower estimate)	-$3,872,364,448	-45%	$4,814,548,767	$3,784,766,990
Discount rate for benefits (7%)	3%	7%	-$3,875,099,068	-45%	$4,811,814,147	$3,782,032,370
Discount rate for benefits (3%), with Adjustment to Monetized Benefits to Reflect Increases in Real Per Capita Income Over Time	2% annual increase in benefit valuation	0%	-$4,374,670,466	-50%	$4,312,242,750	$3,282,460,972

[a] Document ID 0543; [b] Document ID 0469

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant except that the value of VSLs increase with income. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming economic conditions remain constant for the sixty year time horizon.

** Except as otherwise noted in the FEA, OSHA accounted for respirator use for all workers whose exposures would still exceed the PEL after all feasible controls are in place. In addition, OSHA added to that number an additional 10% of the remaining population to account for special circumstances in which additional workers would require respirators. For this sensitivity analysis, the additional 10% was doubled to 20%.

In the second example, OSHA doubled the estimated familiarization time needed to understand the requirements of the new standard

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relative to OSHA's best estimate, which ranged from 4 to 40 hours depending on establishment size (see Chapter V for more detail). As shown in Table VII–31A, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of the final rule increased by $16.0 million annually, or by about 1.5 percent, while net benefits declined by the same amount annually, from approximately $7,657 million to $7,641 million annually.

In the third example, OSHA doubled the estimated daily amount of housekeeping per worker necessary to comply with the standard, from 10 minutes to 20 minutes. As shown in Table VII–31A, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of the final rule increased by $12.5 million annually, or by about 1.2 percent, while net benefits declined by the same amount annually, from approximately $7,657 million to $7,645 million annually.

In the fourth example, OSHA examined the effect of increasing its estimate of the frequency with which thorough cleaning of the workplace would be performed in general industry. The Agency examined the effect of increasing the frequency from only one initial thorough cleaning to the initial cleaning plus an annual thorough cleaning, or alternately, a thorough cleaning every 5 years. As shown in Table VII–31A, if thorough cleaning were an annual cost, the total estimated costs of the final rule increased by $17.2 million annually, or by about 1.7 percent, while net benefits declined by the same amount annually, from $7,657 million to $7,640 million annually. In the second variation of this test, for a thorough cleaning every 5 years, as shown in Table VII–31A, the increase in annual costs is only 0.2 percent.

In the fifth example, OSHA increased its estimate of respirator use. In Chapter V of the FEA, OSHA explained that it calculated the costs of respirators for general industry and maritime workers who will still be exposed above the PEL after all feasible controls are in place. In addition, to be conservative, OSHA added costs to provide respirators to 10 percent of the remaining population. For this sensitivity test, OSHA doubled its estimate of the amount of additional respirator use in general industry from 10 percent to 20 percent. As shown in Table VII–31A, the total estimated costs of the final rule increased by $20.0 million annually, or by about 1.9 percent, while net benefits decreased by the same amount annually, from approximately $7,657 million to $7,637 million annually.

In the sixth example, reflecting in part the range of comments the Agency received on the issue (discussed in detail in Chapter V), OSHA explored the effect of increasing, and alternately decreasing, by 50 percent the size of the productivity impact arising from the use of engineering controls in construction. As shown in Table VII–31A, if OSHA's estimates of other input parameters remained unchanged, under the first variation, the total estimated costs of the final rule increased by $99.6 million annually, or by about 9.7 percent, while net benefits declined by the same amount annually, from $7,657 million to $7,558 million annually. Under the second variation, the decrease in costs and increase in net benefits would be of the same magnitude, with final estimated net benefits rising to $7,757 million.

As shown in Table VII–31B, OSHA also performed sensitivity tests on several input parameters used to predict the benefits of the final rule. In the first two tests, in an extension of results previously presented in Table VII–27, the Agency examined the effect on annualized net benefits of employing the high-end estimate of the benefits, as well as the low-end estimate. As discussed previously, the Agency examined the sensitivity of the benefits to both the valuation of individual silica-related disease cases prevented, as well as the number of lung cancer deaths prevented. Table VII–31B presents the effect on annualized net benefits of using the extreme values of these ranges, the high count of cases prevented and the high valuation per case prevented, and the low count and the low valuation per case prevented. As indicated, using the high estimate of cases prevented and their valuation, the benefits rise by 45 percent to $12.6 billion, yielding net benefits of $11.5 billion. For the low estimate of both cases prevented and their valuation, the benefits decline by 45 percent, to $4.8 billion, yielding net benefits of $3.8 billion.

In the third sensitivity test of benefits, OSHA examined the effect of raising the discount rate for benefits to 7 percent. The fourth sensitivity test of benefits examined the effect of removing the adjustment to monetized benefits to reflect increases in real per capita income over time. The results of the first of these sensitivity tests for net benefits was previously shown in Table VII–29 and is repeated in Table VII–31B. Raising the interest rate to 7 percent lowers the estimated benefits by 45 percent, to $4.8 billion, yielding annualized net benefits of $3.8 billion. Removing the two-percent annual increase to monetized benefits to reflect increases in real per capita income over time decreases the benefits by 50 percent, to $4.3 billion, yielding net benefits of $3.3 billion.

b. ''Break-Even'' Analysis

OSHA also performed sensitivity tests on several other parameters used to estimate the net costs and benefits of the final rule. However, for these, the Agency performed a ''break-even'' analysis, asking how much the various cost and benefits inputs would have to vary in order for the costs to equal, or break even with, the benefits. The results are shown in Table VII–32.

OSHA also performed sensitivity tests on several other parameters used to estimate the net costs and benefits of the final rule. However, for these, the Agency performed a ''break-even'' analysis, examining how much the various cost and benefits inputs would have to vary in order for the costs to equal, or break even with, the benefits

Table VII-32

Break-Even Sensitivity Analysis

	OSHA's Best Estimate of Annualized Cost or Benefit Factor	Factor Value at which Estimated Benefits Equal Costs	Required Factor Dollar/Number Change	Percentage Factor Change
Total Costs	$1,029,781,777	$8,686,913,216	$7,657,131,438	743.6%
Engineering Control Costs	$661,456,736	$8,318,588,262	$7,657,131,438	1157.6%
Benefits Valuation per Case Avoided				
Monetized Benefit per Death Avoided*	$9,000,000	$1,066,896	-$7,933,104	-88.1%
Monetized Benefit per Illness Avoided*	$2,632,000	$312,008	-$2,319,992	-88.1%
Cases Avoided				
Deaths Avoided*	642	76	-566	-88.1%
Illnesses Avoided*	918	109	-809	-88.1%

*Note: These numbers represent a reduction in the composite valuation of an avoided fatality or illness or in the composite number of cases avoided.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

estimated. The results are shown in Table VII–32.

In the first break-even test on cost estimates, OSHA examined how much costs would have to increase in order for costs to equal estimates benefits. As shown in Table VII–32, this point would be reached if costs increased by $7.7 billion.

In a second test, looking specifically at the estimated engineering control costs, the Agency found that these costs would also need to increase by $7.7 billion for costs to equal estimates benefits.

In a third sensitivity test, on benefits, OSHA examined how much its estimated monetary valuation of an avoided illness or an avoided fatality would need to be reduced in order for the costs to equal the benefits. Since the total valuation of prevented mortality and morbidity are each estimated to exceed at least $2.6 billion, while the estimated costs are $1.0 billion, an independent break-even point for each is impossible. In other words, for example, if no value is attached to an avoided illness associated with the rule, but the estimated value of an avoided fatality is held constant, the rule still has substantial net benefits. Only through a reduction in the estimated net value of both components is a break-even point possible.

OSHA, therefore, examined how large an across-the-board reduction in the monetized value of all avoided illnesses and fatalities would be necessary for the benefits to equal the costs. As shown in Table VII–32, for costs to equal estimated benefits, the estimated value per life saved would have to decline to $1.10 million per life saved, and an equivalent percentage reduction to about $0.3 million per illness prevented.

In a break-even sensitivity test, OSHA estimated how many silica-related fatalities and illnesses would be required for benefits to equal costs. As shown in Table VII–32, a reduction of 88 percent, relative to the morbidity and mortality estimates is required to reach the break-even point—566 fewer fatalities prevented annually, and 809 fewer silica-related illnesses prevented annually.

H. Regulatory Alternatives

This section discusses several major regulatory alternatives to the final OSHA silica standard, pursuant to Executive Orders 13653 and 12866. The presentation of regulatory alternatives in this chapter serves two important functions. The first is to demonstrate that OSHA explored less costly ways (compared to the final rule) to provide workers an adequate level of protection from exposure to respirable crystalline silica. The second is tied to the Agency's statutory requirement, which underlies the final rule, to reduce significant risk to the extent feasible. If OSHA had been unable to support its findings of significant risk and feasibility based on evidence presented during notice and comment, the Agency would then have had to consider regulatory alternatives that do satisfy its statutory obligations.

Each regulatory alternative presented here is described and analyzed relative to the final rule. Where relevant, the Agency notes that some regulatory alternatives are not permissible based on the required legal findings OSHA has made regarding significant risk and feasibility. The regulatory alternatives have been organized into four categories similar to those used in the PEA: (1) Alternative PELs to the new PEL of 50 μg/m^3; (2) regulatory alternatives that affect ancillary provisions; (3) a regulatory alternative that would modify the methods of compliance; and (4) regulatory alternatives concerning when different provisions of the final rule would take effect.

Alternative PELs

OSHA selected a new PEL for respirable crystalline silica of 50 μg/m^3 for all industries covered by the final rule and developed and included Table 1 for many work activities within the construction sector. The final rule is based on the requirements of the Occupational Safety and Health Act (OSH Act) and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act (29 U.S.C. 655(b)(5)), OSHA is required to promulgate a standard that reduces the risk of material impairment of health to the extent that it is technologically and economically feasible to do so (*see* Section II, Pertinent Legal Authority, for a full discussion of the legal requirements for promulgating new health standards under the OSH Act).

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. The Agency has also developed estimates of the risk of silica-related diseases assuming exposure over a working lifetime at the final PEL and action level, as well as at OSHA's preceding PELs. These analyses are presented in a background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' and its final findings are described in this preamble in Section V, Health Effects, and Section VI, Final Quantitative Risk Assessment and Significance of Risk. The available evidence indicates that employees exposed to respirable crystalline silica well below the previous PELs are at increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also can result in the development of kidney and autoimmune diseases and in death from other nonmalignant respiratory diseases. As discussed in Section VI Significance of Risk, in this preamble, OSHA finds that worker exposure to respirable crystalline silica at the previous and new PELs constitutes a significant risk and that the final standard will substantially reduce this risk.

Section 6(b) of the OSH Act (29 U.S.C. 655(b)) requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the final rule is presented in the FEA, and is summarized in this section (Section VII) of this preamble. For general industry and maritime, OSHA has concluded that the final PEL of 50 μg/m^3 is technologically feasible for all affected industries. In other words, OSHA has found that engineering and work practice controls will be sufficient to reduce and maintain silica exposures to the PEL of 50 μg/m^3 or below in most operations most of the time in the affected industries in general industry, and the rule is also feasible in maritime (feasibility for maritime (shipyards) partly depends on it being subject to other standards regulating abrasive blasting). For those few operations where the PEL cannot be achieved even when employers install all feasible engineering and work practice controls, employers in general industry and maritime can supplement controls with respirators to achieve exposure levels at or below the PEL.

For construction, determined that the engineering and work practice controls specified in Table 1 are feasible for all affected activities and in most cases will keep exposures at or below 50 μg/m^3 most of the time. For those few activities where the engineering and work practice controls specified in Table 1 are not sufficiently protective of worker health, Table 1 specifies respirator use to supplement those controls. A limited number of activities, such as tunneling and abrasive blasting, are not dealt with under Table 1, but are governed more directly by the PEL of 50 μg/m^3, as in general industry and maritime. For construction, while a few tasks like abrasive blasting and those specified on Table 1 as requiring respirators cannot

achieve the PEL most of the time with engineering and work practice controls alone, OSHA has concluded that the PEL of 50 μg/m³ is technologically feasible for the construction industry overall because most operations can meet the PEL using the specified controls in Table 1or under the traditional approach.

OSHA developed quantitative estimates of the compliance costs of the final rule for each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide a screening analysis of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts. Industries with unusually high costs as a percentage of revenues or profits were further analyzed for possible economic feasibility issues. After performing these analyses, OSHA has concluded that compliance with the requirements of the final rule would be economically feasible in every affected industry sector.

OSHA has examined two regulatory alternatives (named Regulatory Alternatives #1 and #2) that would modify the PEL for the final rule. Under Regulatory Alternative #1, the final PEL would be changed from 50 μg/m³ to 100 μg/m³ for all industry sectors covered by the rule, and the action level would be changed from 25 μg/m³ to 50 μg/m³ (thereby keeping the action level at one-half of the PEL). Under Regulatory Alternative #2, the new PEL would be lowered from 50 μg/m³ to 25 μg/m³ for all industry sectors covered by the rule, while the action level would remain at 25 μg/m³ (because of difficulties in accurately measuring exposure levels below 25 μg/m³). For the construction sector under this second alternative, Table 1 requirements would also be modified to include respiratory protection for all workers covered under Table 1 (because none are expected to be mostly under 25 μg/m³ for any of the tasks), and all these covered workers would be subject to the medical surveillance provision.

Tables VII–33 and VII–34 present, for informational purposes, the estimated costs, estimated benefits, and estimated net benefits of the final rule under the new PEL of 50 μg/m³ and for the regulatory alternatives of a PEL of 100 μg/m³ and a PEL of 25 μg/m³ (Regulatory Alternatives #1 and #2), using alternative discount rates of 3 and 7 percent. These two tables also present the incremental costs, the estimated incremental benefits, and the estimated incremental net benefits of going from a PEL of 100 μg/m³ to the new PEL of 50 μg/m³ and then of going from the new PEL of 50 μg/m³ to a PEL of 25 μg/m³. Table VII–33 breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table VII–34 breaks out costs and benefits by major industry sector.

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Table VII-33: Annualized, Costs, Benefits, and Incremental Benefits of OSHA's Final Silica Standard, Compared with 100 μg/m³ and 25 μg/m³ Regulatory Alternatives*

Millions ($2012)

	Regulatory Alternative #2					Final Rule					Regulatory Alternative #1		
		25 μg/m³		Incremental Costs Between 50 and 25 μg/m³			50 μg/m³		Incremental Costs Between 100 and 50 μg/m³			100 μg/m³	
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls		$651	$674		$0	$0		$661	$674		$241	$261		$421	$413
Respirators	$82	$82	$82		$49	$49		$33	$33		$32	$32		$1	$1
Exposure Assessment		$141	$142		$45	$45		$88	$98		$32	$32		$64	$65
Medical Surveillance		$485	$492		$388	$392		$96	$100		$73	$75		$24	$24
Familiarization and Training		$96	$102		$0	$0		$94	$102		$0	$2		$96	$100
Regulated Area		$12	$12		$9	$9		$3	$3		$3	$3		$0	$0
Written Control Plan		$47	$47		$0	$0		$44	$47		$0	$1		$44	$47
Total Annualized Costs (point estimate)		**$1,521**	**$1,552**		**$491**	**$496**		**$1,030**	**$1,056**		**$381**	**$406**		**$649**	**$650**
Estimated Annual Benefits: Number of Cases Prevented	Cases			Incremental Benefits Between 50 and 25 μg/m³–Cases			Cases			Incremental Benefits Between 100 and 50 μg/m³–Cases			Cases		
Fatal Lung Cancers (midpoint estimate) **	178			54			124			62			62		
Fatal Silicosis & other Non-Malignant Respiratory Diseases**	438			113			325			154			170		
Fatal Renal Disease**	321			128			193			110			83		
Silica-Related Mortality**	937	9,340	5,119	295	**$2,942**	**$1,612**	642	$6,398	$3,507	326	$3,248	$1,783	316	$3,151	$1,724
Silicosis Morbidity**	1,040	2,593	1,478	122	**$304**	**$173**	918	$2,289	$1,305	440	$1,098	$626	477	$1,191	$679
Estimated Monetized Annual Benefits (midpoint estimate) **		**$11,933**	**$6,598**		**$3,246**	**$1,786**		**$8,687**	**$4,812**		**$4,346**	**$2,409**		**$4,341**	**$2,403**
Net Benefits**		**$10,412**	**$5,046**		**$2,755**	**$1,290**		**$7,657**	**$3,756**		**$3,965**	**$2,003**		**$3,692**	**$1,753**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Table VII-34: Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Silica Standard compared with 100 μg/m³ and 25 μg/m³ Regulatory Alternatives, by Major Industry Sector*

Millions ($2012)

	Regulatory Alternative #2			Incremental Costs Between 50 and 25 μg/m³			Final Rule			Incremental Costs Between 100 and 50 μg/m³			Regulatory Alternative #1		
	25 μg/m³						50 μg/m³						100 μg/m³**		
Discount Rate		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**
Annualized Costs															
Construction		$1,046	$1,059		$387	$387		$659	$673		$104	$120		$555	$553
General															
Industry/Maritime		$475	$492		$104	$109		$371	$384		$276	$286		$95	$97
Total Annualized Costs		**$1,521**	**$1,552**		**$491**	**$496**		**$1,030**	**$1,056**		**$381**	**$406**		**$649**	**$650**
Estimated Annual Benefits:															
Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	754	$7,514	$4,119	209	$2,085	$1,143	545	$5,430	$2,976	233	$2,324	$1,276	311	$3,106	$1,700
General															
Industry/Maritime	183	$1,826	$1,001	86	$857	$470	97	$968	$531	93	$924	$506	4	$44	$24
Total	937	$9,340	$5,119	295	$2,942	$1,612	642	$6,398	$3,507	326	$3,248	$1,783	316	$3,151	$1,724
Silicosis Morbidity															
Construction	573	$1,430	$815	43	$107	$61	530	$1,323	$754	80	$201	$114	450	$1,122	$640
General															
Industry/Maritime	466	$1,163	$663	79	$197	$112	387	$966	$551	360	$898	$512	27	$69	$39
Total	1,040	$2,593	$1,478	122	$304	$173	918	$2,289	$1,305	440	$1,098	$626	477	$1,191	$679
Estimated Monetized Annual Benefits (midpoint estimate)				**Incremental Benefits Between 50 and 25 μg/m³**						**Incremental Benefits Between 100 and 50 μg/m³**					
Construction***		$8,945	$4,934		$2,192	$1,204		$6,753	$3,730		$2,524	$1,391		$4,228	$2,340
General															
Industry/Maritime***		$2,988	$1,664		$1,054	$582		$1,934	$1,081		$1,821	$1,018		$113	$63
Total***		**$11,933**	**$6,598**		**$3,246**	**$1,786**		**$8,687**	**$4,812**		**$4,346**	**$2,409**		**$4,341**	**$2,403**
Estimated Net Benefits															
Construction***		$7,898	$3,875		$1,805	$817		$6,094	$3,058		$2,420	$1,271		$3,674	$1,787
General															
Industry/Maritime***		$2,513	$1,171		$950	$473		$1,564	$698		$1,545	$732		$18	($34)
Total***		**$10,412**	**$5,046**		**$2,755**	**$1,290**		**$7,657**	**$3,756**		**$3,965**	**$2,003**		**$3,692**	**$1,753**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

As previously noted, Tables VII–33 and VII–34 also show the costs and estimated benefits of a PEL of 25 μg/m³ (Regulatory Alternative #2), as well as

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the incremental costs and benefits of going from the final PEL of 50 μg/m³ to a PEL of 25 μg/m³. Because OSHA determined that a PEL of 25 μg/m³ would not be feasible (that is, engineering and work practices would not be sufficient to reduce and maintain silica exposures to a PEL of 25 μg/m³ or below in most operations most of the time in the affected industries), the Agency did not attempt to identify engineering controls or their costs for affected industries to meet this PEL. Instead, for purposes of estimating the costs of going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³, OSHA assumed that all workers exposed between 50 μg/m³ and 25 μg/m³ would have to wear respirators to achieve compliance with the 25 μg/m³ PEL. OSHA then estimated the associated additional costs for respirators, exposure assessments, medical surveillance, and regulated areas (the latter three for ancillary requirements specified in the final rule).

As Tables VII–33 and VII–34 show, going from the final rule to Regulatory Alternative #2 (PEL of 25 μg/m³) is estimated to prevent, annually, an additional 295 silica-related fatalities and an additional 122 cases of silicosis. These estimates support OSHA's finding that there is significant risk remaining at the final PEL of 50 μg/m³. However, the Agency has determined that a PEL of 25 μg/m³ is not technologically feasible for most sectors or operations, and for that reason, has not selected it.

Regulatory Alternatives That Affect Ancillary Provisions

Section 6(b)(7) of the OSH Act, 29 U.S.C. 655(b)(7), requires standards to prescribe, where appropriate, the monitoring or measuring of employee exposure for the protections of employees. Section 6(b)(7) also requires the standards to prescribe, where appropriate, the type and frequency of medical exams to be provided by employers ''in order to most effectively determine whether the health of [exposed] employees is adversely affected by such exposure.'' The final rule contains several ancillary provisions (provisions other than the PEL), including requirements for exposure assessment, medical surveillance, familiarization and training, regulated areas (in general industry and maritime), and a written exposure control plan.

OSHA's reasons for including each of the ancillary provisions are detailed in Section XV of this preamble, Summary and Explanation of the Standards. In particular, OSHA has determined that requirements for exposure assessment (or alternately, using specified exposure control methods for selected construction operations) provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is particularly important because workers exposed at levels below the new PEL are still at significant risk of death and illness (OSHA's decision not to lower the PEL further was due to limitations on technological feasibility, rather than a determination that significant risk was eliminated at the new PEL). Medical surveillance will allow for identification of respirable crystalline silica-related adverse health effects at an early stage so that appropriate intervention measures can be taken. Regulated areas and a written exposure control plan are important in part because they help limit exposure to respirable crystalline silica to as few employees as possible. Finally, worker training is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize potential health hazards. Worker training on silica-related work practices is particularly important in controlling silica exposures because engineering controls frequently require action on the part of workers to function effectively.

As shown in Table VII–33, these ancillary provisions represent approximately $340 million (or about 35 percent) of the total annualized costs of the final rule of $962 million (using a 3 percent discount rate). The three most expensive of the ancillary provisions are the requirements for medical surveillance, with annualized costs of $96 million; the requirements for training and familiarization, with annualized costs of $94 million; and exposure assessment, with annualized costs of $71 million.

The requirements for exposure assessment in general industry and maritime are triggered by the action level. The exposures of workers in construction for whom all Table 1 requirements have been met do not have to be assessed, but if Table 1 requirements are not met, the requirements for exposure assessment in construction would also be triggered by the action level. As described in this preamble, OSHA has defined the action level for the standard as an airborne concentration of respirable crystalline silica of 25 μg/m³ calculated as an 8-hour time-weighted average. In this final rule, as in other OSHA health standards, the action level has been set at one-half of the PEL.

As explained in Chapter IV of the FEA, OSHA finds that proper implementation of engineering and work practice controls, particularly those specified in Table 1, will eliminate much of the variability in silica exposure that characterizes baseline conditions in the general industry, maritime, and construction sectors. OSHA recognizes, however, that some variability is unavoidable and uncontrollable even with such controls. Because of this variability of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level should provide reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day fall between the PEL and the action level, there is some chance that on another day, when exposures are not measured, actual exposure may exceed the PEL. When exposure measurements are below the PEL but above the action level, the employer cannot be certain that employees have not been exposed to respirable crystalline silica concentrations in excess of the PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring.

As specified in the final rule, all workers in general industry and maritime exposed to respirable crystalline silica at or above the action level of 25 μg/m³ are subject to the medical surveillance requirements. In the construction sector, medical surveillance is triggered by respirator use for 30 days or more per year (which generally corresponds to a risk of exposure above 50 μg/m³ that prompted the Table 1 respirator requirement), For the final rule, the medical surveillance requirements will apply to an estimated 141,594 workers in general industry and 270,581 workers in construction. OSHA estimates that 989 possible ILO 2/0 silicosis cases will be referred to specialists annually as a result of this medical surveillance.

OSHA's conclusion is that the requirements triggered by the action level will result in a very real and necessary, but non-quantifiable, reduction in risk beyond that provided by the PEL alone. OSHA has determined that these ancillary provisions (periodic exposure assessment, medical surveillance in general industry/maritime) will reduce significant risk in at least three ways: (1) Providing economic incentives to employers to

reduce exposures to below 25 μg/m^3 to avoid the costs of medical surveillance and exposure monitoring; (2) helping to ensure the PEL is not exceeded; and (3) providing medical exams to workers exposed at the action level, resulting in additional specialist referrals for X-ray findings consistent with silicosis and allowing employees who find out they have a silica-related disease to take action, such as changing jobs or wearing a respirator for additional protection. In sum, the ancillary provisions triggered by the action level in the final rule provide significant benefits to worker health by providing additional layers and types of protection to employees exposed to respirable crystalline silica. Medical surveillance is particularly important for this rule because those exposed at the action level are still at significant risk of illness. OSHA did not estimate, and the benefits analysis does not include, monetary benefits resulting from early discovery of illness. OSHA's choice of using an action level for exposure monitoring of one-half of the PEL is based on the Agency's enforcement experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

In response to comments on the proposed rule and PEA, among other changes discussed in Chapter V, OSHA added familiarization costs and increased estimated training costs in the FEA, and increased the cost of an industrial hygienist when conducting exposure monitoring. These changes, however, were the result of OSHA revisions to its cost estimates, not changes to the text of the regulation. Medical surveillance and exposure assessments were the ancillary provisions that were the focus of regulatory alternatives in the PEA. For these reasons, the Agency has examined four regulatory alternatives (Regulatory Alternatives #3, #4, #5, and #6) involving changes to one or the other of these two ancillary provisions. These four regulatory alternatives are defined below and the incremental cost impact of each is summarized in Table VII–35. In addition, OSHA has qualitatively considered a regulatory alternative (Regulatory Alternative #7) that would remove all ancillary provisions.

Table VII-35: Cost of Regulatory Alternatives Affecting Ancillary Provisions

	Cost			Incremental Cost Relative to Final Rule		
3% Discount Rate						
	Construction	**GI & M**	**Total**	**Construction**	**GI & M**	**Total**
Final Rule	$658,971,248	$370,810,530	$1,029,781,777	$0	$0	$0
Alternative 3: PEL=50; AL=50	$658,971,248	$299,027,174	$957,998,422	$0	-$71,783,356	-$71,783,356
Alternative 4: PEL=50; AL=25 with medical surveillance triggered by the PEL	$658,971,248	$347,860,049	$1,006,831,297	$0	-$22,950,480	-$22,950,480
Alternative5: PEL=50; AL=25 with medical exams annually	$725,253,746	$414,461,893	$1,139,715,639	$66,282,499	$43,651,363	$109,933,862
Alternative 6: PEL=50; AL=25 with medical surveillance triggered by the PEL and medical exams annually	$725,253,746	$357,463,770	$1,082,717,516	$66,282,499	-$13,346,760	$52,935,739
	Cost			**Incremental Cost Relative to Final Rule**		
7% Discount Rate						
	Construction	**GI & M**	**Total**	**Construction**	**GI & M**	**Total**
Final Rule	$672,602,589	$383,525,832	$1,056,128,421	$0	$0	$0
Alternative 3: PEL=50; AL=50	$659,564,804	$289,423,402	$948,988,206	-$13,037,785	-$94,102,430	-$107,140,215
Alternative 4: PEL=50; AL=25 with medical surveillance triggered by the PEL	$659,564,804	$347,005,802	$1,006,570,606	-$13,037,785	-$36,520,030	-$49,557,815
Alternative 5: PEL=50; AL=25 with medical exams annually	$724,872,111	$418,572,113	$1,143,444,225	$52,269,522	$35,046,281	$87,315,804
Alternative 6: PEL=50; AL=25 with medical surveillance triggered by the PEL and medical exams annually	$724,872,111	$349,890,676	$1,074,762,788	$52,269,522	-$33,635,156	$18,634,366

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Under Regulatory Alternative #3, the action level would be raised from 25 µg/m^3 to 50 µg/m^3 in the standard for general industry and maritime, while keeping the PEL at 50 µg/m^3. As a result, exposure monitoring and medical surveillance requirements would be triggered only if workers were exposed above 50 µg/m^3. No changes would be made to the construction standard because the medical surveillance trigger for that standard is respirator use, not an action level. As shown in Table VII–35, Regulatory Alternative #3 would reduce the annualized cost of the final rule by about $85 million, using a discount rate of 3 percent, and about $86 million using a discount rate of 7 percent.

Under Regulatory Alternative #4, the action level in general industry and maritime would remain at 25 µg/m^3 but

medical surveillance would now be triggered by the PEL, not the action level. As a result, medical surveillance requirements would be triggered only if workers in general industry and maritime were exposed above the PEL of 50 μg/m^3. No changes would be made to the construction standard. This alternative is similar to Alternative #3, but because the action level would remain lower, the amount of exposure monitoring would not decrease in Alternative #4 (applicable to general industry and maritime (and for construction employers following the exposure monitoring method of compliance)), exposure monitoring is required when levels exceed the action level). As shown in Table VII–35, Regulatory Alternative #4 would reduce the annualized cost of the final rule by about $28 million, using a discount rate of 3 percent and about $29 million using a discount rate of 7 percent).

Under Regulatory Alternative #5, the only change to the final rule would be to the medical surveillance frequency requirements. Instead of requiring qualifying workers to be offered a medical check-up every three years, an annual medical check-up would be required to be offered. Assuming all workers will accept this offer, as shown in Table VII–35, Regulatory Option #5 would increase the annualized cost of the final rule by about $110 million, using a discount rate of 3 percent (and by about $108 million, using a discount rate of 7 percent).

Under Regulatory Alternative #6, medical surveillance would be triggered by the PEL (in general industry and maritime), not the action level, and all workers (including in construction) subject to medical surveillance would be required to have a medical check-up annually rather than triennially. As shown in Table VII–35, Regulatory Alternative #6 would cause a net increase of the annualized cost of the final rule by about $42 million, using a discount rate of 3 percent (and by about $40 million, using a discount rate of 7 percent).

While the Agency expects there will be substantial benefits related to its ancillary provisions, it does not have the same quantitative basis for estimating benefits, and therefore does not have quantitative estimates for the benefits of the preceding four regulatory alternatives.

The final regulatory alternative affecting ancillary provisions, Regulatory Alternative #7, would eliminate all of the ancillary provisions of the final rule, including exposure assessment, medical surveillance, training, regulated areas, and the written exposure control plan. This alternative would be difficult to justify legally in light of 29 U.S.C. 655(b)(5) and (b)(7) along with case law requiring OSHA to use ancillary provisions to reduce significant risk remaining at the PEL when these provisions result in more than a de minimis benefit to workers (*see* Section II, Pertinent Legal Authority). In any event, it should be noted that elimination of the ancillary provisions does not mean that all costs for ancillary provisions would disappear. In order to meet the PEL, employers would still commonly need to conduct exposure monitoring, train workers on the use of controls, and set up some kind of regulated areas (in general industry and maritime) to indicate where respirator use would be required. It is also likely that some employers would follow the many recommendations to provide medical surveillance for employees and establish a written exposure control plan. OSHA has not attempted to estimate the extent to which the costs of these activities would be reduced if they were not formally required.

OSHA finds that the benefits estimated under the final rule will not be fully achieved if employers do not implement the ancillary provisions of the final rule. For example, OSHA believes that the effectiveness of the final rule depends on regulated areas and the written exposure control plan to further limit exposures and on medical surveillance to identify disease cases when they do occur. For construction work, the written exposure control plan is an integral part of the overall scheme to protect workers engaged in activities covered by Table 1. Without this provision, workers would risk exposures from the activities of others and exposure monitoring would need to be significantly increased to ensure protection for those workers.

Both industry and worker groups have recognized that a comprehensive standard, as opposed to a PEL alone, is needed to protect workers exposed to respirable crystalline silica. For example, the industry consensus standards for crystalline silica, ASTM E 1132—06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626—09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, as well as the draft proposed silica standard for construction developed by the Building and Construction Trades Department, AFL–CIO, have each included comprehensive programs. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance (Document ID 1466; 1504; 1509.

3. A Regulatory Alternative That Modifies the Methods of Compliance

The final standard in general industry and maritime requires employers to implement engineering and work practice controls to reduce employees' exposures to or below the PEL. Where engineering and/or work practice controls are insufficient, employers are still required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. Under the final construction standard, employers are given two options for compliance. The first option specifies, in Table 1 of the final rule, the exposure control methods and respiratory protection required for compliance when performing the specified task or operating the specified machines. Employers choosing this option must fully and properly implement the control methods and respiratory protection on the table to be considered to be in compliance with Table 1. The second option largely follows the requirements in the general industry and maritime standard: employers must conduct exposure monitoring and provide sufficient controls to ensure that their workers are not exposed above the PEL.

One regulatory alternative (Regulatory Alternative #8) involving methods of compliance would be to eliminate Table 1 as a compliance option in the construction sector. This was suggested by one commenter (Document ID 1950), as a means of promoting innovation.

As discussed in the Summary and Explanation in detail, OSHA fashioned the final rule as a sensible compromise between providing clear direction for employers, in a manner that reduces compliance burdens, and allowing for flexibility and innovation when desired. Table 1 is an option in the final rule that promotes both goals. While OSHA assumes that most establishments will choose to follow Table 1, in part to avoid the cost of monitoring, it is not a requirement. Employers are free to follow the other option (paragraph (d) of the standard) and conduct the required monitoring and devise their own means of complying with the PEL if they choose. To eliminate Table 1, therefore, would actually provide less flexibility and impose additional costs upon employers. OSHA therefore did not quantify costs or benefits for eliminating Table 1. Nonetheless, the Agency

seriously doubts that there would be any additional benefits under Alternative #8, and concludes that removing the Table 1 option would significantly increase exposure monitoring costs by taking away a carefully crafted ''safe harbor'' provision from employers.

Regulatory Alternatives That Affect the Timing of the Standard

The final rule will become effective 90 days following publication of the final rule in the **Federal Register**. The provisions outlined in the construction standard will become enforceable one year following the effective date, except for those governing sample analysis (two years). The provisions set forth in the general industry and maritime standards will become enforceable two years following the effective date, with the exception that the engineering and work practice control requirements in the hydraulic fracturing industry will become enforceable five years after the effective date.

There are many theoretical options that OSHA could explore with regard to compliance dates. These include: Requiring the fracking industry to follow the same compliance schedule as all other general industry and maritime employers; going back to the dates originally proposed (one year for engineering controls, two years for laboratories, six months for all other provisions); allowing more time for all employers to comply with the final rule; or allowing less time for all employers to come into compliance. These options are explored in detail in the Summary and Explanation for **DATES**. As indicated in that discussion, there are technical issues, and there may be additional costs, associated with advancing the compliance dates ahead of those laid out in the final rule; in all cases, pushing back the compliance deadlines will also push back the onset of benefits generated by the final rule. OSHA has not quantified the costs or benefits of either advancing or delaying any of the compliance dates because the timing of the effective dates has the same percentage effect on both benefits and costs.

I. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended in 1996, requires an agency to prepare a Final Regulatory Flexibility Analysis (FRFA) whenever it promulgates a final rule that is required to conform to the notice-and-comment rulemaking requirements of section 553 of the Administrative Procedure Act (APA) (*see* 5 U.S.C. 601–612). For OSHA rulemakings, the FRFA analysis must contain:

1. A statement of the need for, and objectives of, the rule;
2. a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
4. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
5. a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
6. a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected; and for a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities. 5 U.S.C. 604.

The Regulatory Flexibility Act further states that the required elements of the FRFA may be performed in conjunction with or as part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of the FRFA. 5 U.S.C. 605.

In addition to these elements, OSHA also includes, in this section, the recommendations from the Small Business Advocacy Review (SBAR) Panel and OSHA's responses to those recommendations.

While a full understanding of OSHA's analysis and conclusions with respect to costs and economic impacts on small entities requires a reading of the complete FEA and its supporting materials, this FRFA summarizes the key aspects of OSHA's analysis as they affect small entities.

The Need for and Objectives of the Rule

Exposure to crystalline silica has been shown to increase the risk of several serious diseases. Crystalline silica is the only known cause of silicosis, which is a progressive respiratory disease in which respirable crystalline silica particles cause an inflammatory reaction in the lung, leading to lung damage and scarring, and, in some cases, to complications resulting in disability and death. In addition, many well-conducted investigations of exposed workers have shown that exposure increases the risk of mortality from lung cancer, chronic obstructive pulmonary disease (COPD), and renal disease. OSHA's detailed analyses of the scientific literature and silica-related health risks were presented in OSHA's Review of Health Effects Literature and Preliminary QRA in the NPRM (Document ID 1711, pp. 7–229), and are included in Section VI Significance of Risk in this preamble.

OSHA reviewed numerous studies and found that they all demonstrated positive, statistically significant exposure-response relationships between exposure to crystalline silica and lung cancer mortality (*see* the Health Risk section in this preamble for more detail). In addition, OSHA noted that in 2009 the International Agency for Research on Cancer (IARC) reaffirmed its finding that respirable crystalline silica is a human carcinogen, identifying in its analysis an overall positive exposure-response relationship between cumulative exposure to crystalline silica and lung cancer mortality (*see* Section VI, Significance of Risk; Document ID 1711, pp. 269–292). Based on studies, OSHA estimates that the lifetime lung cancer mortality excess risk associated with 45 years of exposure to respirable crystalline silica ranges from 11 to 54 deaths per 1,000 workers at the preceding general industry PEL of 100 $\mu g/m^3$ respirable crystalline silica, with that risk reduced to 5 to 23 deaths per 1,000 workers at the new PEL of 50 $\mu g/m^3$ respirable crystalline silica.

OSHA has also quantitatively evaluated the mortality risk from non-malignant respiratory disease, including silicosis and COPD. Risk estimates for silicosis mortality are based on a study by Mannetje *et al.* (2002b, Document ID 1089), as reanalyzed by ToxaChemica, Inc. (2004, Document ID 0469), which pooled data from six worker cohort studies to derive a quantitative relationship between silica exposure and death rate for silicosis. For non-malignant respiratory disease generally, risk estimates are based on an epidemiologic study of diatomaceous earth workers, which included a quantitative exposure-response analysis (Park *et al.*, 2002, Document ID 0405). For 45 years of exposure to the preceding general industry PEL, OSHA's estimates of excess lifetime risk are 11 silicosis deaths per 1,000 workers for

the pooled analysis and 85 non-malignant respiratory disease deaths per 1,000 workers based on Park *et al.*'s (2002) estimates (Document ID 0405). At the new PEL, OSHA estimates silicosis and non-malignant respiratory disease mortality at 7 and 44 deaths per 1,000, respectively. As noted by Park *et al.* (2002) (Document ID 0405), it is likely that silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis; thus, Mannetje *et al.*'s analysis of deaths may tend to underestimate the true risk of silicosis mortality, while Park *et al.*'s (2002) analysis would more fairly capture the total respiratory mortality risk from all non-malignant causes, including silicosis and COPD.

OSHA also identified five studies that quantitatively described relationships between exposure to respirable crystalline silica and silicosis morbidity, as diagnosed from chest radiography. Based on the results of these studies, OSHA estimates a cumulative risk for silicosis morbidity of 60 to 773 cases per 1,000 workers for a 45-year exposure to the preceding general industry PEL of 100 μg/m^3 respirable crystalline silica, and 20 to 170 cases per 1,000 workers exposed at the new PEL of 50 μg/m^3 (*see* Section VI, Significance of Risk, Table VI–1).

OSHA's estimates of crystalline silica-related renal disease mortality risk are derived from an analysis by Steenland *et al.* (2002, Document ID 0448), in which data from three cohort studies were pooled to derive a quantitative relationship between exposure to silica and the relative risk of end-stage renal disease mortality. The cohorts included workers in the U.S. gold mining, industrial sand, and granite industries. OSHA's analysis for renal disease mortality shows estimated lifetime excess risk of 39 deaths per 1,000 workers at the preceding general industry PEL of 100 μg/m^3 respirable crystalline silica, and 32 deaths per 1,000 workers exposed at the new PEL of 50 μg/m^3 (*see* Section VI, Significance of Risk, Table VI–1).

The objective of the final rule is to reduce the numbers of fatalities and illnesses occurring among employees exposed to respirable crystalline silica in general industry, maritime, and construction sectors. This objective will be achieved by requiring employers to install engineering controls where appropriate and to provide employees with the equipment, respirators, training, exposure monitoring, medical surveillance, and other protective measures necessary for them to perform their jobs safely. The legal basis for the rule is the responsibility given to the U.S. Department of Labor through the Occupational Safety and Health Act of 1970 (OSH Act). The OSH Act provides that, in promulgating health standards dealing with toxic materials or harmful physical agents, the Secretary ''shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' 29 U.S.C. 655(b)(5) (*see* Section II, Pertinent Legal Authority for a more detailed discussion).

Summary of Significant Issues Raised by Comments on the Initial Regulatory Flexibility Analysis (IRFA) and OSHA's Assessment of, and Response to, Those Issues

Small business representatives commented on all aspects of this rule, and their comments and OSHA's responses are covered throughout this preamble and the FEA. This section of the FRFA focuses only on comments that directly concern this FRFA or the screening analysis that precedes it.

One commenter questioned the use of SBA definitions for small businesses, arguing that some definitions include firms with 500 employees or more, which, according to the commenter, are too large to constitute ''small'' businesses. The commenter commended OSHA for also including an analysis of very small entities with fewer than 20 employees (Document ID 2351, Attachment 1, p. 8). OSHA determined that both the analysis of the impacts on SBA-defined small entities and the analysis of the impacts on very small entities (those with fewer than twenty employees) are useful and important for examining small business impacts.

Two commenters were concerned that their industries had not been covered in the IRFA. The American Railroad Association noted that small railroads had not been covered (Document ID 2366, Attachment 1, p. 4). The commenter is correct that OSHA did not examine small entities in this sector in the IRFA. For the FEA, OSHA has added a discussion of small entities in the railroad industry to Chapter VI, Economic Impacts. The Sorptive Minerals Institute also stated that their industry was not covered in the IRFA (Document ID 4230, Attachment 1, p. 16). As discussed in Chapter IV, the sorptive mineral industry was covered as part of a larger industry. In any case, OSHA has excluded exposures that result from the processing of sorptive clays from the scope of the final rule.

Many commenters were concerned that OSHA had not used economic data that included the effects of the recent ''great recession''. This issue was addressed in the Chapter VI Introduction, but some commenters specifically discussed this topic in reference to small entities (Document ID 1822, Attachment 1, p. 1; 2187, Attachment 1, p. 2; 2322, p. 13; 3433, p. 8; 4231, Attachment 1, pp. 15–17). Complete data of the kind that OSHA needs for a thorough analysis of economic impacts were not yet available at the time the PEA was developed. As discussed in Chapter II, Industrial profile, the FEA, including this FRFA, uses 2012, the most recent year with complete data, as a base year and used average profits from years including the recession and surrounding years.

Some commenters were concerned with OSHA's estimates of small business profits. One commenter pointed out that OSHA had relied entirely on C corporation data, even though many affected firms might be S corporations, partnerships or sole proprietorships (Document ID 2296, Attachment 1, p. 23). This is true, but there are no published data on S corporation, partnership, or sole proprietorship profits, and thus C corporation data is the best available data. As another commenter pointed out, reported profits of small business are generally lower than the total returns earned by owners who also act as executives for their firms. The same commenter explained that smaller firms have a great deal of flexibility in deciding what portions of entity gains are reported as profits, what portions are reported as management salaries, and what portions are reported as management bonuses (Document ID 2163, Attachment 1, p. 7). As a result, it is possible that OSHA has underestimated small firm profits and thus overestimated potential impacts on profits.

Stuart Sessions argued that OSHA should have analyzed whether smaller firms have higher or lower profits than larger firms (Document ID 4231, Attachment 1, pp. 11–12). The limited data supplied by Mr. Sessions, however, did not show that small firms either had larger or smaller profits than bigger firms on an across-industry basis (Document ID 4231, Attachment 1, p. 11). Mr. Sessions developed an economic model that used a combination of multiple data sources to determine profit rates of small firms (RMA and BizMiner). In Chapter III Industrial Profile, Revenue and Profit,

OSHA discusses why the Agency's analysis does not use these alternate data sources suggested by Mr. Sessions. Mr. Sessions, testifying on behalf of the Construction Industry Safety Coalition, also testified that the use of data aggregated to the four-digit NAICS code level in OSHA's analysis shields small businesses from being captured properly in the analysis, and that ''the analysis at the six-digit level would show substantial impacts for masonry contractors who are small business . . ., which the analysis currently doesn't show'' (Document ID 3580, Tr. 1402). Mr. Sessions further claimed that, even though OSHA analyzed the costs to employers with 20 or fewer employees, the analysis still ''hid'' a lot of small businesses (Document ID 3580, Tr. 1402). The use of Internal Revenue Service's Corporation Source Book profit data at a four-digit NAICS code level is explained in Chapter III along with a discussion explaining why alternative data sources suggested by Mr. Sessions are not applied in the FEA.

At least one commenter argued that OSHA might have inaccurately estimated small firm revenues as a result of OSHA's method of projecting revenues for years when Census data are not available (Document ID 4231, Attachment 1, pp. 15–17). This argument is now moot, as OSHA is using data from the 2012 Economic Census, and is not using projected revenues in this analysis.

Some commenters argued that OSHA had not adequately accounted for diseconomies of scale in small firms (Document ID 4231, Attachment 1, pp. 2–5; 2307, Attachment 10, p. 25; 2322, Attachment 1, pp. 15–16). During his testimony, Stuart Sessions testified that it was his ''guess . . . that small businesses are substantially more likely to be noncompliant currently than large businesses,'' and requested that OSHA conduct additional analysis to ''handle the differential compliance rates between small and large business'' (Document ID 3580, Tr. 1399). As discussed in Chapter V, OSHA has changed its approach to estimating costs of small firms to account for diseconomies of scale in small firms. However, there is no evidence, other than Mr. Sessions's ''guess,'' that small firms are less compliant than large firms.

Janet Kaboth, testifying on behalf of a small company in the brick manufacturing industry, stated that small businesses are more impacted by the rule because they have more difficulty accessing capital to upgrade engineering controls:

> [Engineering controls] must be purchased and paid for in the first year of compliance. . . . It is extremely unlikely that a small entity such as Whitacre Greer would be able to obtain a bank loan . . . for something that does not reduce costs or increase revenue and additionally adds cost (Document ID 3589, Tr. 3397–3399).

As discussed in Chapter VI, Economic Impacts, small firms will typically be able to pay for the first year costs of engineering controls from a single year's profits. Thus, there is no need to account for possible difficulties in obtaining credit.

A different commenter requested that OSHA provide additional guidance in Table 1 of the construction standard as a way to mitigate the impact on small businesses (Document ID 2322, p. 6). OSHA has done so, and agrees that it will likely ease compliance for small construction businesses because it provides them with task-specific guidance that will allow them to avoid more complicated exposure monitoring processes.

Many companies, associations, and private individuals submitted comments requesting a new SBAR Panel based a number of changes that have occurred since the SBAR Panel for this rule was held in 2003. The first and most common concern was that the economic data and information gathered during the Panel have become outdated and do not represent the dramatic changes in economic conditions that have resulted from the boom and bust economic cycle that occurred in the years following 2003 (Document ID 2224, p. 2; 2004, p. 1; 3580, Tr. 1274–1276; 1779, p. 2; 1767, p. 2; 1783, p. 1; 2140, p. 1; 3495, p. 2; 1798, p. 6; 1811, pp. 1–2; 2023, p. 1; 2222, p. 1; 2224, p. 2; 2230, p. 1; 2248, Attachment 1, p. 5; 2294, p. 2; 2300, p. 2; 2305, p. 13; 2279, p. 11; 2289, p. 9; 2391, p. 2; 3275, pp. 2–3; 2075, p. 4; 2083, p. 1; 2114, Attachment 1, p. 2; 2150, p. 2; 2170, Attachment 1, p. 1; 2210, Attachment 1, pp. 1–2; 4194, p. 5; 4210, Attachment 1, p. 2; 4217, Attachment 1, p. 7). Some commenters claimed that their industries have not recovered from the recession of 2008 and feel that their economic circumstances as small entities have changed as a result (Document ID 1779, p. 2; 1767, p. 2; 1783, p. 1; 2140, p. 1; 3495, p. 2).

OSHA conducted the SBAR Panel early in the rulemaking process in order to address small business concerns during the development of the proposed rule. The Agency used information gathered during the SBAR Panel to make significant changes to the proposed rule itself, as well as to the cost, impact, and other analyses contained in the proposal. OSHA's proposal contained six pages of tables that described every recommendation from the SBAR Panel, along with the Agency's responses.

OSHA's extensive rulemaking process included small business feedback not only from the original SBREFA review in 2003, but also from the subsequent written comment period in 2013 and 2014, as well as from the public hearings held in 2014. The rulemaking record shows the major issues that arose with respect to technological feasibility, costs, economic feasibility, and possible alternatives to the proposed rule represented largely the same issues addressed by small entity representatives (SERs) in 2003. To the extent there may be new issues that have arisen since the SBAR Panel made its recommendations, OSHA is confident that commenters, including small entities and the Small Business Administration's Office of Advocacy, were able to raise those issues and express whatever concerns they had about them later in the rulemaking process. OSHA has addressed comments regarding recent and current economic conditions under which small businesses are operating by considering this information in developing the final rule and supporting analyses.

A second concern raised by commenters who were advocating for OSHA to hold a new SBAR Panel, related to the changes in technology and work practices that have taken place over the last ten years. For example, one commenter claimed that the comments of the SERs were not reflective of the greater use of tools with dust collection capability, and other devices currently being used that release water at the point of cutting, to control silica dust (Document ID 2210, Attachment 1, p. 1). However, the commenters who wanted OSHA to account for improved technology and work practices did not generally provide information to supplement or update the information OSHA received from the SERs, despite opportunities to do so.

While there has been progress in the development and adoption of technologies that reduce silica exposures, the record (including comments from the commenters calling for a new Panel) brought out few, if any, fundamentally new technologies for reducing silica exposure. In any event, the advancement of technologies that would improve silica control or reduce the cost impact of the final rule would not necessitate a new SBAR panel.

There were also a number of construction firms that expressed disappointment at not being able to

comment on Table 1, as presented in the proposed rule, prior to the proposed rule being issued (Document ID 2187, p. 22; 4217, Attachment 1, p. 7; 3580, Tr. 1274–1276). It is typical for OSHA to modify a rule as a result of the SBREFA process. The SBREFA process is a one-time requirement, not a requirement to conduct a new Panel every time a rule is altered in response to SBAR Panel recommendations. The commenters, who did have the opportunity to comment on Table 1 once it was proposed, did not present any compelling argument regarding how the timing of their opportunity to comment impacted their ability to communicate their recommendations about Table 1 to OSHA. The Agency notes that it has made a number of significant changes to Table 1 since the proposal, most in response to post-proposal comments, so it is clear that commenters had ample opportunities to recommend improvements to Table 1.

No SERs from the hydraulic fracturing industry were included in the 2003 SBAR panel. OSHA did not determine that this industry would be affected by this rule until the preparation of the NPRM and the PEA. As a result, OSHA has received comments from associations and businesses requesting a new SBAR Panel that would allow a more detailed analysis of the potential impacts on small entities in this industry. Commenters pointed out that the unique economic circumstances of the hydraulic fracturing industry were not presented for public comment or analysis on regulatory alternatives and small business impacts during the Agency's 2003 SBAR Panel (Document ID 2301, Attachment 1, p. 63; 3589, pp. 15–16; 2288, p. 5).

OSHA is not required to assure that every industry affected by a rule is represented on the Panel by a SER. The hydraulic fracturing industry had extensive opportunities to comment throughout this rulemaking process. In fact, a number of commenters, including several trade associations, submitted comments and testified at the hearing, providing analysis of the hydraulic fracturing industry for the record. OSHA sees no indication that the record would be better developed by convening a different SBAR panel with a SER from the hydraulic fracturing industry. OSHA has, however, extended the compliance deadline for these firms to install the required engineering controls required by this final rule to five years; three more years than for establishments in general industry and four more years than for construction firms.

Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration and OSHA's Response to Those Comments

The Chief Counsel for Advocacy of the Small Business Administration (''Advocacy'') provided OSHA with comments on this rule on February 11, 2014 (Document ID 2349). Advocacy provided comment on OSHA's risk assessment and benefits analysis; technological feasibility analysis; cost analysis; current economic conditions; preferred alternatives; and procedural issues.

Risk Assessment and Benefits Issues

With respect to the risk assessment, Advocacy was concerned that OSHA was attributing benefits to reducing the PEL to 50 μg/m^3 that perhaps would better be attributed to eliminating exposures above the existing PEL of 100 μg/m^3 (Document ID 2349, pp. 3–4). OSHA does not think this is the case. As discussed in the section on significant risk, OSHA did not assess the risk of silica exposure by attributing existing known cases of silicosis or any other disease to various PELs. Rather, OSHA examined risk assessment studies that assessed the long term consequences of various levels of exposure to silica. Such studies focus on estimating the morbidity and mortality that result from changing lifetime exposure levels from the preceding PELs of 100 μg/m^3 in general industry and 250 μg/m^3 in construction to the new PEL of 50 μg/m^3.

Advocacy also expressed concerns about the accuracy of older exposure data (Document ID 2349, p. 4). OSHA's exposure profile, used for examining feasibility and benefits, now shows only exposures measured after 1990 and includes data from OSHA's OIS system for 2011 to 2014.

Advocacy was also concerned that OSHA might not have adequately accounted for varying risk levels associated with different types of silica (Document ID 2349, p. 4). OSHA carefully considered this issue in the risk assessment section and found there were insufficient data to demonstrate significant risk for silica exposures that result from processing sorptive clays. As a result, OSHA excluded this processing activity from the scope of the final standard. OSHA found that, while the risk from other forms of silica may vary, there is evidence of significant risk for all of the other forms of respirable crystalline silica.

Advocacy also reported that small business representatives were concerned that ''OSHA's assumption that silica exposure occurs over a working life of eight hours per day for 45 years does not reflect modern working conditions'' (Document ID 2349, p. 4). OSHA is required by the OSH Act to consider the risk of a hazard over a worker's entire working life (see 29 U.S.C. 655(b)(5)). In Chapter VII of the FEA, OSHA also examined other possible average tenure assumptions.

Advocacy also reported that small business representatives ''noted the uncertainty of assessing silica-related risk because of confounding factors, such as smoking or exposure to other chemicals, and the long latency period for silica-related illness to appear'' (Document ID 2349, p. 4). OSHA notes in Section VI, Significance of Risk, in this preamble that study after study finds that incidence of the diseases caused by exposure to silica rises with increasing exposures to silica. In order to see this type of result, and for those results to be driven by smoking as a confounding factor, it would be necessary not just that the silica-using population smoke more than the comparable non-silica using population, but also that smoking rates rise as silica exposures increase. This seems very unlikely and there is no evidence in the record that this is the case.

Technological Feasibility Issues

Advocacy noted that small business representatives had raised many concerns about whether the controls OSHA indicated as appropriate to achieve the PEL were feasible in all circumstances and could, in fact, allow an employer to fully achieve the PEL (Document ID 2349, p. 4). OSHA has thoroughly examined all comments on this kind of issue across all affected industries in Chapter IV of the FEA, and OSHA notes that employers may raise infeasibility as a defense in enforcement actions. Advocacy also noted that small business representatives were concerned about whether available methods of measuring exposure were sufficiently accurate to correctly measure the action level and PEL (Document ID 2349, p. 4). OSHA has explained in Chapter IV of the FEA why existing equipment is sufficiently accurate to correctly measure airborne respirable silica at the levels established by the new PEL and action level.

Advocacy said that one small business representative ''noted that increasing the volume of air needed for additional ventilation could result in a violation of a facility's air permit'' (Document ID 2349, p. 5). While the Agency does not believe that most small employers exhaust large enough volumes of air that the additional

ventilation required by this final standard will result in needing to alter air permits, OSHA does acknowledge that this may be an issue for some employers. In order to reduce the burden, should this be the case, OSHA has given general industry employers an additional year to meet the PEL, and has added costs for firms subject to air permitting requirements to alter their permits to more fully assess the economic feasibility of this rule.

Advocacy also said that one small business representative ''noted that creating regulated areas is not feasible in many open-design facilities'' (Document ID 2349, p. 5). Regulated area requirements have been a part of OSHA health standards for many years and employers have consistently found ways to make them work. The Agency does not expect that establishing a regulated area for silica would be any more difficult than establishing such an area for any of the other substances for which OSHA has regulated area requirements. In addition, OSHA does not have a regulated area requirement in construction where workplaces (such as in road building or repair) are more mobile.

Cost Issues

Advocacy stated that small business representatives generally felt that OSHA underestimated costs, and were particularly concerned about OSHA's ''cost per exposed worker'' approach and OSHA's estimates of the number of workers whose exposures are controlled per engineering control (Document ID 2349, p. 5). The specific methodological issues that Advocacy mentions are issues for OSHA's general industry and maritime cost estimates, but not for construction cost estimates because the cost estimation methodologies for the construction sector are quite different and do not use the ''cost per exposed worker'' approach. OSHA has provided detailed responses to comments on costs in Chapter V. In general industry and maritime, OSHA continues to use the cost per exposed worker approach and defends this approach in Chapter V. OSHA has lowered its estimate of the number of workers whose exposures are reduced per engineering control in response to comments from small business representatives and others.

Advocacy also noted that small business representatives objected to OSHA focusing on the incremental cost of moving from the preceding PELs to the new PEL. Advocacy reported that small business representatives believed OSHA should have included the costs of reaching the preceding PEL in its analysis (Document ID 2349, p. 5). Contrary to Advocacy's suggestion, OSHA did not conduct the analysis this way because it would require an assumption that employers are not complying with OSHA's existing requirements to meet the preceding PEL, but would now choose to comply with a more stringent requirement. OSHA's exposure profiles do indicate that many employers are failing to meet the preceding PELs, but the question that the Agency has to address with this analysis for this rulemaking is whether OSHA should require employers to meet a lower PEL than the preceding PEL. The costs of meeting the preceding PEL are not relevant to that decision.

Issues Concerning Current Economic Conditions

Advocacy reported that ''small business representatives stated that OSHA was using older economic data that does not reflect current economic conditions, and [thus] that OSHA's cost pass-through assumptions are unrealistic'' (Document ID 2349, p. 5). For the FEA, OSHA is using 2012 as the base year for economic data and includes data from the recent recession in analyzing average industry profits and historical changes in profits and prices. OSHA has updated its findings on the ability of firms to pass costs on to buyers in light of the updated data, resolving Advocacy's concern on this issue.

Regulatory Alternatives

Advocacy commended OSHA for following the advice of small business representatives and adopting the Table 1 approach for the construction sector, but urged OSHA to make the table clearer, more workable, and more specific, and to relieve employers of any remaining duty to conduct exposure monitoring when engaged in Table 1 tasks (Document ID 2349, p. 6). OSHA has revised Table 1, as Advocacy and small business representatives suggested, to provide employers with a clear alternative to exposure monitoring and to provide greater clarity and specificity in the descriptions of controls.

Advocacy also urged OSHA to consider the option of leaving the PEL unchanged and instead improving enforcement, noting that this was the option most favored by small business representatives (Document ID 2349, p. 3). However, the OSH Act commands OSHA to protect workers from harmful substances by setting

> . . . the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' 29 U.S.C. 655(b)(5).

The record does not indicate that workers are currently protected in accordance with the Act. There are currently two entirely different PELs, 100 μg/m^3 in general industry and 250 μg/m^3 in construction. The record does not suggest either that employers in construction cannot feasibly reach a lower PEL or that there is no significant risk below 250 μg/m^3. The record shows that most employers in construction currently reach a PEL of 50 μg/m^3 most of the time (*see* Chapter IV) and that it is economically feasible to do so (*see* Chapter VI).

OSHA did consider the option of lowering the construction PEL to 100 μg/m^3 and leaving the general industry PEL unchanged. However, this action would not be in accordance with the OSH Act given that there is still significant risk at a PEL of 100 μg/m^3 and that a lower PEL is both technologically and economically feasible. As shown in OSHA's risk assessment, there is still significant risk of material impairment of health at levels all the way down to a lower PEL of 25 μg/m^3, but OSHA found compliance with the lower PEL of 25 μg/m^3 to be technologically infeasible for all industries.

Finally, Advocacy urged OSHA to consider the option of abandoning the hierarchy of controls, which is OSHA's longstanding policy of preferring engineering controls and administrative controls over personal protective equipment such as respirators (Document ID 2349, pp. 4–5). This issue is addressed in the summary and explanation section discussion of the methods of compliance provision. It should also be noted that OSHA defines technological feasibility in terms of what can be accomplished with engineering controls, not in terms of what can be accomplished with respirators.

Issues With Respect to Small Business Participation

Advocacy also expressed concern that small businesses did not have adequate opportunity for participation in the rulemaking process and that the SBAR panel was held over ten years before the proposed rule was issued (Document ID 2349, p. 7). OSHA responded to these concerns in section two of this FRFA.

A Description and Estimate of the Number of Small Entities To Which the Rule Will Apply

OSHA has analyzed the impacts associated with this final rule, including the type and number of small entities to which the standard will apply. In order to determine the number of small entities potentially affected by this rulemaking, OSHA used the definitions of small entities developed by the Small Business Administration (SBA) for each industry.

OSHA estimates that approximately 646,000 small business or government entities would be affected by the silica standard. Within these small entities, roughly 1.4 million workers are exposed to crystalline silica and would be protected by this final standard. A breakdown, by industry, of the number of affected small entities is provided in Table III–6 in Chapter III of the FEA.

OSHA estimates that approximately 579,000 very small entities would be affected by the silica standard. Within these very small entities, roughly 785,000 workers are exposed to crystalline silica and would be protected by the standard. A breakdown, by industry, of the number of affected very small entities is provided in Table III–7 in Chapter III of the FEA.

A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

Tables VII–36 and VII–37 show the average costs of the silica standard and the costs of compliance as a percentage of profits and revenues by NAICS code for, respectively, small entities (classified as small by SBA) and very small entities (those with fewer than 20 employees). The costs for SBA defined small entities ranges from a low of $295 per entity for entities in NAICS 238200 Building Equipment Contractors, to a high of about $161,651 for NAICS 213112 Support Activities for Oil and Gas Operations.

The cost for very small entities ranges from a low of $223 for entities in NAICS 238200 Building Equipment Contractors, to a high of about $119,072 for entities in NAICS 213112 Support Activities for Oil and Gas Operations.

Tables VII–38a and VII–38b show the unit costs which form the basis for OSHA's cost estimates for the average small entity and very small entity.

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Table VII-36: Average Costs and Impacts for Small Entities Affected by the Final Silica Standard for General Industry, Maritime, and Construction (2012 dollars)

NAICS	Industry	Cost per Affected Entity	Cost to Profit	Cost to Revenue
213112	Support Activities for Oil and Gas Operations	$161,651	18.15%	1.29%
324121	Asphalt Paving Mixture and Block Manufacturing	$610	0.07%	0.00%
324122	Asphalt Shingle and Coating Materials Manufacturing	$10,782	0.81%	0.05%
325510	Paint and Coating Manufacturing	$887	0.29%	0.01%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$8,161	38.57%	0.52%
327120	Clay Building Material and Refractories Manufacturing	$34,727	33.59%	0.45%
327211	Flat Glass Manufacturing	$3,282	1.72%	0.05%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$6,171	7.50%	0.20%
327213	Glass Container Manufacturing	$81,273	2.20%	0.06%
327320	Ready-Mix Concrete Manufacturing	$9,821	11.51%	0.16%
327331	Concrete Block and Brick Manufacturing	$9,363	13.11%	0.19%
327332	Concrete Pipe Manufacturing	$12,926	14.53%	0.21%
327390	Other Concrete Product Manufacturing	$9,139	18.59%	0.27%
327991	Cut Stone and Stone Product Manufacturing	$7,343	24.70%	0.43%
327992	Ground or Treated Mineral and Earth Manufacturing	$16,878	9.60%	0.17%
327993	Mineral Wool Manufacturing	$8,768	5.76%	0.10%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$21,200	20.90%	0.37%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	$1,194	0.16%	0.00%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	$1,262	0.17%	0.00%
331221	Rolled Steel Shape Manufacturing	$1,210	0.16%	0.00%
331222	Steel Wire Drawing	$1,254	0.38%	0.01%
331314	Secondary Smelting and Alloying of Aluminum	$1,249	0.17%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	$1,280	0.11%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$1,218	0.12%	0.00%
331511	Iron Foundries	$38,050	6.38%	0.28%
331512	Steel Investment Foundries	$26,727	4.64%	0.20%

Table VII-36: Average Costs and Impacts for Small Entities Affected by the Final Silica Standard for General Industry, Maritime, and Construction (2012 dollars) (continued)

NAICS	Industry	Cost per Affected Entity	Cost to Profit	Cost to Revenue
331513	Steel Foundries (except Investment)	$31,446	6.97%	0.30%
331524	Aluminum Foundries (except Die-Casting)	$8,437	4.06%	0.18%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$6,092	2.67%	0.12%
332111	Iron and Steel Forging	$1,199	0.19%	0.01%
332112	Nonferrous Forging	$1,186	0.19%	0.01%
332117	Powder Metallurgy Part Manufacturing	$1,174	0.35%	0.01%
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$1,179	0.51%	0.02%
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	$1,181	0.46%	0.02%
332216	Saw Blade and Handtool Manufacturing	$1,203	0.77%	0.03%
332323	Ornamental and Architectural Metal Work Manufacturing	$1,081	1.95%	0.05%
332439	Other Metal Container Manufacturing	$1,221	0.76%	0.02%
332510	Hardware Manufacturing	$1,178	0.40%	0.02%
332613	Spring Manufacturing	$1,245	0.42%	0.02%
332618	Other Fabricated Wire Product Manufacturing	$1,213	0.51%	0.02%
332710	Machine Shops	$1,147	1.36%	0.06%
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	$1,851	1.91%	0.06%
332911	Industrial Valve Manufacturing	$1,213	0.17%	0.01%
332912	Fluid Power Valve and Hose Fitting Manufacturing	$1,211	0.18%	0.01%
332913	Plumbing Fixture Fitting and Trim Manufacturing	$1,198	0.13%	0.01%
332919	Other Metal Valve and Pipe Fitting Manufacturing	$1,193	0.17%	0.01%
332991	Ball and Roller Bearing Manufacturing	$1,237	0.21%	0.01%
332996	Fabricated Pipe and Pipe Fitting Manufacturing	$1,172	0.28%	0.02%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$1,153	0.56%	0.03%
333318	Other Commercial and Service Industry Machinery Manufacturing	$1,162	0.48%	0.01%
333413	Industrial and Commercial Fan and Blower and Air Purification	$1,202	0.58%	0.02%

Table VII-36: Average Costs and Impacts for Small Entities Affected by the Final Silica Standard for General Industry, Maritime, and Construction (2012 dollars) (continued)

NAICS	Industry	Cost per Affected Entity	Cost to Profit	Cost to Revenue
	Equipment Manufacturing			
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	$1,166	0.51%	0.02%
333511	Industrial Mold Manufacturing	$1,161	0.92%	0.04%
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	$1,150	1.17%	0.04%
333515	Cutting Tool and Machine Tool Accessory Manufacturing	$1,166	1.13%	0.04%
333517	Machine Tool Manufacturing	$1,169	0.45%	0.02%
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	$1,171	0.52%	0.02%
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	$1,235	0.55%	0.01%
333613	Mechanical Power Transmission Equipment Manufacturing	$1,196	0.63%	0.01%
333911	Pump and Pumping Equipment Manufacturing	$1,195	0.29%	0.01%
333912	Air and Gas Compressor Manufacturing	$1,201	0.22%	0.01%
333991	Power-Driven Handtool Manufacturing	$1,160	0.44%	0.02%
333992	Welding and Soldering Equipment Manufacturing	$1,159	0.45%	0.02%
333993	Packaging Machinery Manufacturing	$1,170	0.50%	0.02%
333994	Industrial Process Furnace and Oven Manufacturing	$1,188	0.51%	0.02%
333995	Fluid Power Cylinder and Actuator Manufacturing	$1,210	0.32%	0.01%
333996	Fluid Power Pump and Motor Manufacturing	$1,158	0.38%	0.01%
333997	Scale and Balance Manufacturing	$1,184	0.65%	0.02%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$1,156	0.64%	0.02%
334519	Other Measuring and Controlling Device Manufacturing	$1,163	0.46%	0.02%
335210	Small Electrical Appliance Manufacturing	$1,077	0.16%	0.01%
335221	Household Cooking Appliance Manufacturing	$968	0.13%	0.01%
335222	Household Refrigerator and Home Freezer Manufacturing	$1,005	0.08%	0.00%
335224	Household Laundry Equipment Manufacturing	$958	0.50%	0.02%
335228	Other Major Household Appliance Manufacturing	$986	0.12%	0.00%
336111	Automobile Manufacturing [1]	$1,031	-1.57%	0.01%
336112	Light Truck and Utility Vehicle Manufacturing	$1,017	-1.16%	0.01%

Table VII-36: Average Costs and Impacts for Small Entities Affected by the Final Silica Standard for General Industry, Maritime, and Construction (2012 dollars) (continued)

NAICS	Industry	Cost per Affected Entity	Cost to Profit	Cost to Revenue
336120	Heavy Duty Truck Manufacturing	$1,164	-0.49%	0.00%
336211	Motor Vehicle Body Manufacturing	$1,207	0.91%	0.01%
336212	Truck Trailer Manufacturing	$1,220	0.95%	0.01%
336213	Motor Home Manufacturing	$1,139	0.97%	0.01%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$1,144	1.11%	0.01%
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$1,179	0.62%	0.01%
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$1,151	0.42%	0.01%
336340	Motor Vehicle Brake System Manufacturing	$1,241	0.40%	0.01%
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$1,178	0.41%	0.01%
336370	Motor Vehicle Metal Stamping	$1,254	0.41%	0.01%
336390	Other Motor Vehicle Parts Manufacturing	$1,199	0.49%	0.01%
336611	Ship Building and Repairing	$7,778	1.30%	0.08%
336612	Boat Building	$6,551	1.79%	0.11%
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	$1,186	0.12%	0.00%
337110	Wood Kitchen Cabinet and Countertop Manufacturing	$900	3.24%	0.09%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$1,177	0.97%	0.03%
339114	Dental Equipment and Supplies Manufacturing	$6,215	1.95%	0.14%
339116	Dental Laboratories	$878	2.33%	0.17%
339910	Jewelry and Silverware Manufacturing	$988	1.28%	0.05%
339950	Sign Manufacturing	$1,088	1.69%	0.07%
423840	Industrial Supplies Merchant Wholesalers	$1,469	1.05%	0.03%
444110	Home Centers	$1,219	0.61%	0.04%
482110	Rail transportation [2]	N/A	N/A	N/A
561730	Landscaping Services	$716	5.49%	0.16%
621210	Offices of Dentists	$312	0.51%	0.04%
236100	Residential Building Construction	$333	1.6%	0.04%
236200	Nonresidential Building Construction	$879	1.0%	0.02%

Table VII-36: Average Costs and Impacts for Small Entities Affected by the Final Silica Standard for General Industry, Maritime, and Construction (2012 dollars) (continued)

NAICS	Industry	Cost per Affected Entity	Cost to Profit	Cost to Revenue
237100	Utility System Construction	$1,806	2.4%	0.08%
237200	Land Subdivision	$459	-1.7%	0.02%
237300	Highway, Street, and Bridge Construction	$2,449	1.9%	0.06%
237900	Other Heavy and Civil Engineering Construction	$1,368	2.2%	0.06%
238100	Foundation, Structure, and Building Exterior Contractors	$1,306	3.7%	0.13%
238200	Building Equipment Contractors	$295	0.7%	0.03%
238300	Building Finishing Contractors	$581	2.5%	0.08%
238900	Other Specialty Trade Contractors	$1,241	3.0%	0.10%
221100	Electric Utilities	$458	0.2%	0.00%
999200	State Governments	N/A	N/A	N/A
999300	Local Governments	N/A	N/A	N/A

N/A = Not applicable.

[1] During the recession, some industries had a negative “net income.” For example, NAICS code 3361, Motor Vehicle Manufacturing (the four digit NAICS industry that includes the six digit NAICS industries 336111 Automobile Manufacturing, 336112 Light Truck and Utility Vehicle Manufacturing, and 336120 Heavy Duty Truck Manufacturing), had a large negative “net income” for 2008 and 2009, pulling the average profit rate down to -7.76 percent. Similarly, NAICS code 237200, Land Subdivision, had a large negative “net income” for 2008 through 2010, pulling the average profit rate down to -2.7 percent. Such negative average profit rates resulted in negative cost to profit ratios for some of the industries in this table.

[2] Costs and impact to rail transportation were estimated separately. See the discussions in Chapter V and Chapter VI in the FEA for more information

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA (2016).

Table VII-37: Average Costs for Very Small Entities (<20 employees) Affected by the Final Silica Standard for General Industry, Maritime, and Construction (2012 dollars)

NAICS	Industry [1]	Cost per Affected Entity	Cost to Profit	Cost to Revenue
213112	Support Activities for Oil and Gas Operations	$119,072	29.46%	2.09%
324121	Asphalt Paving Mixture and Block Manufacturing	$234	0.07%	0.00%
324122	Asphalt Shingle and Coating Materials Manufacturing	$3,670	1.44%	0.09%
325510	Paint and Coating Manufacturing	$325	0.48%	0.02%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$4,542	90.64%	1.21%
327120	Clay Building Material and Refractories Manufacturing	$8,136	58.51%	0.78%
327211	Flat Glass Manufacturing	$3,969	20.44%	0.54%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$3,951	22.66%	0.59%
327213	Glass Container Manufacturing	$3,927	6.66%	0.17%
327320	Ready-Mix Concrete Manufacturing	$4,291	15.91%	0.23%
327331	Concrete Block and Brick Manufacturing	$4,322	19.52%	0.28%
327332	Concrete Pipe Manufacturing	$4,612	22.11%	0.32%
327390	Other Concrete Product Manufacturing	$3,912	29.24%	0.42%
327991	Cut Stone and Stone Product Manufacturing	$3,835	30.81%	0.54%
327992	Ground or Treated Mineral and Earth Manufacturing	$6,671	16.33%	0.29%
327993	Mineral Wool Manufacturing	$3,966	17.42%	0.31%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$12,216	51.05%	0.89%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	N/A	N/A	N/A
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	N/A	N/A	N/A
331221	Rolled Steel Shape Manufacturing	N/A	N/A	N/A
331222	Steel Wire Drawing	N/A	N/A	N/A
331314	Secondary Smelting and Alloying of Aluminum	N/A	N/A	N/A
331420	Copper Rolling, Drawing, Extruding, and Alloying	N/A	N/A	N/A
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except	N/A	N/A	N/A
331511	Iron Foundries	$6,324	10.03%	0.44%
331512	Steel Investment Foundries	$4,163	5.72%	0.25%
331513	Steel Foundries (except Investment)	$6,287	12.27%	0.53%
331524	Aluminum Foundries (except Die-Casting)	$3,776	11.29%	0.49%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$4,564	8.79%	0.38%
332111	Iron and Steel Forging	N/A	N/A	N/A
332112	Nonferrous Forging	N/A	N/A	N/A
332117	Powder Metallurgy Part Manufacturing	N/A	N/A	N/A
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	N/A	N/A	N/A
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except	N/A	N/A	N/A
332216	Saw Blade and Handtool Manufacturing	N/A	N/A	N/A

Table VII-37: Average Costs and Impacts for Very Small Entities (<20 employees) Affected by the Final Silica Standard for General Industry, Maritime, and Construction (2012 dollars) continued

NAICS	Industry	Cost per Affected Entity	Cost to Profit	Cost to Revenue
332323	Ornamental and Architectural Metal Work Manufacturing	$1,158	6.22%	0.17%
332439	Other Metal Container Manufacturing	N/A	N/A	N/A
332510	Hardware Manufacturing	N/A	N/A	N/A
332613	Spring Manufacturing	N/A	N/A	N//A
332618	Other Fabricated Wire Product Manufacturing	N/A	N/A	N/A
332710	Machine Shops	N/A	N/A	N/A
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied	$1,158	5.51%	0.16%
332911	Industrial Valve Manufacturing	N/A	N/A	N/A
332912	Fluid Power Valve and Hose Fitting Manufacturing	N/A	N/A	N/A
332913	Plumbing Fixture Fitting and Trim Manufacturing	N/A	N/A	N/A
332919	Other Metal Valve and Pipe Fitting Manufacturing	N/A	N/A	N/A
332991	Ball and Roller Bearing Manufacturing	N/A	N/A	N/A
332996	Fabricated Pipe and Pipe Fitting Manufacturing	N/A	N/A	N/A
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	N/A	N/A	N/A
333318	Other Commercial and Service Industry Machinery Manufacturing	N/A	N/A	N/A
333413	Industrial and Commercial Fan and Blower and Air Purification	N/A	N/A	N/A
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	N/A	N/A	N/A
333511	Industrial Mold Manufacturing	N/A	N/A	N/A
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	N/A	N/A	N/A
333515	Cutting Tool and Machine Tool Accessory Manufacturing	N/A	N/A	N/A
333517	Machine Tool Manufacturing	N/A	N/A	N/A
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	N/A	N/A	N/A
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	N/A	N/A	N/A
333613	Mechanical Power Transmission Equipment Manufacturing	N/A	N/A	N/A
333911	Pump and Pumping Equipment Manufacturing	N/A	N/A	N/A
333912	Air and Gas Compressor Manufacturing	N/A	N/A	N/A
333991	Power-Driven Handtool Manufacturing	N/A	N/A	N/A
333992	Welding and Soldering Equipment Manufacturing	N/A	N/A	N/A
333993	Packaging Machinery Manufacturing	N/A	N/A	N/A
333994	Industrial Process Furnace and Oven Manufacturing	N/A	N/A	N/A
333995	Fluid Power Cylinder and Actuator Manufacturing	N/A	N/A	N/A
333996	Fluid Power Pump and Motor Manufacturing	N/A	N/A	N/A
333997	Scale and Balance Manufacturing	N/A	N/A	N/A
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	N/A	N/A	N/A
334519	Other Measuring and Controlling Device Manufacturing	N/A	N/A	N/A
335210	Small Electrical Appliance Manufacturing	$1,165	1.62%	0.06%
335221	Household Cooking Appliance Manufacturing	N/A	N/A	N/A
335222	Household Refrigerator and Home Freezer Manufacturing	N/A	N/A	N/A
335224	Household Laundry Equipment Manufacturing	N/A	N/A	N/A

Table VII-37: Average Costs and Impacts for Very Small Entities (<20 employees) Affected by the Final Silica Standard for General Industry, Maritime, and Construction (2012 dollars) continued

NAICS	Industry	Cost per Affected Entity	Cost to Profit	Cost to Revenue
335228	Other Major Household Appliance Manufacturing	N/A	N/A	N/A
336111	Automobile Manufacturing	N/A	N/A	N/A
336112	Light Truck and Utility Vehicle Manufacturing	N/A	N/A	NA
336120	Heavy Duty Truck Manufacturing	N/A	N/A	N/A
336211	Motor Vehicle Body Manufacturing	N/A	N/A	N/A
336212	Truck Trailer Manufacturing	N/A	NA	NA
336213	Motor Home Manufacturing	N/A	N/A	N/A
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	N/A	N/A	N/A
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	N/A	N/A	N/A
336330	Motor Vehicle Steering and Suspension Components (except Spring)	N/A	N/A	N/A
336340	Motor Vehicle Brake System Manufacturing	N/A	N/A	N/A
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	N/A	N/A	N/A
336370	Motor Vehicle Metal Stamping	N/A	N/A	N/A
336390	Other Motor Vehicle Parts Manufacturing	N/A	N/A	N/A
336611	Ship Building and Repairing	$1,778	2.12%	0.13%
336612	Boat Building	$1,773	2.41%	0.15%
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	N/A	N/A	N/A
337110	Wood Kitchen Cabinet and Countertop Manufacturing	$828	7.03%	0.19%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	N/A	N/A	N/A
339114	Dental Equipment and Supplies Manufacturing	$2,919	5.92%	0.43%
339116	Dental Laboratories	$748	3.49%	0.26%
339910	Jewelry and Silverware Manufacturing	$534	2.17%	0.09%
339950	Sign Manufacturing	$1,211	6.21%	0.24%
423840	Industrial Supplies Merchant Wholesalers	$1,241	1.66%	0.05%
444110	Home Centers	$935	1.14%	0.07%
482110	Rail transportation [2]	N/A	N/A	N/A
561730	Landscaping Services	$770	8.13%	0.24%
621210	Offices of Dentists	$308	0.57%	0.04%
236100	Residential Building Construction	$282	1.9%	0.04%
236200	Nonresidential Building Construction	$546	1.2%	0.03%
237100	Utility System Construction	$965	2.8%	0.09%
237200	Land Subdivision [3]	$388	-2.7%	0.04%
237300	Highway, Street, and Bridge Construction	$1,086	2.0%	0.06%
237900	Other Heavy and Civil Engineering Construction	$795	2.6%	0.07%
238100	Foundation, Structure, and Building Exterior Contractors	$828	3.9%	0.13%
238200	Building Equipment Contractors	$223	1.0%	0.04%
238300	Building Finishing Contractors	$448	2.9%	0.10%
238900	Other Specialty Trade Contractors	$825	3.3%	0.11%
221100	Electric Utilities	$451	1.0%	0.01%
999200	State Governments	N/A	N/A	N/A
999300	Local Governments	N/A	N/A	N/A

N/A = Not applicable.

[1] In the PEA, OSHA identified a number of industries as having captive foundries and estimated that some very small entities in those industries would have captive foundries. For the FEA, the Agency determined that this assumption was incorrect and that entities with fewer than 20 employees would not have enough workers to perform foundry operations as well as their primary business operations. For the sake of comparability between the PEA and FEA, OSHA has left those industries in this table but shows that very small entities in those industries will have no costs associated with this final rule.

[2] Costs and impact to rail transportation were estimated separately. See the discussions in Chapter V and Chapter VI for more information.

[3] During the recession some industries had a negative "net income". For example, the NAICS code 237200, Land Subdivision, had a large negative "net income" for 2008 through 2011, pulling the average profit rate down to -2.7 percent. This negative average profit rate resulted in a negative cost to profit ratio for this industry.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016.

Table VII-38a: Source Information for the Unit Cost Estimates Used in OSHA's Final Cost Analysis for General Industry and Maritime

Control [a]	Description	Ventilation Airflow (cfm)	Capital Cost [b]	Operating Cost	Annualized Capital Cost	Comment or Source
Local exhaust ventilation (LEV)	Average capital and operating cost assumptions; per cfm	N/A	$13.34	$3.70	$1.56	Estimated by industrial ventilation consultants, capital cost [a]; operating costs reflect current energy prices
Conveyor covers (unventilated)	Conveyor covers (2 ft. bed, including all hardware); per linear foot	N/A	$20.73	NA	$2.43	$17.10 per linear foot for 100 ft. (Landola, 2003) [a]
Maintenance percentage	Standard rate for maintenance of capital equipment	N/A	N/A	N/A	N/A	10% - estimated as a percentage of capital cost
Dust suppressants	Kleen Products 50lb poly bag green sweeping compound	N/A	N/A	$676.47	$0.00	$0.28/lb, 2 lbs/day; 5 minutes/day (www.fastenal.com).
HEPA vacuum for housekeeping	NILFISK VT60 wet/dry hepa vac, 15 gal	N/A	$3,632.58	$511.20	$793.19	Nilfisk, HEPA vacuum (http://www.sylvane.com/nilfisk.html)
HEPA vacuum for housekeeping	NILFISK, large capacity	N/A	$8,002.49	$988.90	$1,747.38	Nilfisk, HEPA vacuum (McCarthy, 2003)
Saw enclosure	8x8x8 wood/plastic	N/A	$526.90	$52.69	$115.05	Fabrication costs estimated by ERG, assuming in-plant work. Five-year life.
Cab enclosures	Enclosed cabs	N/A	$15,762	$5,517	$3,441.81	ERG estimate based on vendor interviews.

Table VII-38a: Source Information for the Unit Cost Estimates Used in OSHA's Final Cost Analysis for General Industry and Maritime(continued)

Control [a]	Description	Ventilation Airflow (cfm)	Capital Cost [b]	Operating Cost	Annualized Capital Cost	Comment or Source
LEV for hand held grinders	Shrouds + vacuum	N/A	$1,737.51	$608.13	$379.39	Vacuum plus shroud adapter (http://www.proventilation.com/products/productDetail.asp?id=15); 35% for maintenance and operating costs.
Upgraded abrasive blast cabinet	Improved maintenance and purchases for some	N/A	$4,850	$1,000	$568.57	Assumes addit.maint. (of up to $2,000) or new cabinets ($8,000) (Norton, 2003) [a]
Yard dust suppression	100 ft, 1" contractor hose and nozzle	N/A	$212.19	$0.00	$110.89	Contactor hose and nozzle; 2 year life; (www.pwmall.com) [a]
Wet methods to clean concrete mixing equip.	10 minutes per day per operator	N/A	$0.00	$1,024.04	$0.00	10 mins per day per mixer operator
HEPA vacuum substitute for compressed air	Incremental time to remove dust by vacuum	N/A	NA	$536.47	$0.00	5 min per day per affected worker
Spray system for wet concrete finishing	Shop-built sprayer system	N/A	$213.42	$21.34	$111.54	Assumes $100 in materials and 4 hours to fabricate. Also 10% for maint.
Improved spray booth for pottery	Maintenance time & materials	N/A	$121.25	$118.42	$239.67	Annual: $100 materials plus 4 hours maintenance time [a]
Improved LEV for ceramics spray booth	Increased air flow; per cfm	N/A	$3.33	$0.92	$3.33	25% of installed CFM price
Exhaust for saw, cut stone industry	Based on saw LEV (e.g., pg. 10-158, 159, 160, ACGIH, 2001)	645	$8,602.67	$2,385.88	$1,008.50	Includes 545 cfm for saw base and 100 cfm for blade guard; updated to ACGIH 2013; VS-65-02, pg 13-79
LEV for hand chipping in cut stone	Granite cutting and finishing; (pg. 10-94, ACGIH, 2001)	600	$8,002.49	$2,219.43	$938.14	ERG estimate of CFM requirements
Exhaust trimming machine	Based on abrasive cut-off saw; (pg. 10-134) (ACGIH, 2001)	500	$6,668.74	$1,849.52	$781.78	Opening of 2 sq ft assumed, with 250 cfm/sq.ft

Table VII-38a: Source Information for the Unit Cost Estimates Used in OSHA's Final Cost Analysis for General Industry and Maritime(continued)

Control [a]	Description	Ventilation Airflow (cfm)	Capital Cost [b]	Operating Cost	Annualized Capital Cost	Comment or Source
Bag opening	Bag opening station; (pg. 10-19, ACGIH, 2001)	1,513	$20,179.60	$5,596.66	$2,365.66	3.5'x1.5' opening; with ventilated bag crusher (200 cfm)
Conveyor ventilation	Conveyor belt ventilation; (pg. 10-70, ACGIH, 2001)	700	$9,336.23	$2,589.33	$1,094.49	Per take-off point, 2' wide belt.
Bucket elevator ventilation	Bucket elevator ventilation (pg. 10-68; ACGIH,2001)	1,600	$21,339.96	$5,918.47	$2,501.69	2'x3'x30' casing; 4 take-offs @250 cfm; 100 cfm per sq ft of cross section
Bin and hopper ventilation	Bin and hopper ventilation (pg. 10-69; ACGIH, 2001)	1,050	$14,004.35	$3,884.00	$1,641.74	350 cfm per ft2; 3' belt width
Screen ventilation	Ventilated screen (pg. 10-173, ACGIH, 2001)	1,200	$16,004.97	$4,438.86	$1,876.27	4'x6' screen; 50 cfm per ft2
Batch operator workstation	Bin & hopper ventilation for unvented mixers (pg. 10-69, ACGIH, 2001)	1,050	$14,004.35	$3,884.00	$1,641.74	ERG estimate of CFM requirements
LEV for hand grinding operator (pottery)	Hand grinding bench (pg. 10-135, ACGIH, 2001)	3,750	$50,015.54	$13,871.42	$5,863.35	ERG estimate of CFM requirements
LEV, mixer and muller hood	Mixer & muller hood (pg. 10-87, ACGIH, 2001)	1,050	$14,004.35	$3,884.00	$1,641.74	ERG estimate of CFM requirements
LEV for bag filling stations	Bag filling station (pg. 10-15, ACGIH, 2001)	1,500	$20,006.21	$5,548.57	$2,345.34	Includes costs for air shower
Installed manual spray mister	Manual controls, system covers 100 ft of conveyor	N/A	$10,609.36	$1,060.94	$1,243.74	National Environmental Services Company (Kestner, 2003). [a]
Install cleaning hoses, reslope floor, drainage	Plumbing for hose installations, floor resloping and troughs	N/A	$36,412.40	$3,323.52	$4,268.64	ERG estimate. Includes cost of water and labor time.
Substitute alt., non-silica, blasting media	Alternative media estimated to cost 22 percent more	N/A	$0.00	$5,156.25	$0.00	Based on 220,000 square feet of coverage per year per crew
Shakeout conveyor enclosure	Ventilated shakeout conveyor enclosure	10,000	$133,374.76	$36,990.46	$15,635.59	ERG estimate

Table VII-38a: Source Information for the Unit Cost Estimates Used in OSHA's Final Cost Analysis for General Industry and Maritime(continued)

Control [a]	Description	Ventilation Airflow (cfm)	Capital Cost [b]	Operating Cost	Annualized Capital Cost	Comment or Source
Shakeout side-draft ventilation	Shakeout double side-draft table (pg. 10-23, ACGIH, 2001)	28,800	$384,119.32	$106,532.52	$45,030.50	ERG estimate of CFM requirements
Shakeout enclosing hood	Ventilated enclosing hood (pg. 10-23, ACGIGH, 2001); 4'x4' openings	7,040	$93,895.83	$26,041.28	$11,007.46	ERG estimate of opening size required
Small knockout table	Portable grinding table pg. 10-136), ACGIH, 2001), 3'x3' opening	1,350	$18,005.59	$4,993.71	$2,110.80	ERG estimate of opening size required
Large knockout table	Hand grinding table (pg. 10-135), ACGIH, 2001), 4'x6' surface	4,800	$64,019.89	$17,755.42	$7,505.08	ERG estimate of bench surface area
Ventilated abrasive cutoff saw	Ventilated cut-off saw (pg. 10-134, ACGIH, 2001, 2'x3' opening	1,500	$20,006.21	$5,548.57	$2,345.34	ERG estimate of opening size required
Hand grinding bench (foundry)	Bench with LEV (pg. 10-135, ACGIH, 2001); 3'x5'	3,750	$50,016	$13,871.42	$5,863.35	ERG estimate of CFM requirements; 250 cfm/sq. ft.
Forming operator bench (pottery)	Bench with LEV (pg. 10-149, ACGIH, 2001), 3'x4'	1,400	$18,672	$5,178.66	$2,188.98	ERG estimate of CFM requirements; 125 cfm per linear foot
Hand grinding bench (pottery)	Bench with LEV (pg. 10-135, ACGIH, 2001); 3'x4'	2,400	$32,010	$8,877.71	$3,752.54	ERG estimate of CFM requirements; 200 cfm/sq. ft.
Hand tool hardware	Retrofit suction attachment	200	$464	$739.81	$54.42	ERG estimate of CFM requirements [a]
Clean air island	Clean air supplied directly to worker	2,500	$33,343.69	$9,247.61	$3,908.90	ERG estimate of CFM requirements; 125 cfm/sq. ft. for 20 square feet
Water fed chipping equipment drum cleaning	Shop-built water feed equipment	N/A	$242.50	$0.00	$242.50	ERG estimate. $200 in annual costs [a]
Ventilation for drum cleaning	Ventilation blower and ducting	N/A	$823.98	$205.99	$179.92	Electric blower (1,277 cfm) and 25 ft. of duct. Northern Safety Co. (p. 193) [a]
Control room	10'x10' ventilated control room with HEPA filter	200	$20,327.53	$739.81	$2,383.01	ERG estimate based on Means, 2003, ACGIH, 2001[d]

Table VII-38a: Source Information for the Unit Cost Estimates Used in OSHA's Final Cost Analysis for General Industry and Maritime(continued)

Control [a]	Description	Ventilation Airflow (cfm)	Capital Cost [b]	Operating Cost	Annualized Capital Cost	Comment or Source
Control room improvement	Repair and improve control room enclosure	N/A	$2,240	NA	$262.60	ERG estimate. Assumes repairs are 20% of new control room cost.
Improved bag valves	Bags with extended polyethylene valve, incremental cost per bag	N/A	$0.01	NA	NA	Cecala et. al., 1986 [a]
Respirator	Half-mask respirator	N/A	NA	NA	$520.32	ERG, 2003 [Economic Analysis of APF rule], Updated to 2012 [d]
Improved maintenance on process equipment enclosures (concrete II)	Maintenance time & materials	N/A	$303.12	$250.59	$553.71	Annual: $250 materials plus 8 hours maintenance time [a]
Improved maintenance on process equipment enclosures (Mineral Proc)	Maintenance time & materials	N/A	$303.12	$257.08	$560.21	Annual: $250 materials plus 8 hours maintenance time [a]
Initial cleaning	per square foot	N/A	$0.00	$0.15	$0.15	ERG estimate
Self-contained dust collection system			$800.00	$80.00	$93.78	Self-contained dust collection system. Darby Dental Lab Supply, 2005 (www.darbylab.com)

[a] For local exhaust ventilation (LEV), maintenance, and conveyor covers, OSHA applied the following estimates:

LEV: capital cost=$13.34 per cfm; operating cost=$3.70 per cfm; annualized capital cost=$1.56 per cfm; based on current energy prices and the estimates of consultants to ERG (2015)

Maintenance: estimated as 10% of capital cost

Conveyor Covers: estimated as $17.10 per linear foot for 100 ft. (Landola, 2003, Document ID 0745); capital cost=$20.73 per linear ft., including all hardware; annualized capital cost=$2.84 per linear ft.

[b] Adjusted from 2003 price levels using an inflation factor of 1.212 based on GDP Implicit price deflator for 2003 and 2012.

[c] Mean expense per office-based physician visit to a pulmonary specialist for diagnosis and treatment, based on data from the 2004 MEPS. Inflated to 2012 levels using the consumer price index for medical services. Inflation based on the BLS Consumer Price Index for Urban Consumers for medical services.

[d] Document ID 1612

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA (2016).

Table VII-38b: Source Information for the Unit Cost Estimates Used in OSHA's Final Cost Analysis for Construction

Control Equipment	Equipment Cost	Average Lifetime (yrs)	Average Annualized Cost	Average Ann. Cost/Day of Use [a]		Maintenance and Operating Cost/Day [b]		Total Ann. Cost/Day of Use	Source; Comments
Wet kit, with water tank	$227	2	$118.49	$0.79		$0.17		$0.96	Contractors Direct, 2009; Bertland Tools Outlet, 2009; Mytoolstore, 2009
Dust shrouds: grinder	$97	1	$97.33	$0.65		$0.14		$0.79	Contractors Direct, 2009; Bertland Tools Outlet, 2009; DustBuddy, 2009; Martin 2008
Water tank, portable (unspec. capacity)	N/A	N/A	N/A	$15.50	[c]	$0.00	[c]	$15.50	RS Means - based on monthly rental cost
Water tank, small capacity (hand pressurized)	$74	1	$76.09	$0.51		$0.11		$0.61	Contractors Direct, 2009; Mytoolstore, 2009
Hose (water), 20', 2" diameter	N/A	N/A	N/A	$1.65	[c]	$0.00	[c]	$1.65	RS Means - based on monthly cost
Custom water spray nozzle and attachments	$363	1	$374.15	$2.49		$0.52		$3.02	New Jersey Laborers' Health and Safety Fund, 2007
Hose (water), 200', 2" diameter	N/A	N/A	N/A	$16.45	[c]	$0.00	[c]	$16.45	RS Means - based on monthly rental cost
Vacuum, 10-15 gal with HEPA	$725	2	$378.89	$2.53		$0.53		$3.06	ICS, 2009; Dust Collection, 2009; Edco, 2009; CS Unitec, 2009
Vacuum, 10-15 gal with HEPA (infrequent use)	$725	2	$378.89	$5.05		$0.53		$5.58	ICS, 2009; Dust Collection, 2009; Edco, 2009; CS Unitec, 2009
Vacuum, large capacity with HEPA	$2,108	2	$1,101.66	$7.34		$1.54		$8.89	ICS, 2009; Edco, 2009; Aramsco, 2009
Electric blower (1,277 cfm) and 25 ft. of duct	$950	5	$207.44	$1.38		$0.29		$1.67	Northern Safety Co., 2003. Inflated to 2009 dollars.
Dust extraction kit (rotary hammers)	$215	1	$214.81	$1.43		$0.30		$1.73	Grainger 2009; Mytoolstore, 2009; Toolmart, 2009
Dust extraction kit (rotary hammers) (infrequent use)	$215	1	$214.81	$2.86		$0.30		$3.16	Grainger 2009; Mytoolstore, 2009; Toolmart, 2009
Dust control/quarry drill	N/A	N/A	N/A	$17.33	[c]	$0.00	[c]	$17.33	RS Means Heavy Construction Cost Data 2008 [e]

Table VII-38b: Source Information for the Unit Cost Estimates Used in OSHA's Final Cost Analysis for Construction (continued)

Control Equipment	Equipment Cost	Average Lifetime (yrs)	Average Annualized Cost	Average Ann. Cost/Day of Use [a]		Maintenance and Operating Cost/Day [b]		Total Ann. Cost/Day of Use	Source; Comments
Dustless drywall sander	$133	1	$133.33	$0.89		$0.19		$1.08	Home Depot, 2009; LSS 2009; Dustless Tech, 2009
Water misting cannon	$19,190	10	$2,249.65	$15.00		$3.15		$18.15	New Jersey Used Equipment, 2015
Cab enclosure /w ventilation and air conditioning	$13,000	10	$1,524.00	$10.16		$2.13		$12.29	Estimates from equipment suppliers and retrofitters
Foam dust suppression system	$14,550	10	$1,706	$11.37		$2.39		$13.76	Midyett, 2003.
Water tank, engine driven discharge, 5000 gal.	N/A	N/A	N/A	$121.50	[c]	$0.00	[c]	$121.50	RS Means - based on monthly rental cost
Water tank, engine driven discharge, 10,000 gal	N/A	N/A	N/A	$168.38	[c]	$0.00	[c]	$168.38	RS Means - based on monthly rental cost
Half-face respirator	$27	2	$468.74	$3.12		$0.66		$3.78	[d]
Dust booth	$10,605	10	$1,243	$8.29		$1.74		$10.03	ERG estimate based on Cerala, et al., 2002 & 2005
Tunnel dust suppression system supplement	$7,928	5	$1,731.03	$11.54		$2.42		$13.96	Raring, 2003.

N/A=Not applicable. For cost items that are assumed to be leased or rented (as on a per job basis), equipment lifetimes are not relevant and have not been defined.

[a] Except where noted, daily equipment cost is based on the annualized equipment cost divided by 150 to reflect the assumed average number days of use per year.

[b] Except where noted, daily operating and maintenance costs are calculated as 10% and 25%, respectively, of annualized equipment costs divided by 250.

[c] Daily equipment costs derived from RS Means monthly rental rates which include maintenance and operating costs.

[d] Derived by ERG based on vendor-derived capital cost of $27.00, 2 year equipment life, accessory cost of $295.52. Also includes annualized training cost of $50.34, fit test cost of $26.45, and respirator cleaning cost of $81.49 to derive total annual costs of $468.74.

[e] Document ID 1331

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on OSHA, 2016, vendors' equipment prices and R.S. Means, Heavy Construction Cost Data, 2009

Description of the Steps OSHA Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes and Statement of the Reasons for Selecting the Alternative Adopted in the Final Rule

OSHA has made a number of changes in the final silica rule that will serve to minimize significant impacts on small entities consistent with the objectives of the OSH Act.

First, OSHA has made two changes to the scope of the rule that will minimize impacts for small business. OSHA has eliminated from the scope of the rule exposures that result from the processing of sorptive clays. OSHA's analysis did not determine whether any or all of the processers of sorptive minerals are small businesses, but to the extent they are, this change will reduce impacts on such entities. OSHA has also rewritten the scope of the rule with respect to the coverage of employers whose employees are exposed to silica at levels below the action level. The final rule does not apply to employers in general industry and maritime where the employer has objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 μg/m^3 as an 8-hour time-weighted average under any foreseeable conditions, and does not apply in construction where employee exposure will remain below 25 μg/m^3 as an 8-hour time-weighted average under any foreseeable conditions (*see Scope* in Section XV, Summary and Explanation of the Standards). OSHA expects that these changes may remove all compliance duties for some small businesses, possibly including carpenters, plumbers, and electricians, whose employees' only exposures to respirable crystalline silica is in small amounts for short-duration tasks that are performed infrequently.

OSHA also revised Table 1 for the construction industry in ways that will minimize impacts on small businesses. OSHA requested comment on the approach for construction in the NPRM. After carefully reviewing the comments received on this issue, the Agency significantly revised the structure of the construction rule to focus on the tasks known to generate high exposures to respirable crystalline silica and to expand Table 1 to cover almost all of them (tunnel boring and abrasive blasting are the exceptions). Under this final rule, where employers fully and properly implement the specified engineering controls, work practices, and respiratory protection for each employee engaged in a task identified on Table 1, the employer is not also required to conduct exposure assessments to determine compliance with the PEL. Specifying the kinds of dust controls for construction tasks that are expected to reduce exposures to the 50 μg/m^3 target, as an option in lieu of a performance-oriented approach involving a PEL and regular exposure assessment, will make compliance easier for construction employers. Some commenters indicated that this specific guidance is particularly beneficial to small businesses that may not have as many resources to develop their own compliance plans (*e.g.*, Document ID 2322–A1, p. 16). The Agency also revised the notes and specifications on Table 1 to clarify what is required for employers to fully and properly implement the specified engineering controls, work practices, and respiratory protection for tasks on Table 1 (*see Specified Exposure Control Methods* in Section XV, Summary and Explanation of the Standards).

After carefully reviewing the comments received on respiratory protection requirements for the construction standard and the exposure data in the record (described in Chapter IV of the FEA), OSHA identified those situations where respiratory protection is necessary and made significant revisions to the respiratory protection requirements specified on Table 1 based on those findings. The result is that respiratory protection is not required for most of the tasks covered by Table 1 (*see Specified Exposure Control Methods* in Section XV, Summary and Explanation of the Standards).

For this final rule, the Agency has significantly revised the requirements for initial exposure assessment and periodic exposure assessment in order to provide employers with greater flexibility. The standard allows the employer to use either the performance option or the scheduled monitoring option for initial and periodic exposure assessments. OSHA also clarified that the performance option provides employers with flexibility in the methods used to assess employee exposures, and provided examples of how employers can accurately characterize employee exposures using the performance option (*see* Exposure Assessment discussion in Section XV, Summary and Explanation of the Standards).

At the suggestion of many commenters, OSHA has eliminated regulated area/access control plan requirements in construction. Employers in construction now have more flexibility in determining the best way to control exposures through a written exposure control plan.

In the final rule, OSHA has agreed with many commenters to eliminate the requirements for protective clothing, and thus has reduced costs to small businesses.

OSHA requested comment on the use of wet methods as a substitute for dry sweeping in the NPRM. After carefully reviewing the comments received on this issue, the Agency revised the provision to prohibit dry sweeping only where such activity could contribute to employee exposure to respirable crystalline silica. Moreover, the standard contains an exception to the prohibition on dry sweeping in such circumstances if wet sweeping, HEPA-filtered vacuuming, or other methods that minimize the likelihood of exposure are not feasible (*see Housekeeping* in Section XV, Summary and Explanation of the Standards).

In the NPRM, OSHA requested comment on the prohibition of employee rotation to achieve compliance when exposure levels exceed the PEL. After carefully reviewing the comments received on this issue, OSHA removed the prohibition on employee rotation from the rule (*see Methods of Compliance* in Section XV, Summary and Explanation of the Standards).

OSHA examined the issue of a 30-day exemption in the NPRM. After carefully reviewing the comments received on this issue, the Agency decided not to include a 30-day exemption from the requirement to implement engineering and work practice controls. However, OSHA clarified that where engineering controls are not feasible, such as for certain maintenance and repair activities, the use of respirators is permitted (*see Methods of Compliance* and *Respiratory Protection* in Section XV, Summary and Explanation of the Standards).

OSHA adopted these alternatives to reduce costs and regulatory burdens consistent with the requirements of the OSH Act and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act, OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so (*see* Section II, Pertinent Legal Authority, for a full discussion of OSHA legal requirements).

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. The Agency has also developed estimates of the risk of silica-related diseases

assuming exposure over a working lifetime at the proposed PEL and action level, as well as at OSHA's preceding PELs. These analyses are summarized in this preamble in Section V, Health Effects and Quantitative Risk Analysis. The available evidence indicates that employees exposed to respirable crystalline silica well below the preceding PELs are still at increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also may result in the development of kidney and autoimmune diseases and in death from other nonmalignant respiratory diseases, including chronic obstructive pulmonary disease (COPD).

As discussed in Section VI, Significance of Risk, in this preamble, OSHA determined that worker exposure to respirable crystalline silica constitutes a significant risk and that the final standard will substantially reduce this risk. Further, there is significant risk well below the new PEL of 50 μg/m^3, but OSHA has determined that achieving a PEL of 25 μg/m^3 is not technologically feasible.

Section 6(b) of the OSH Act requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the final rule is presented in the FEA and FRFA. OSHA has concluded that the new PEL of 50 μg/m^3 is technologically feasible for all affected sectors in general industry and maritime and that Table 1 is technologically feasible for construction.

For those few operations where the new PEL is not technologically feasible, even when workers use recommended engineering and work practice controls, employers can supplement controls with respirators to achieve exposure levels at or below the new PEL.

OSHA developed quantitative estimates of the compliance costs of the final rule for each of the affected industry sectors in Chapter V of the FEA. The estimated compliance costs were compared with industry revenues and profits to provide a screening analysis of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts in Chapter VI of the FEA. Industries with unusually high costs as a percentage of revenues or profits were further analyzed for possible economic feasibility issues. After performing these analyses, OSHA has concluded that compliance with the requirements of the final rule will be economically feasible in every affected industry sector.

OSHA has also provided analyses of the costs and benefits of alternative PELs, though it should be pointed out these are for informational purposes only. Benefit cost analysis cannot be used as a decision criteria for OSHA health standards under the OSH Act. OSHA has examined two regulatory alternatives (named Regulatory Alternatives #1 and #2) that would have modified the PEL for the final rule. Under Regulatory Alternative #1, the PEL would have been 100 μg/m^3 for all affected industry sectors, and the action level would have been 50 μg/m^3 (thereby keeping the action level at one-half of the PEL). For the construction sector under Regulatory Alternative #1, Table 1 requirements for respirator use would have been eliminated for all workers performing Table 1 tasks. Under this alternative, only abrasive blasters and underground construction workers would have been required to wear respiratory protection, and only workers wearing respirators in these operations would have been subject to the medical surveillance provision. Under Regulatory Alternative #2, the PEL would have been 25 μg/m^3 for all affected industry sectors, while the action level would have remained at 25 μg/m^3 (because of difficulties in accurately measuring exposure levels below 25 μg/m^3). For the construction sector under Regulatory Alternative #2, Table 1 requirements would have been modified to include respiratory protection for all workers covered under Table 1, and all these covered workers would have been subject to the medical surveillance provision.

Table VII–39 presents, for informational purposes, the estimated costs, benefits, and net benefits of the final rule under Regulatory Alternatives #1 and #2, using alternative discount rates of 3 and 7 percent. The tables also present the incremental costs, the incremental benefits, and the incremental net benefits of going from a PEL of 100 μg/m^3 to the new PEL of 50 μg/m^3 and then of going from the new PEL of 50 μg/m^3 to a PEL of 25 μg/m^3 for general industry and maritime, as well as the effects in construction of the corresponding changes to Table 1 under Regulatory Alternatives #1 and #2. Table VII–39 breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

Because OSHA determined that a PEL of 25 μg/m^3 would not be feasible (that is, engineering and work practices would not be sufficient to reduce and maintain silica exposures to a PEL of 25 μg/m^3 or below in most operations most of the time in the affected industry sectors in general industry and maritime), the Agency did not attempt to identify engineering controls or their costs for this alternative PEL. Instead, for purposes of estimating the costs of going from a PEL of 50 μg/m^3 to a PEL of 25 μg/m^3, OSHA assumed that all workers exposed between 50 μg/m^3 and 25 μg/m^3 would have to wear respirators to achieve compliance with a PEL of 25 μg/m^3. OSHA then estimated the associated additional costs for respirators, exposure assessments, medical surveillance, and regulated areas (the latter three for ancillary requirements specified in the final rule). For the construction sector under Regulatory Alternative #2, as previously indicated, Table 1 requirements would be modified to include respiratory protection for all covered workers, and all covered workers would be subject to the medical surveillance provision.

As shown in Table VII–39, going from the final rule to Regulatory Alternative #2 would prevent, annually, an additional 295 silica-related fatalities and an additional 122 cases of silicosis. These estimates support OSHA's finding that there is significant risk remaining at the new PEL of 50 μg/m^3. However, the Agency has determined that it cannot select Regulatory Alternative #2 because a PEL of 25 μg/m^3 is not technologically feasible and this alternative would require extensive use of respirators for those using Table 1 under the construction standard (*see* the Technological Feasibility Summary in this preamble for a further discussion of the feasibility of a PEL of 25 μg/m^3).

Recommendations From the SBAR Panel and OSHA's Responses

Table VII–40 lists all of the SBAR Panel recommendations and OSHA's responses to these recommendations.

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Table VII-39: Estimated Annualized Costs, Benefits and Incremental Benefits of OSHA's Final PEL of 50 µg/m³ and Alternatives of 25 µg/m³ and 100 µg/m³

Millions ($2012)

	25 µg/m³			Incremental Costs/Benefits Between 50 and 25 µg/m³			50 µg/m³			Incremental Costs/Benefits Between 100 and 50 µg/m³s			100 µg/m³		
Discount Rate		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**
Annualized Costs															
Engineering Controls		$661	$674		$0	$0		$661	$674		$241	$261		$421	$413
Respirators		$82	$82		$49	$49		$33	$33		$32	$32		$1	$1
Exposure Assessment		$141	$142		$45	$45		$96	$98		$32	$32		$64	$65
Medical Surveillance		$485	$492		$388	$392		$96	$100		$73	$75		$24	$24
Familiarization and Training		$96	$102		$0	$0		$96	$102		$0	$2		$96	$100
Regulated Area		$12	$12		$9	$9		$3	$3		$3	$3		$0	$0
Written Control Plan		$44	$47		$0	$0		$44	$47		$0	$1		$44	$47
Total Annualized Costs (point estimate)		**$1,521**	**$1,552**		**$491**	**$496**		**$1,030**	**$1,056**		**$381**	**$406**		**$649**	**$650**
Annual Benefits: Number of Cases Prevented**	**Cases**			**Cases**			**Cases**			**Cases**			**Cases**		
Fatal Lung Cancers (midpoint estimate)**	178			54			124			62			62		
Fatal Silicosis & other Non-Malignant Respiratory Diseases**	438			113			325			154			170		
Fatal Renal Disease**	321			128			193			110			83		
Silica-Related Mortality**	937	9,340	5,119	295	**$2,942**	**$1,612**	642	$6,398	$3,507	326	$3,248	$1,783	316	$3,151	$1,724
Silicosis Morbidity**	1,040	2,593	1,478	122	**$304**	**$173**	918	$2,289	$1,305	440	$1,098	$626	477	$1,191	$679
Monetized Annual Benefits (midpoint estimate)**		**$11,933**	**$6,598**		**$3,246**	**$1,786**		**$8,687**	**$4,812**		**$4,346**	**$2,409**		**$4,341**	**$2,403**
Net Benefits**		**$10,412**	**$5,046**		**$2,755**	**$1,290**		**$7,657**	**$3,756**		**$3,965**	**$2,003**		**$3,692**	**$1,753**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

Table VII-40: SBAR Panel Recommendations and OSHA Responses	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommended that OSHA give consideration to the alternative of improved enforcement of and expanded outreach for the existing rule rather than a new rule. In addition, the Panel recommended that OSHA carefully study the effects of existing compliance and outreach efforts, such as the Special Emphasis Program on silica, with a view to better delineating the effects of such efforts. This examination should include (1) a year-by-year analysis of the extent of noncompliance discovered in OSHA compliance inspections, and (2) the kinds of efforts OSHA made to improve enforcement and outreach.	As discussed in Chapter II of the FEA, Need for Regulation (and summarized in Section II of this preamble), OSHA has reviewed existing enforcement and outreach programs, as well as other legal and administrative remedies, and believes that a standard is the most effective means to protect workers from exposure to silica. The rulemaking record indicates that workers did not receive adequate protection from silica hazards under OSHA's previous standards. A review of OSHA's compliance assistance and enforcement efforts and their effects on preceding PELs for respirable crystalline silica are discussed in Section III of this preamble, Events Leading to the Final Standards.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(General Industry) The Panel recommended that OSHA revise its economic and regulatory flexibility analyses as appropriate to reflect the SERs' comments on underestimation of costs, and that the Agency compare OSHA's revised estimates to alternative estimates provided and methodologies suggested by the SERs. For those SER estimates and methodological suggestions that OSHA does not adopt, the Panel recommends that OSHA explain its reasons for preferring an alternative estimate and solicit comment on the issue.	OSHA reviewed its cost estimates in response to the comments received from the SERs and evaluated the alternative estimates and methodologies suggested by the SERs. In some cases (such as for exposure monitoring, medical surveillance, and training) OSHA revised its cost estimates in response to SER comments. However, OSHA has not made all cost changes suggested by the SERs. OSHA has retained (or simply updated) those cost estimates that it determined reflect sound methodology and reliable data. OSHA requested comments on the Agency's estimated costs and on the assumptions applied in the preliminary cost analysis. OSHA's final analysis of costs is presented in Chapter V of the FEA and reflects the final Agency response to comments from SERs and other small entities who participated in the rulemaking.
The Panel recommended that prior to publishing a proposed standard, OSHA should carefully consider the ability of each potentially affected industry to meet any proposed PEL for silica, and that OSHA should recognize, and incorporate in its cost estimates, specific issues or hindrances that different industries may have in implementing effective controls.	The FEA reflects OSHA's judgment on technological feasibility and includes responses to specific issues raised by the Panel, SERs, and other small entities who participated in the rulemaking. OSHA solicited comment on the accuracy and reasonableness of its preliminary judgments and included this topic in the NPRM. OSHA's final analysis of technological feasibility presented in Chapter IV of the FEA includes the final Agency response to comments from SERs and the other small entities who participated in the rulemaking.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommended that OSHA carefully review the basis for its estimated exposure monitoring costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	Table 1 in the final construction standard is designed to relieve establishments in construction from requirements for exposure assessment for identified tasks. For the final rule, OSHA clarified that Table 1 provides an alternative method of compliance, not just a partial safe-harbor as in the NPRM. OSHA also further expanded the tasks covered by Table 1 in recognition of the exposure control challenges facing many construction employers, including small entities. As a result, OSHA estimates that monitoring costs in construction will be minimal. For general industry, OSHA developed cost estimates in the FEA for exposure monitoring as a function of the size of the establishment. OSHA's cost estimates now reflect the fact that smaller entities will tend to experience larger unit costs. In the PEA and in the FEA, OSHA estimated higher exposure monitoring costs for small entities because an industrial hygienist could not take as many samples a day in a small establishment as in a large one. For the FEA, in response to public comment, OSHA raised the unit fee for industrial hygiene technician and revised other unit estimates (primarily as a result of converting to 2012 dollars). See Chapter V of the FEA for details of OSHA's unit costs for exposure monitoring in general industry and maritime.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommended that OSHA carefully review the basis for its estimated health screening compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA's cost estimates for health screening are a function of the size of the establishment. OSHA's cost estimates now reflect the fact that smaller entities will tend to experience larger unit costs. In the PEA, OSHA estimated higher medical surveillance costs (than was estimated in the Preliminary Initial Regulatory Flexibility Analysis (PIRFA)) for small entities because smaller establishments would be more likely to send the workers off-site for medical testing. OSHA has carried forward that methodology for the FEA. In addition, for the PEA and the FEA, OSHA significantly increased the total costs of exposure sampling and x-rays in medical surveillance by assuming no existing compliance with those provisions in the proposed and final rule (as compared to an average of 32.6 percent and 34.8 percent existing compliance, respectively, in the PIRFA). A full discussion of OSHA's consideration of medical surveillance costs is included in Chapter V of the FEA and in this preamble.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA carefully review the basis for its estimated hygiene compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA removed the specific hygiene provisions presented in the PIRFA from the proposed and final rules, which has resulted in the elimination of compliance costs for change rooms, shower facilities, lunch rooms, and hygiene-specific housekeeping requirements. In the NPRM, OSHA requested comment on the requirements for use of protective clothing. After carefully reviewing the comments received on this issue, the Agency removed the requirement for protective clothing from the rule (see Regulated Areas in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(General Industry) While some SERs currently provide both protective clothing and hygiene facilities, others provide neither. Those SERs that do not currently provide either felt that these provisions were both highly expensive and unnecessary. Some SERs stated that these provisions were pointless because silica is not a take-home hazard or a dermal hazard. Others suggested that such provisions only be required when the PEL is exceeded. The Panel recommended that OSHA carefully consider the need for these provisions, and solicit comment on the need for these provisions, and how they might be limited.	OSHA removed the specific hygiene provisions presented in the PIRFA from the proposed and final rules, which has resulted in the elimination of compliance costs for change rooms, shower facilities, lunch rooms, and hygiene-specific housekeeping requirements. In the NPRM, OSHA requested comment on the requirements for use of protective clothing. After carefully reviewing the comments received on this issue, the Agency removed the requirement for protective clothing from the rule (see Regulated Areas in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommended that OSHA carefully review the issue of dry sweeping in the analysis, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	In the NPRM, OSHA requested comment on the use of wet methods as a substitute for dry sweeping. After carefully reviewing the comments received on this issue, the Agency revised the provision to prohibit dry sweeping where such activity could contribute to employee exposure to respirable crystalline silica, but provided an exception for situations in which wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure are not feasible (see Housekeeping in Section XV of this preamble). As a result, OSHA has mitigated the potential burden the prohibition on dry sweeping might have imposed on affected employers.
(General Industry) Some SERs were concerned that the prohibition on dry sweeping was not feasible or cost effective in their industries. The Panel recommended that OSHA consider this issue and solicit comment on the costs and necessity of such a prohibition.	In the NPRM, OSHA requested comment on the prohibition on dry sweeping. After carefully reviewing the comments received on this issue, the Agency revised the provision to prohibit dry sweeping where such activity could contribute to employee exposure to respirable crystalline silica, unless wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure are not feasible (see Housekeeping in Section XV of this preamble). As a result, OSHA has mitigated the potential burden the prohibition on dry sweeping might have imposed on affected employers.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommended that OSHA carefully review the basis for its training costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	One participant in the silica SBAR process objected to ERG's analytical assumption (used in the PIRFA) that training is needed only for those workers exposed above the action level and suggested that training might be necessary for all at-risk workers. For the proposed rule, the scope of this requirement was revised so that the provision would apply to all workers with any potential occupational exposure to respirable crystalline silica; OSHA estimated training costs in the PEA accordingly. The final rule requires training for each covered employee. However, the rule does not apply in general industry and maritime where the employer has objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 μg/m^3 as an 8-hour time-weighted average under any foreseeable conditions and does not apply in construction where employee exposure will remain below 25 μg/m^3 as an 8-hour time-weighted average under any foreseeable conditions. For the PEA and the FEA, for employers where the rule applies, OSHA estimated higher training costs for small entities because of smaller-sized training classes and significantly increased training costs by assuming zero current compliance for all of the affected establishments (compared to an average of 56 percent existing compliance for all establishments in the PIRFA).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) SERs raised cost issues similar to those in general industry, but were particularly concerned about the impact in construction, given the high turnover rates in the industry. The Panel recommended that OSHA carefully review the basis for its estimated compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	The cost estimates in the FEA reflect OSHA's best judgment and take the much higher labor turnover rates in construction into account when calculating costs. For this analysis of the final rule, OSHA used the most recent BLS turnover rate of 70 percent for construction (versus a turnover rate of 25 percent for general industry). OSHA believes that the estimates in the FEA capture the effect of high turnover rates in construction, and in Chapter III, Profile of Affected Industries the Agency addresses the comments received on this issue in response to the NPRM.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA (1) carefully review the basis for its estimated labor costs, and issues related to the use of FTEs in the analysis, (2) consider the concerns raised by the SERs, and (3) ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA used the exposure profiles to estimate the number of full-time-equivalent (FTE) workers in construction who are exposed above the PEL. This would be the exposure profile if all exposed workers worked full-time only at the specified silica-generating tasks. In OSHA's preliminary analysis, the actual number of workers exposed above the PEL was estimated to be from two to five times the number of FTE workers, depending on the activity. For the FEA, OSHA developed a more nuanced approach to estimating the number of affected workers. OSHA first divided the construction sector into four subsectors in order to account for likely differences among them with respect to the frequency with which such silica-related tasks are performed. OSHA calculated that there are an estimated 387,710 FTE workers affected by the rule. In Chapter V, Costs of Compliance, OSHA converts these FTEs to 2.02 million affected construction workers disaggregated by occupation, thus resulting in an average ratio of over 5 workers per FTE. The estimate of the total number of at-risk workers takes into account the fact that most workers, regardless of construction occupation, spend some time working on jobs where no silica contamination is present. For the control cost analysis, however, it matters only how many worker-days there are in which exposures are above the PEL. These are the worker-days in which controls are required. The control costs (as opposed to the program costs) are independent of the number of at-risk workers associated with these worker-days. OSHA emphasizes that the use of FTEs does not "discount" its estimates of aggregate control costs.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) Some SERs requested that OSHA apply a 30-day exclusion for implementing engineering and work practice controls, as was reflected in the draft standard for general industry and maritime. The Panel recommended that OSHA consider this change and request comment on the appropriateness of exempting operations that are conducted fewer than 30 days per year from the hierarchy requirement.	In the NPRM, OSHA requested comment on the issue of a 30-day exemption. After carefully reviewing the comments received on this issue, the Agency decided, with respect to general industry, maritime, and construction, that permitting employers to use respirators instead of feasible engineering and work practice controls for exposures occurring for 30 days or less per year would not best effectuate the purpose of the rule. OSHA also determined that it is reasonably necessary and appropriate to require the use of all feasible engineering and work practice controls in the construction industry, even for tasks of short duration, in order to protect employees from exposures to respirable crystalline silica. However, OSHA clarified in the final rules for construction, general industry, and maritime, that where engineering controls are not feasible to reduce exposures to or below the PEL, such as for certain maintenance and repair activities, respirators may be used instead (see Methods of Compliance and Respiratory Protection in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA consider and seek comment on the need to prohibit employee rotation as a means of complying with the PEL and the likelihood that employees would be exposed to other serious hazards if the Agency were to retain this provision.	In the NPRM, OSHA requested comment on the prohibition of employee rotation to achieve compliance when exposure levels exceed the PEL. After carefully reviewing the comments received on this issue, OSHA removed the prohibition on employee rotation from the rule (see Methods of Compliance in Section XV of this preamble).
(Construction) Some SERs questioned the scientific and legal basis for the draft prohibitions on the use of compressed air, brushing, and dry sweeping of silica-containing debris. Others raised feasibility concerns such as in instances where water or electric power was unavailable or where use of wet methods could damage construction materials. The Panel recommended that OSHA carefully consider the need for and feasibility of these prohibitions given these concerns, and that OSHA seek comment on the appropriateness of such prohibitions.	OSHA requested comment on the prohibitions against the use of compressed air, brushing, and dry sweeping of silica-containing debris in the NPRM. After carefully reviewing the comments received on this issue, the Agency revised the rule to (1) prohibit dry sweeping where such activity could contribute to employee exposure to respirable crystalline silica, unless wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure are not feasible and (2) prohibit the use of compressed air where such an activity could contribute to employee exposures to respirable crystalline silica, unless it is used in conjunction with a ventilation system that effectively captures the dust cloud or no alternative method is feasible (see Housekeeping in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA carefully consider whether regulated area provisions should be included in the draft proposed standard, and, if so, where and how regulated areas are to be established. OSHA should also clarify in the preamble and in its compliance assistance materials how compliance is expected to be achieved in the various circumstances raised by the SERs.	After carefully reviewing the comments received on the requirement for regulated areas in construction, OSHA removed the requirement from the construction standard and instead requires a written exposure control plan (see Regulated Areas and Written Exposure Control Plan in Section XV of this preamble).
(Construction) The Panel recommended that OSHA clarify how the regulated area requirements would apply to multi-employer worksites in the draft standard or preamble, and solicit comments on site control issues.	In the NPRM, OSHA requested comment on the applicability of the regulated area requirements to multi-employer worksites in construction. After carefully reviewing the comments received on this issue, OSHA removed the requirement for regulated areas from the construction standard and instead, requires a written exposure control plan that provides for a competent person to restrict access to work areas when necessary (see Regulated Areas and Written Exposure Control Plan in Section XV of this preamble). In addition, OSHA has added costs to account for additional controls for sole proprietors (self-employed workers) whose activities on a multi-employer site could expose others to silica. OSHA also amended the written exposure control plan provisions to clarify the employer's responsibility to account for silica exposures caused by sole proprietors and others when it develops its exposure control plan.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) Many SERs were concerned with the extent to which they felt the draft proposed standard would require the use of respirators in construction activities. The Panel recommended that OSHA carefully consider its respiratory protection requirements, the respiratory protection requirements in Table 1, and the PEL in light of this concern.	In the NPRM, OSHA requested comment on the use of respirators in construction activities. After carefully reviewing the comments received on this issue and the exposure data in the record (described in Chapter IV of the FEA), OSHA identified those situations where respiratory protection is necessary and made significant revisions to the respiratory protection requirements specified in Table 1 based on those findings. The result is that respiratory protection is not required for most of the tasks covered by Table 1 (see Specified Exposure Control Methods in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA carefully address the issues of reliability of exposure measurement for silica and laboratory requirements. The Panel also recommended that OSHA seek approaches to a construction standard that can mitigate the need for extensive exposure monitoring to the extent possible.	In the NPRM and PEA, OSHA raised the issue of reliability of exposure measurement and laboratory requirements for silica, and in Chapter IV of the FEA the Agency addresses comments on the issue. In the NPRM, the Agency also requested comment on the requirement for exposure assessment in the construction standard. After carefully reviewing the comments received on this issue, OSHA is not requiring employers to conduct exposure assessments for employees engaged in a task identified in Table 1, where the specified engineering controls, work practices, and respiratory protection are fully and properly implemented (see Specified Exposure Control Methods in Section XV of this preamble). Where construction employers are required to conduct exposure assessments, the Agency revised the rule to provide employers with greater flexibility for meeting this requirement using the performance option (see Exposure Assessment in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) As in general industry, many SERs were concerned about all of these [protective clothing requirement] provisions because, they contended, silica is not recognized as either a take-home or dermal hazard. Further, many said that these provisions would be unusually expensive in the context of construction work. Other SERs pointed out that protective clothing could lead to heat stress problems in some circumstances. The Panel recommended that OSHA carefully re-examine the need for these provisions in the construction industry and solicit comment on this issue.	In the NPRM, OSHA requested comment on the requirements for use of protective clothing. After carefully reviewing the comments received on this issue, the Agency removed the requirement for protective clothing from the rule (see Regulated Areas in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA explicitly examine the issue of availability of specialists called for by these [medical surveillance] provisions, and re-examine the costs and feasibility of such requirements based on their findings with respect to availability, as needed.	In the NPRM, OSHA requested comment on the availability of B Readers and pulmonary specialists to enable employers to achieve compliance with the medical surveillance provisions. After carefully reviewing the comments received on this issue, the Agency retained the requirement for B Readers given the ample evidence of sufficient numbers of B Readers and the value of B Reader interpretation according to ILO methods. The Agency also retained the requirement for examination by a specialist based on X-ray evidence of silicosis or if otherwise deemed appropriate by the physician or other licensed health care professional (PLHCP). OSHA expanded the definition of specialist to include occupational medicine specialists, in addition to pulmonary disease specialists. The record indicates a substantial number of pulmonary disease specialists are available in the U.S., and the addition of occupational medicine specialists should increase the number of qualifying specialists by about 20 percent (see Medical Surveillance in Section XV of this preamble). OSHA also requested comment on the costs for medical examinations and re-examined its estimates, as discussed in more detail in Section XV Medical Surveillance.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(General Industry) The Panel recommended that OSHA explicitly examine and report on the availability of specialists called for by these [medical surveillance] provisions, and re-examine the costs and feasibility of such requirements based on their findings with respect to availability, as needed.	In the NPRM, OSHA requested comment on the availability of B Readers and pulmonary specialists. After carefully reviewing the comments received on this issue, the Agency retained the requirement for B Readers given the ample evidence of sufficient numbers of B Readers and the value of B Reader interpretation according to ILO methods. The Agency also retained the requirement for examination by a specialist based on X-ray evidence of silicosis or if otherwise deemed appropriate by the PLHCP. OSHA expanded the definition of specialist to include occupational medicine specialists, in addition to pulmonary disease specialists. The record indicates a substantial number of pulmonary disease specialists are available in the U.S., and the addition of occupational medicine specialists should increase the number of qualifying specialists by about 20 percent (see Medical Surveillance in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA carefully consider the need for pre-placement physicals in construction, the possibility of delayed initial screening (so only employees who had been on the job a certain number of days would be required to have initial screening), and solicit comment on this issue.	OSHA does not require pre-placement physicals in the rule. In the NPRM, OSHA requested comment on the timing for initial examinations. After carefully reviewing the comments received on this issue, the Agency continued to only require medical surveillance in the construction standard for employees required to use a respirator for 30 or more days a year, and with respect to that group of employees, OSHA retained the requirement for employers to provide initial examinations within 30 days after initial assignment. Giving employers a 30-day period to offer medical surveillance offers them flexibility in accomplishing the screening (see Medical Surveillance in Section XV of this preamble). OSHA has also clarified that employees do not need a second "initial" screening when they switch employers but are still within the valid time period (3 years) for their initial screening.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) Like the general industry SERs, construction SERs raised the issue that they would prefer a warning label with wording similar to that used in asbestos and lead. The Panel recommended that OSHA consider this suggestion and solicit comment on it.	In the NPRM, OSHA requested comment on the requirements for warning labels. After carefully reviewing the comments received on this issue, the Agency has not included new requirements or specifications for warning labels in this standard. Warning labels are specified by OSHA's hazard communication standard (HCS) (29 CFR 1926.59;29 CFR 1910.1200). OSHA has structured the hazard communication requirements in the silica rule to be as consistent as possible with HCS to avoid a duplicative administrative burden on employers who must comply with both HCS and this rule (see Communication of Respirable Crystalline Silica Hazards to Employees in Section XV of this preamble).
(Construction) Some SERs questioned whether hazard communication requirements made sense on a construction site where there are tons of silica-containing dirt, bricks, and concrete. The Panel recommended OSHA consider how to address this issue in the context of hazard communication.	In the NPRM, OSHA requested comment on the applicability of hazard communication requirements to construction. After carefully reviewing the comments received on this issue, the Agency retained the requirements for hazard communication in the construction standard (see Communication of Respirable Crystalline Silica Hazards to Employees in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA carefully review the recordkeeping requirements with respect to both their utility and burden.	In the NPRM, OSHA requested comment on the recordkeeping requirements. After carefully reviewing the comments received on this issue, the Agency retained the recordkeeping requirements in the rule (see Recordkeeping in Section XV of this preamble). OSHA has also reviewed the recordkeeping requirements as required by the Paperwork Reduction Act. Detailed analysis of the recordkeeping requirements can be found in OSHA's information collection request submitted to OMB.
The Panel recommended that OSHA, to the extent permitted by the availability of economic data, update economic data to better reflect recent changes in the economic status of the affected industries consistent with its statutory mandate.	OSHA has prepared the FEA using the most current economic data available, including data introduced into the record by SERs and other small entities who participated in the rulemaking. The profits data now encompasses a time period that includes 2008 and reflects the economic effects of the great recession.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
SERs in construction, and some in general industry, felt the estimate of affected small entities and employees did not give adequate consideration to workers who would be subject to exposure at a site but were not directly employed by firms engaged in silica-associated work, such as employees of other subcontractors at a construction site, visitors to a plant, etc. The Panel recommended that OSHA carefully examine this issue, considering both the possible costs associated with such workers, and ways of clarifying what workers are covered by the standard.	The OSH Act authorizes OSHA to protect employees. OSHA does not have authority to regulate sole proprietors without employees (self-employed workers). Therefore it would not be appropriate to include them in the estimates of entities regulated by the rule. Nevertheless, the final cost analysis for construction accounts for costs related to the presence of self-employed workers on or near multi-employer work sites. OSHA also adjusted the written exposure control plan requirements in construction to account for exposures to an employer's employees caused by the activities of another entity. To address concerns about the number of entities who might be impacted by the rule as the result of tasks that produce low levels of silica exposure and do not comprise a significant portion of their employees' work days, OSHA adjusted the scope of both the general industry and construction standards. The rule does not apply in general industry and maritime where the employer has objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 $\mu g/m^3$ as an 8-hour time-weighted average under any foreseeable conditions, and does not apply in construction where employee exposure will remain below 25 $\mu g/m^3$ as an 8-hour time-weighted average under any foreseeable conditions (see Scope in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommended that OSHA clarify in any rulemaking action how its action is or is not related to designating silica-containing materials as hazardous wastes.	The contents of OSHA's final rule have no direct bearing on whether silica waste is classified as hazardous for EPA purposes. The relationship between the final rule and EPA requirements is discussed in Chapter X, Environmental Impacts, in the FEA and in Section XIV, Environmental Impacts, of this preamble.
Some SERs also noted the issue that the use of wet methods in some areas may violate EPA rules with respect to suspended solids in runoff unless provision is made for recycling or settling the suspended solids out of the water. The Panel recommended that OSHA investigate this issue, add appropriate costs if necessary, and solicit comment on this issue.	In the PEA, a preliminary analysis of wet methods for dust controls indicated that in most cases the amount of slurry discharged is not sufficient to cause a run off to storm drains. OSHA solicited comment on this topic in the NPRM. The comments received corroborated OSHA's preliminary finding. OSHA's final analysis of environmental impacts in Chapter X of the FEA contains the Agency's response to comments on this issue.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommended that OSHA (1) carefully consider and solicit comment on the alternative of improved outreach and support for the existing standard; (2) examine what has and has not been accomplished by existing outreach and enforcement efforts; and (3) examine and fully discuss the need for a new standard and if such a standard can accomplish more than improved outreach and enforcement.	OSHA analyzed past outreach and compliance initiatives and their effects on compliance with current PELs in Section III, Events Leading to the Final Standard, of this preamble. An explanation of OSHA's choice of the new PEL is provided in several places, including in this FRFA in the section preceding this one.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended, if there is to be a standard for construction, that OSHA: (1) seek ways to greatly simplify the standard and restrict the number of persons in respirators; (2) consider the alternative of a standard oriented to engineering controls and work practices in construction; and (3) analyze and solicit comment on ways to simplify the standard.	In the NPRM, OSHA requested comment on the approach for construction in the NPRM. After carefully reviewing the comments received on this issue, the Agency significantly revised the structure of the construction rule to focus on the tasks known to generate high exposures to respirable crystalline silica. Where employers fully and properly implement the specified engineering controls, work practices, and respiratory protection for each employee engaged in a task identified in Table 1, the employer is not also required to conduct exposure assessments to determine compliance with the PEL. The Agency also revised the notes and specifications in Table 1 to clarify what is required for employers to fully and properly implement the specified engineering controls, work practices, and respiratory protection for tasks in Table 1 (see Specified Exposure Control Methods in Section XV of this preamble). The clear and specific guidance in Table 1, along with the opportunity Table 1 provides for employers to avoid exposure monitoring costs will make compliance easier and less expensive. After carefully reviewing the comments received on respiratory protection requirements for the construction standard and the exposure data in the record (described in Chapter IV of the FEA), OSHA identified those situations where respiratory protection is necessary and made significant revisions to the respiratory protection requirements specified in Table 1 based on those findings. The result is that respiratory protection is not required for most of the tasks covered by Table 1 (see Specified Exposure Control Methods in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommended that, if there is to be a standard, OSHA consider and solicit comment on maintaining the existing PEL. The Panel also recommends that OSHA examine each of the ancillary provisions on a provision-by-provision basis in light of the comments of the SERs on the costs and lack of need for some of these provisions.	In the NPRM, OSHA requested comment on the PEL and ancillary requirements. After carefully reviewing the comments received on this issue, OSHA retained the proposed PEL because it is necessary for any new rule to meet the legal requirement to reduce significant risk to the extent feasible. Because the new PEL is a fixed value, OSHA also believes that it is easier to understand when compared to the preceding PELs, which differed between Construction and General Industry (see Permissible Exposure Limit in Section XV of this preamble). OSHA has reexamined the costs of the ancillary provisions in light of further comments (see Chapter V of the FEA) and addresses the need for the ancillary provisions in their respective sections in Section XV Summary and Explanation of this preamble.
(General Industry) The Panel recommended that OSHA carefully examine the technological and economic feasibility of the draft proposed standard in light of these SER comments.	The FEA reflects OSHA's judgments on the technological and economic feasibility of the final standard and includes responses to specific issues raised by the Panel and other rulemaking participants. In the NPRM, OSHA solicited comment on the accuracy and reasonableness of the Agency's preliminary judgments; this final analysis reflects the Agency's review of and response to all issues raised by SERs and other small entities who participated in the rulemaking.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(General Industry) The Panel recommended that OSHA carefully consider whether regulated area provisions should be included in the draft proposed standard, and, if so, where and how regulated areas are to be established. OSHA should also clarify in the preamble and in its compliance assistance materials how compliance is expected to be achieved in the various circumstances raised by the SERs.	After carefully reviewing the comments received on the requirement for regulated areas in general industry and maritime, OSHA retained the requirement to establish regulated areas where exposures are or are reasonably expected to be above the PEL and removed the access control plan option from the standard. The provision requires employers to demarcate the regulated area, post signs with specified language at all entrances, limit access to the area, and provide appropriate respiratory protection to any employee or designated representative entering the area (see Regulated Areas and Written Exposure Control Plan in Section XV of this preamble).
(General Industry) The Panel recommended that OSHA carefully examine the issues associated with reliability of monitoring and laboratory standards in light of the SER comments, and solicit comment on these issues.	In the NPRM, OSHA requested comment on the specified sampling and analytical methods. After carefully reviewing the comments received on this issue, the Agency retained the sampling and analytical methods requirements (see Appendices in Section XV of this preamble and Chapter IV of the FEA).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(General Industry) Some SERs preferred the more performance-oriented Option 2 provision included in the draft exposure assessment requirements, stating that fixed-frequency exposure monitoring can be unnecessary and wasteful. However, other SERs expressed concern over whether such a performance-oriented approach would be consistently interpreted by enforcement officers. The Panel recommended that OSHA continue to consider Option 2 but, should OSHA decide to include it in a proposed rule, clarify what would constitute compliance with the provision. Some SERs were also concerned about the wording of the exposure assessment provision	In the NPRM, OSHA requested comment on the exposure assessment requirements for general industry and maritime. After carefully reviewing the comments received on this issue, the Agency significantly revised the requirements for initial exposure assessment and periodic exposure assessment in order to provide employers with the greater flexibility they had requested. The standard allows the employer to use either the performance option or the scheduled monitoring option for exposure assessments. OSHA also clarified that the performance option provides employers with flexibility in the methods used to assess employee exposures and provided examples of how employers can accurately characterize employee exposures using the performance option (see Exposure Assessment in the Summary and Explanation Section of this preamble, Section XV).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(General Industry) Some SERs were also concerned about the wording of the exposure assessment provision of the draft proposed standard. These SERs felt that the wording could be taken to mean that an employer needed to perform initial assessments annually. The Panel recommended that OSHA clarify this issue.	In the final rule, OSHA has clarified the regulatory text to ensure it does not suggest that employers must repeat initial assessments annually. OSHA has also provided employers with greater flexibility to use either the performance option or the scheduled monitoring option to meet their ongoing exposure assessment obligations (see Exposure Assessment in Section XV of this preamble).
(General Industry) The SER comments included several suggestions regarding the nature and wording of the health screening requirements. (e.g., OSHA, 2003, Document ID 0937, pp. 25-28.) The Panel recommended that OSHA consider revising the standard in light of these comments, as appropriate.	OSHA has considered these comments and revised the standard where appropriate. Revisions included naming this section of the rule medical surveillance; removing the symptom trigger for medical exams; removing the requirement for the medical and work history to be administered by a health care provider and adding smoking history as a requirement of histories; redefining the size of allowable X-ray films and limiting X-ray readings to only B Readers; defining who can offer medical exams as physicians or other licensed health care providers (PLHCPs); and decreasing the frequency for periodic examinations (see Medical Surveillance in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(General Industry) Though the provision for hazard communication simply repeats such provisions already in existence, some SERs urged OSHA to use this opportunity to change the requirement so that warning labels would only be required of substances that were more than 1% (rather than the current 0.1%) by weight of silica. The Panel recommended that OSHA consider this suggestion and solicit comment on it.	In the NPRM, OSHA requested comment on the requirement for warning labels. After carefully reviewing the comments received on this issue, the Agency has not included new requirements or specifications for warning labels in this standard. OSHA has structured the hazard communication requirements in the silica rule to be as consistent as possible with HCS to promote the harmonization of the classification and labelling of chemicals and avoid duplicative administrative burden on employers who must comply with both the HCS and this rule (see Communication of Respirable Crystalline Silica Hazards to Employees in Section XV of this preamble).
(General Industry) The Panel recommended that OSHA carefully review the recordkeeping requirements with respect to both their utility and burden.	In the NPRM, OSHA requested comment on the recordkeeping requirements. After carefully reviewing the comments received on this issue, the Agency retained the recordkeeping requirements in the rule (see Recordkeeping in Section XV of this preamble). OSHA has also reviewed the recordkeeping requirements as required by the Paperwork Reduction Act. Detailed analysis of the recordkeeping requirements can be found in OSHA's information collection request submitted to OMB.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) The Panel recommended that OSHA continue to evaluate the appropriateness of and consider modifications to scope Option 2 [the standard would apply whenever employees perform a list of activities that involve the application of certain forces to concrete, brick, block, mortar, rock, soil or other material containing crystalline silica, and to abrasive blasting operations where there is potential for exposure to crystalline silica] that can more readily serve to limit the scope of the standard.	OSHA retained Scope Option 1 [the rule would apply wherever there is occupational exposure to airborne respirable crystalline silica in construction workplaces], but revised the provision to exempt situations in which employee exposure will remain below 25 μg/m^3 as an 8-hour time-weighted average under any foreseeable conditions. (see Scope in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) Many SERs found the requirements for a competent person hard to understand. Many SERs took the competent person requirement as requiring a person with a high level of skills, such as the ability to conduct monitoring. Other SERs said this requirement would require training a high percentage of their employees as competent persons because they typically had many very small crews at many sites. In general, the SERs thought this requirement as written would be difficult to comply with and costly. The Panel recommended that OSHA seek ways to clarify OSHA's intent with respect to this requirement and more clearly delineate the responsibilities of competent persons.	OSHA clarified the role and responsibilities of the competent person in the construction standard. In paragraph (b) of the construction standard for respirable crystalline silica, OSHA defines competent person as an individual who is capable of identifying existing and foreseeable respirable crystalline silica hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The definition also specifies that the competent person have the knowledge and ability necessary to fulfill the responsibilities set forth in paragraph (g). In paragraph (g)(4) of the construction standard, the employer is required to designate a competent person to make frequent and regular inspections of job sites, materials, and equipment to implement the written exposure control plan. None of these provisions require the competent person to have the ability to conduct air monitoring (see Definitions and Written Exposure Control Plan in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) Many SERs did not understand that Table 1 was offered as an alternative to exposure assessment and demonstration that the PEL is being met. Some SERs, however, understood the approach and felt that it had merit. These SERs raised several issues concerning the use of Table 1, including: • The Table should be expanded to include all construction activities covered by the standard, or the scope of the standard should be reduced to only those activities covered by Table 1; • The control measures endorsed in Table 1 need to be better established, as necessary; and • Table 1 should require less use of, and possibly no use of, respirators. The Panel recommended that OSHA carefully consider these suggestions, expand Table 1, and make other modifications, as appropriate.	In the NPRM, OSHA requested comment on the approach for construction. After carefully reviewing the comments received on this issue, the Agency significantly revised the structure of the construction rule to focus on the tasks known to generate high exposures to respirable crystalline silica. Where employers fully and properly implement the specified engineering controls, work practices, and respiratory protection for each employee engaged in a task identified in Table 1, the employer is not required to also conduct exposure assessments to determine compliance with the PEL. The Agency also revised the notes and specifications in Table 1 to clarify what is required for employers to fully and properly implement the engineering controls, work practices, and respiratory protection for tasks in Table 1 (see Specified Exposure Control Methods in Section XV of this preamble). The clear and specific guidance in Table 1, along with the opportunity Table 1 provides for employers to avoid monitoring costs, will make compliance easier and less expensive. After carefully reviewing the comments received on respiratory protection requirements for the construction standard and the exposure data in the record (described in Chapter IV of the FEA), OSHA identified those situations where respiratory protection is necessary and made significant revisions to the respiratory protection requirements specified in Table 1 based on those findings. The result is that respiratory protection is not required for most of the tasks covered by Table 1 (see Specified Exposure Control Methods in Section XV of this preamble).

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The Panel recommends that OSHA thoroughly review the economic impacts of compliance with a proposed silica standard and develop more detailed feasibility analyses where appropriate.	OSHA significantly expanded its economic impact and economic feasibility analyses in Chapter VI of the PEA. As part of that impact analysis, OSHA added data on normal year-to-year variations in prices and profit rates in affected industries to provide a context for evaluating potential price and profit impacts of the proposed rule. Sections were also added to estimate the potential international trade impacts and macroeconomic impacts of the proposed rule. OSHA invited comment in the PEA on the issues of the economic impacts and the economic feasibility of the proposed rule. Chapter VI in the FEA discusses comments on economic impacts, OSHA's response to those comments, and the Agency's final analysis of economic impacts and regulatory flexibility.
(Construction) The panel recommends that OSHA re-examine its cost estimates for respirators to make sure that the full cost of putting employees in respirators is considered.	For the PEA, OSHA re-examined and updated its cost estimates for each type of respirator. Unit respirator costs included the cost of the respirator itself and the annualized cost of respirator use, to include accessories (e.g., filters), training, fit testing, and cleaning. In addition, OSHA added a cost for employers to establish a respirator program. For the FEA, all costs have been updated to 2012 dollars. OSHA solicited comment on this issue in the PEA; in the FEA, OSHA's final estimate of costs for respiratory protection (see Chapter V) conveys the Agency's response to public comment.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(Construction) Some SERs indicated that the unit costs were underestimated for monitoring, similar to the general industry issues raised previously. In addition, special issues for construction were raised (i.e., unpredictability of exposures), suggesting the rule would be costly, if not impossible to comply with. The Panel recommends that OSHA carefully review the basis for its estimated compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	To reflect the fact that an industrial hygienist could not typically take as many samples a day in a small establishment as in a large one, OSHA developed cost estimates for exposure monitoring as a function of the size of the establishment. OSHA's cost estimates therefore now reflect the fact that smaller entities will tend to experience larger unit costs for exposure monitoring. To address concerns about unpredictability of exposure in construction, as well as to provide more specific guidance to employers, OSHA designed Table 1 in the final standard to allow establishments in construction the option, for many common tasks, to implement engineering controls, work practices, and respiratory protection without the need for exposure assessment. OSHA has carefully reviewed the basis for its exposure monitoring cost estimates and considered the concerns raised by the SERs. OSHA solicited comments on this issue in the PEA, and in Chapter V of the FEA the final analysis of costs for exposure monitoring reflects the Agency's response to public comment.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
(General Industry) The Panel recommends that OSHA use the best scientific evidence and methods available to determine the significance of risks and magnitude of benefits for occupational exposure to silica. The Panel further recommends that OSHA evaluate existing state silicosis surveillance data to determine whether there are industry-specific differences in silicosis risks, and whether or how the draft standard should be revised to reflect such differences.	OSHA has conducted a comprehensive review of the scientific evidence from toxicological and epidemiological studies on adverse health effects and baseline estimates of the risks of developing silica-related diseases associated with occupational exposure to respirable crystalline silica. This review is summarized in Section V of this preamble, Health Effects and Quantitative Risk Assessment. The significance of these risks is examined in Section VI, Significance of Risk. The benefits associated with the final rule are summarized in Chapter VII of the FEA. Although OSHA's final analysis indicates that a variety of factors may affect the toxicological potency of crystalline silica found in different work environments, OSHA has not identified information that would allow the Agency to calculate how these influences may affect disease risk to workers in any particular workplace setting.

Table VII-40: SBAR Panel Recommendations and OSHA Responses (continued)	
SBAR Panel Recommendation	**OSHA Response**
The SERs, however, also had many specific issues concerning what OSHA should do if it chooses to go forward with a proposed rule. In order to reflect these specific issues, the Panel has made many recommendations concerning issues to be considered if the Agency goes forward with a rule. The Panel also recommends that OSHA take great care in reviewing and considering all comments made by the SERs.	OSHA has carefully considered the Panel recommendations, and the Agency's responses are listed in this table. In addition, specific issues raised in comments by individual SERs are addressed throughout this preamble.

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VIII. Paperwork Reduction Act

The final general industry/maritime (''the general industry standard'') and construction standards (''the standards'') for respirable crystalline silica contain collections of information (also referred to as ''paperwork'' requirements) that are subject to review by the Office of Management and Budget (OMB). In accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3506(c)(2)), OSHA solicited public comments on the *Respirable Crystalline Silica Standards for General Industry, Shipyard Employment and Maritime Terminals (29 CFR 1910.1053) and Construction (29 CFR 1926.1053)* Information Collection Request (ICR) (paperwork burden hour and cost analysis) for the proposed rule. The Department also submitted this ICR to OMB for review in accordance with 44 U.S.C. 3507(d) on September 12, 2013. On January 23, 2014, OMB authorized the Department to use OMB Control Number 1218–0266 in future paperwork submissions involving this rulemaking. OMB commented, ''This OMB action is not an approval to conduct or sponsor an information collection under the Paperwork Reduction Act of 1995'' (*see http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201111-1218-004*).

The proposed rule invited the public to submit comments to OMB, in addition to OSHA, on the proposed collections of information with regard to the following:

- Whether the proposed collections of information are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the collections of information, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information (78 FR 56438).

No public comments were received specifically in response to the proposed ICR and supporting documentation submitted to OMB for review. However, public comments submitted in response to the Notice of Proposed Rulemaking (NPRM), described earlier in this preamble, substantively addressed collections of information and contained information relevant to the burden hour and costs analysis. OSHA considered these comments when it developed the revised ICR associated with these final rules.

The Department of Labor submitted the final ICR on the date of publication, containing a full analysis and description of the burden hours and costs associated with the collections of information of the final rule, to OMB for approval. A copy of the ICR is available to the public at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201509-1218-004* (this link will only become active the day following publication of this notice). OSHA will publish a separate notice in the **Federal Register** that will announce the results of that review. That notice will also include a summary of the collections of information and burdens imposed by the new standard. A Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and the collection of information notice displays a currently valid OMB control number (44 U.S.C. 3507(a)(3)). Also, notwithstanding any other provision of law, no employer shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512).

The major collections of information found in the standards are listed below.

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Table VIII-1 – Collections of Information Contained in the Standards

Title of Collection of Information	**Section Number**
Exposure assessment - General;	29 CFR 1910.1053(d)(1), 29 CFR 1926.1153(c)(1), 29 CFR 1926.1153(d), and 29 CFR 1926.1153(d)(2)(i);
Exposure assessment - Performance option;	29 CFR 1910.1053(d)(2) and 29 CFR 1926.1153(d)(2)(ii);
Exposure assessment - Scheduled monitoring option;	29 CFR 1910.1053(d)(3)(i), 29 CFR 1910.1053(d)(3)(iii)-(d)(3)(v), 29 CFR 1926.1153(d)(2)(iii)(A), and 29 CFR 1926.1153(d)(2)(iii)(C)-(E);
Exposure assessment - Reassessment of exposures;	29 CFR 1910.1053(d)(4) and 29 CFR 1926.1153(d)(2)(iv);
Exposure assessment - Notifying each affected employee in writing of the monitoring results or posting the results;	29 CFR 1910.1053(d)(6)(i) and 29 CFR 1926.1153(d)(2)(vi)(A);
Exposure assessment - Describing corrective actions being taken to reduce employee exposure to or below the PEL in the written notification when an exposure assessment indicates that that employee exposure is above the PEL;	29 CFR 1910.1053(d)(6)(ii) and 29 CFR 1926.1153(d)(2)(vi)(B);
Written exposure control plan - Establishing and implementing a written exposure control plan;	29 CFR 1910.1053(f)(2)(i), 29 CFR 1910.1053(f)(2)(i)(A)-(C), 29 CFR 1926.1153(g)(1), and 29 CFR 1926.1153(g)(1)(i)-(iv);
Written exposure control plan - Reviewing and evaluating the effectiveness of the written exposure control plan annually and updating it as necessary;	29 CFR 1910.1053(f)(2)(ii) and 29 CFR 1926.1153(g)(2);
Written exposure control plan - Making the written exposure control plan readily available for examination and copying;	29 CFR 1910.1053(f)(2)(iii) and 29 CFR 1926.1153(g)(3);
Methods of compliance - Compliance with 29 CFR part 1915 Subpart I;	29 CFR 1910.1053(f)(3);
Respiratory protection - Instituting a respiratory protection program in accordance with 29 CFR 1910.134;	29 CFR 1910.1053(g)(2) and 29 CFR 1926.1153(e)(2);
Medical surveillance - Implementing medical surveillance of employees;	29 CFR 1910.1053(i)(1)(i), 29 CFR 1910.1053(i)(2), 29 CFR 1910.1053(i)(2)(i)-(i)(2)(vi), 29 CFR 1910.1053(i)(3), 29 CFR 1910.1053(i)(7)(i), 29 CFR 1926.1153(h)(1)(i), 29 CFR 1926.1153(h)(2),

	29 CFR 1926.1153(h)(2)(i)-(h)(2)(vi), 29 CFR 1926.1153(h)(3), and 29 CFR 1926.1153(h)(7)(i);
Medical surveillance - Ensuring that the physician or other licensed health care professional (PLHCP), or specialist, has certain specified information;	29 CFR 1910.1053(i)(4), 29 CFR 1910.1053(i)(4)(i)-(iv), 29 CFR 1910.1053(i)(7)(ii), 29 CFR 1926.1153(h)(4), 29 CFR 1926.1153(h)(4)(i)-(iv), and 29 CFR 1926.1153(h)(7)(ii);
Medical surveillance - Ensuring that the PLHCP, or specialist, explains to the employee the results of the medical examination and provides each employee with a copy of their written medical report;	29 CFR 1910.1053(i)(5), 29 CFR 1910.1053(i)(5)(i)-(iv), 29 CFR 1910.1053(i)(7)(iii), 29 CFR 1926.1153(h)(5), 29 CFR 1926.1153(h)(5)(i)-(iv), and 29 CFR 1926.1153(h)(7)(iii);
Medical surveillance - Obtaining a written medical opinion from the PLHCP, or specialist, and ensuring that each employee receives a copy of the PLHCP's written medical opinion;	29 CFR 1910.1053(i)(6)(i), 29 CFR 1910.1053(i)(6)(i)(A)-(C), 29 CFR 1910.1053(i)(6)(ii)(A)-(B), 29 CFR 1910.1053(i)(6)(iii), 29 CFR 1910.1053(i)(7)(iv), 29 CFR 1926.1153(h)(6)(i), 29 CFR 1926.1153(h)(6)(i)(A)-(C), 29 CFR 1926.1153(h)(6)(ii)(A)-(B), 29 CFR 1926.1153(h)(6)(iii), and 29 CFR 1926.1153(h)(7)(iv);
Hazard communication - Including respirable crystalline silica in the program established to comply with the hazard communication standard (29 CFR 1910.1200) and ensuring that each employee has access to labels on containers of crystalline silica and safety data sheets;	29 CFR 1910.1053(j)(1) and 29 CFR 1926.1153(i)(1);
Making and maintaining air monitoring data and objective data records and medical surveillance records for specific periods;	29 CFR 1910.1053(k)(1)(i), 29 CFR 1910.1053(k)(1)(ii), 29 CFR 1910.1053(k)(1)(ii)(A)-(G), 29 CFR 1910.1053(k)(2)(i), 29 CFR 1910.1053(k)(2)(ii), 29 CFR 1910.1053(k)(2)(ii)(A)-(E), 29 CFR 1910.1053(k)(3)(i), 29 CFR 1910.1053(k)(3)(ii), 29 CFR 1910.1053(k)(3)(ii)(A)-(C), 29 CFR 1926.1153(j)(1)(i), 29 CFR 1926.1153(j)(1)(ii), 29 CFR 1926.1153(j)(1)(ii)(A)-(G), 29 CFR 1926.1153(j)(2)(i), 29 CFR 1926.1153(j)(2)(ii), 29 CFR 1926.1153(j)(2)(ii)(A)-(E) 29 CFR 1926.1153(j)(3)(i),

	29 CFR 1926.1153(j)(3)(ii), and 29 CFR 1926.1153(j)(3)(ii)(A)-(C);
Recordkeeping - Making air monitoring data, objective data, and medical surveillance records available.	29 CFR 1910.1053(k)(1)(iii), 29 CFR 1910.1053(k)(2)(iii), 29 CFR 1910.1053(k)(3)(iii), 29 CFR 1926.1153(j)(1)(iii), 29 CFR 1926.1153(j)(2)(iii), and 29 CFR 1926.1153(j)(3)(iii).

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The collections of information in the rule are needed to assist employers in identifying and controlling exposures to respirable crystalline silica in the workplace, and to address respirable crystalline silica-related adverse health effects. OSHA will also use records developed in response to these standards to determine compliance.

The final rule imposes new collections of information for purposes of the PRA. In response to comments on the proposed rule, OSHA has revised provisions of the final rule that affect the collections of information. These revisions include:

—An exception in paragraph (a)(2) of the general industry standard for those circumstances where the employer has objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 micrograms per cubic meter of air (25 $\mu g/m^3$) as an 8-hour time-weighted average (TWA) under any foreseeable conditions. The construction standard also provides an exception where employee exposure will remain below 25 $\mu g/m^3$ as an 8-hour TWA under any foreseeable conditions (paragraph (a)). However, the exception in the construction standard does not require the employer to have objective data to support the exception.

—An additional exemption in the general industry standard for occupational exposures that result from the processing of sorptive clays (paragraph (a)(1)(iii)).

—Revisions to paragraph (d) of the general industry standard (paragraph (d)(2) for construction), which sets forth requirements for assessing employee exposures to respirable crystalline silica, including revisions to:

○ General requirements for exposure assessment. Paragraph (d)(1) of the general industry standard (paragraph (d)(2)(i) in construction) was revised and restructured to allow employers to use either the performance option or the scheduled monitoring option to meet their initial and periodic exposure assessment obligations. More specifically, these revisions include replacing the proposed (d)(1)(ii) and (d)(1)(iii), all of (d)(2), and (d)(3) with a simplified general requirement to assess exposures when exposures are expected to be at or above the action level using either the performance option or the scheduled monitoring option. Thus, the final rule does not contain an initial assessment requirement like the proposed rule. Initial monitoring is only required under the scheduled monitoring option and has to be performed as soon as work begins. The proposed standard included a requirement to assess the exposure of employees expected to be exposed to respirable crystalline silica at or above the action level, which consisted of an initial monitoring of employees, unless monitoring had been performed in the previous 12 months, or the employer had objective data to demonstrate that exposures would be below the action level under any expected conditions, as well as periodic exposure assessments, depending on the results of initial monitoring, following either a scheduled monitoring option or a performance option. These revisions from the proposed rule emphasize the performance option in order to provide additional flexibility for employers who are able to characterize employee exposures through alternative methods. However, the content of the performance option requirement remains the same as the content of the proposed requirement.

○ OSHA has also not established time limitations for air monitoring results used to characterize employee exposures under the performance option. Although the proposed rule limited employers using air monitoring data for initial exposure assessment purposes to data obtained no more than twelve months prior to the rule's effective date, there were no such time restrictions on monitoring data used to conduct periodic exposure assessments under the performance option. Nevertheless, many commenters found the 12-month limit on the use of monitoring results for initial exposure assessments using existing data to be too restrictive. OSHA has been persuaded by these commenters not to establish time limitations for monitoring results used to assess exposures under the performance option, as long as the employer can demonstrate the data accurately characterize current employee exposures to respirable crystalline silica.

○ Scheduled monitoring option. Paragraph (d)(3) of the general industry standard (paragraph (d)(2)(iii) for construction) describes the scheduled monitoring option, which provides employers with a clearly defined, structured approach to assessing employee exposures. OSHA made a number of minor changes to the requirements for periodic monitoring under the scheduled monitoring option (paragraphs (d)(3)(iii)–(d)(3)(v) of the general industry standard, paragraphs (d)(2)(iii)(C)–(d)(2)(iii)(E) in construction) to clarify that the ''most recent'' exposure monitoring sample determines how often an employer must monitor.

○ Revisions to requirements to reassess exposures. Paragraph (d)(4) of the general industry standard (paragraph (d)(2)(iv) in construction) requires employers assessing exposures using either the performance option or the scheduled monitoring option to reassess employee exposures whenever there has been a change in the production, process, control equipment, personnel, or work practices that may reasonably be expected to result in new or additional exposures to respirable crystalline silica at or above the action level, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred. OSHA added the phrase ''or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred'' to the proposed language to make clear that

reassessment of exposures is required whenever there is reason to believe that a change in circumstances could result in new or additional exposures at or above the action level.

—The addition of paragraph (f)(2)(i) of the general industry standard (paragraph (g)(1) of the construction standard), which requires employers to establish and implement a written exposure control plan for all employees covered by the rule. Under paragraph (f)(2)(i)(A)–(C) (paragraphs (g)(1)(i)–(iii) of the construction standard), the written exposure control plan must contain a description of: The tasks in the workplace that involve exposure to respirable crystalline silica; the engineering controls, work practices, and respiratory protection used to limit employee exposure to respirable crystalline silica for each task; and a description of the housekeeping measures used to limit employee exposure to respirable crystalline silica. Paragraph (g)(1)(iv) of the construction standard requires the written exposure control plan to contain a description of the procedures used to restrict access to work areas, when necessary, to minimize the number of employees exposed to respirable crystalline silica and their level of exposure, including exposures generated by other employers or sole proprietors. OSHA did not propose a requirement for a written exposure control plan, but requested comment on whether to include one in the final rule. The final rule does not include the proposed written access control plan that the employer could prepare in lieu of establishing regulated areas that would only apply to areas with PEL exceedances.

—Alterations to paragraph (i)(1)(i) of the general industry standard, which requires employers to make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be occupationally exposed to respirable crystalline silica at or above the action level for 30 or more days per year. Paragraph (h)(1)(i) of the construction standard requires employers to make medical surveillance available to employees who will be required by the standard to use a respirator for 30 or more days per year. In the proposed standards, OSHA specified that employers must make medical surveillance available to those employees who would be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days a year.

—Revisions to the medical surveillance exam requirements in paragraph (i)(2)(iii) of the standard (paragraph (h)(2)(iii) of the standard for construction), which allow digital X-rays, in addition to film X-rays, and no longer allow for an equivalent diagnostic study. The paragraph requires a chest X-ray (a single posteroanterior radiographic projection or radiograph of the chest at full inspiration recorded on film (no less than 14 x 17 inches and no more than 16 x 17 inches) or digital radiography systems) interpreted and classified according to International Labour Office (ILO) International Classification of Radiographs of Pneumoconiosis by a NIOSH-certified B Reader. The only substantive changes from the proposed provision are to (1) specifically allow for the use of digital systems because OSHA concluded that they are an equivalent diagnostic studies as film X-rays and (2) to no longer allow for the use of an equivalent diagnostic study because OSHA concluded there are currently no studies that are equivalent to film and digital X-rays.

—Minor edits to paragraphs (i)(4)(i)–(iv) of the general industry standard (paragraphs (h)(4)(i)–(iv) of the standard for construction), which is entitled: ''Information provided to the PLHCP.'' For example, in paragraphs (i)(4)(i) and (iv) (paragraphs (h)(4)(i) and (iv) in the standard for construction), ''affected employee'' was changed to ''employee''. The word ''affected'' was removed because it is clear that the paragraphs refer to employees who will be undergoing medical examinations. In paragraph (i)(4)(iii) (paragraph (h)(4)(iii) in the standard for construction), ''has used the equipment'' was changed to ''has used or will use the equipment'' to make it consistent with the earlier part of the paragraph that states ''personal protective equipment used or to be used''. Changes to these paragraphs are made to clarify OSHA's intent, which has not changed from the proposed rule.

—Revisions to the information required to be provided by the PLCHP to the employer and the employee. In response to public comments about employee privacy and potential discrimination or retaliation concerning medical findings, the final rule requires a detailed written medical report for the employee and a less detailed written medical opinion for the employer. This is a change from the proposed rule, which required the PLHCP to give the employer a written medical opinion that did not include findings unrelated to respirable crystalline silica exposure, and required the employer to give the employee a copy of the opinion.

○ The contents of the written medical report for the employee are set forth in paragraphs (i)(5)(i)–(iv) of the general industry standard (paragraphs (h)(5)(i)–(iv) of the construction standard). They include: A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment of health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment; any recommended limitations on the employee's use of respirators; any recommended limitations on respirable crystalline silica exposure; and a statement that the employee should be examined by a specialist if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B reader, or if referral to a specialist is deemed appropriate by the PLHCP. The health-related contents of the PLHCP's report to the employee are fairly consistent with the proposed PLHCP's opinion to the employer, but two major exceptions are noted. Because only the employee will be receiving the written medical report, (1) the written medical report should include diagnoses and specific information on health conditions, including those not related to respirable crystalline silica and (2) medical conditions that require further evaluation or follow-up are not limited to those related to respirable crystalline silica exposure. Although the employer will not be responsible for further evaluation of conditions not related to respirable crystalline silica exposure, the PLHCP has an ethical obligation to inform the employee about those conditions. In addition, a minor difference from the proposed opinion is that the report specifies limitations of respirator use rather than personal protective equipment (PPE), because a respirator is the only type of PPE required under this rule.

○ The contents of the PLHCP's written medical opinion for the employer are presented in paragraphs (i)(6)(i)(A)–(C) and (i)(6)(ii)(A)–(B) of the general industry standard (paragraphs (h)(6)(i)(A)–(C) and (h)(6)(ii)(A)–(B) of the construction standard). The contents of the written opinion are to include only the following: The date of the examination, a statement that the examination has met the requirements of the standard, and any recommended

limitations on the employee's use of respirators. Paragraphs (i)(6)(ii)(A)–(B) of the general industry standard (paragraphs (h)(6)(ii)(A)–(B) of the construction standard) state that if the employee provides written authorization, the written opinion provided to the employer must also contain: Any recommended limitations on exposure to respirable crystalline silica and a statement that the employee should be examined by a specialist if the chest X-ray provided in accordance with the standard is classified as 1/0 or higher by the B reader, or if referral to a specialist is otherwise deemed appropriate by the PLHCP. As noted above, OSHA proposed that the employer obtain a more detailed written medical opinion from the PLHCP. In the final rule, the only medically related information that is to be reported to the employer without authorization from the employee is limitations on respirator use.

○ Under paragraph (i)(5) of the general industry standard (paragraph (h)(5) of the construction standard), the employer must ensure that the PLHCP explains the results of the examination to the employee and gives the employee a written report within 30 days of each medical examination performed. Under paragraphs (i)(6)(i) and (i)(6)(iii) of the general industry standard (paragraphs (h)(6)(i) and (h)(6)(iii) of the construction standard), employers must ensure that the PLHCP gives them and that the employee receives a copy of the employer's written medical opinion within 30 days of each medical examination. OSHA had proposed that the employer obtain the PLHCP's medical opinion within 30 days of the medical examination and then provide a copy to the employee within 2 weeks after receiving it.

○ The proposed opinion for the employer called for a statement that the PLHCP had explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment. As noted above, OSHA has retained the requirement that the employer ensure that the PLHCP explains the results to the employee in paragraph (i)(5) of the standard (paragraph (h)(5) of the standard for construction), but no longer requires the PLCHP to include a statement of this fact in the opinion for the employer. OSHA is not mandating how the employer ensures that the employee gets the required information because there are various ways this could be done, such as in a contractual agreement between the employer and PLHCP. PLHCPs could still include the verification in the PLHCP's opinion for the employer if that is a convenient method for them to do so.

—Changes to the provisions regarding referral to a specialist. Paragraphs (i)(5)(iv) and (i)(6)(ii)(B) of the general industry standard (paragraphs (h)(5)(iv) and (h)(6)(ii)(B) of the construction standard) specifies that the PHLCP include a statement that the employee should be examined by a specialist if the X-ray is classified as 1/0 or higher by the B reader, or if referral to a specialist is deemed appropriate by the PLHCP. Those paragraphs now indicate referral to a ''specialist.'' OSHA has added ''specialist'' to the definitions in paragraph (b) of the standards, to allow referrals to specialists who are American Board Certified in Pulmonary Disease or Occupational Medicine. OSHA proposed examination by an American Board Certified Specialist in Pulmonary Disease and concludes that expansion of the specialist definition to include board certified occupational medicine physicians will mean that more physicians will be available for referrals, making appointments easier to get.

—Changes to the requirements regarding information given by the specialist to the employer and employee. Under paragraph (i)(7)(iii) of the general industry standard (paragraph (h)(7)(iii) of the standard for construction), the employer must ensure that the specialist explains medical findings to the employee and gives the employee a written medical report (*i.e.*, a report containing results of the examination, including conditions that might increase the employee's risk from exposure to respirable crystalline silica, conditions requiring further follow-up, recommended limitations on respirator use, and recommended limitations on respirable crystalline silica exposure, as required by paragraph (i)(5) except (i)(5)(iv) of the general industry standard ((h)(5) except (h)(5)(iv) of the construction standard). The reasons why the specialist is to give the employee this information and the changes from the proposed rule are discussed above, under the requirements for the PLHCP's report. Likewise, for the same reasons as addressed above, paragraph (i)(7)(iv) of the standard (paragraph (h)(7)(iv) of the standard for construction) requires the specialist to provide the employer with a medical opinion (*i.e.*,—an opinion indicating the date of the examination, any recommended limitations on the employee's use of respirators, and with the written authorization of the employee, any recommended limitations on the employee's exposure to respirable crystalline silica, as required by paragraph (i)(6) (except (i)(6)(i)(B) and (i)(6)(ii)(B)) of the general industry standard (paragraph (h)(6) (except (h)(6)(i)(B) and (h)(6)(ii)(B)) of the construction standard)).

—Changes to the requirements regarding maintenance of monitoring data records by employers. Paragraph (k)(1)(i) of the general industry standard (paragraph (j)(1)(i) of the construction standard), the substance of which remains unchanged from the proposed standards, requires the employer to make and maintain accurate air monitoring data records of all exposure measurements taken to assess employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of the general industry standard (paragraph (d)(2) of the construction standard). OSHA has added the words ''make and'' prior to ''maintain'' in order to clarify that the employer's obligation is to create and preserve such records. The language in this provision is consistent with OSHA's standard on access to employee exposure and medical records, which refers to employee exposure and medical records that are made or maintained (29 CFR 1910.1020(b)(3)). This clarification has also been made for other records required by the silica rule (29 CFR 1910.1053(k)(2)(i), 29 CFR 1910.1053(k)(3)(i), 29 CFR 1926.1153(j)(2)(i), and 29 CFR 1926.1153(j)(3)(i)). In addition, OSHA now refers to ''measurements taken to assess employee exposure'' rather than ''measurement results used or relied on to characterize employee exposure'' in paragraph (k)(1)(i) of the general industry standard (paragraph (j)(1)(i) of the construction standard). This change is non-substantive, and is intended to clarify OSHA's intent that all measurements of employee exposure to respirable crystalline silica be maintained.

—Changes to the requirement for maintaining air monitoring data records by employers. OSHA has made one modification in the rule to describe the information required in the records that differs from the proposed rule in paragraph (k)(1)(ii)(B) (paragraph (j)(1)(ii)(B) of the construction standard) and that is

to change ''the operation monitored'' to ''the task monitored.'' Both ''task'' and ''operation'' are commonly used in describing work. However, OSHA uses the term ''task'' throughout the rule, and the Agency is using ''task'' in the recordkeeping provision for consistency and to avoid any potential misunderstanding that could result from using a different term. This change neither increases nor decreases an employer's obligations as set forth in the proposed standards.

—Changes to the requirements regarding maintenance of objective data records by employers. Paragraph (k)(2)(i) of the general industry standard (paragraph (j)(2)(i) for construction), the substance of which remains unchanged from the proposed rule, requires employers who rely on objective data to keep accurate records of the objective data. Paragraph (k)(2)(ii) of the general industry standard (paragraph (j)(2)(ii) of the construction standard) requires the record to include: The crystalline silica-containing material in question; the source of the objective data; the testing protocol and results of testing; a description of the process, task, or activity on which the objective data were based; and other data relevant to the process, task, activity, material, or exposures on which the objective data were based. Paragraphs (k)(2)(ii)(D) and (E) of the general industry standard (paragraphs (j)(2)(ii)(D) and (E) of the construction standard) have been modified from the proposed rule to substitute the word ''task'' for ''operation'', and to clarify the requirements for records of objective data. These changes do not affect the employer's obligations as set forth in the proposed standards.

—Changes to the requirements regarding the maintenance of medical surveillance records by employers. In paragraph (k)(3)(ii)(B) and (C) of the general industry standard (paragraph (j)(3)(ii)(B) and (C) of the construction standard), which requires employers to make and maintain medical surveillance records, OSHA has changed the ''PLHCP's and pulmonary specialist's written opinions'' to the ''PLHCPs' and specialists' written medical opinions.'' The change, consistent with paragraph (i) of the general industry standard (paragraph (h) of the construction standard), is made to reflect the revised definition for the term ''specialist'' included in the rule.

IX. Federalism

The Agency reviewed the respirable crystalline silica rule according to the most recent Executive Order on Federalism, Executive Order 13132, which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that would restrict States' policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope (64 FR 43255 (8/10/1999)). The Executive Order allows Federal agencies to preempt State law only with the express consent of Congress. In such cases, Federal agencies must limit preemption of State law to the extent possible.

Under Section 18 of the Occupational Safety and Health Act (29 U.S.C. 667), Congress expressly provided that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to States that obtain Federal approval for such plans as ''State-Plan States.'' Occupational safety and health standards developed by State-Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State-Plan States are free to develop and enforce their own occupational safety and health standards.

This rule complies with Executive Order 13132. The problems addressed by this new respirable crystalline silica rule are national in scope. As explained in Chapter VI, Final Quantitative Risk Assessment and Significance of Risk, employees face a significant risk of material health impairments from exposure to crystalline silica in the workplace. These employees are exposed to respirable crystalline silica in general industry, construction, and shipyard workplaces across the country. Accordingly, the rule establishes requirements for employers in every State to protect their employees from the risks of exposure to respirable crystalline silica. In States without OSHA-approved State plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards. In these States, this rule limits State policy options in the same manner as every standard promulgated by the Agency. In States with OSHA-approved State plans, this rule does not significantly limit State policy options. Any special workplace problems or conditions in a State with an OSHA-approved State plan may be dealt with by its State standard, provided the standard is at least as effective as this rule.

X. State-Plan States

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the 28 States and U.S. territories with their own OSHA-approved occupational safety and health plans (''State-Plan States'') must revise their standards to reflect the new standard or amendment. The State standard must be at least as effective as the Federal standard or amendment, and must be promulgated within six months of the publication date of the final Federal rule (29 U.S.C. 667(c)(2); 29 CFR 1953.5(a)).

A State-Plan State may demonstrate that a standard change is unnecessary because the State standard is already the same as or at least as effective as the new or amended Federal standard. In order to avoid delays in worker protection, the effective date of the State standard and any of its delayed provisions must be the date of State promulgation or the Federal effective date, whichever is later. The Assistant Secretary may permit a longer time period if the State timely demonstrates that good cause exists for extending the time limitation (29 CFR 1953.5(a)). Of the 28 States and territories with OSHA-approved State plans, 22 cover public and private-sector employees: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Six States and territories cover only public-sector employees: Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands.

This respirable crystalline silica rule applies to general industry, construction, and maritime, and imposes additional or more stringent requirements as compared to the existing permissible exposure limits for respirable crystalline silica. This rule requires that all State-Plan States revise their general industry and construction standards appropriately within six months of the date of this notice. In addition, State plans that cover private sector maritime employment or have public employees working in the maritime industry covered by this standard would be required to adopt comparable provisions to their maritime standards within six months of publication of the final rule.

XI. Unfunded Mandates

OSHA reviewed this rule according to the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 13132 (64 FR 43255 (8/

10/1999)). Under Section 202 of the UMRA (2 U.S.C. 1532), an agency must prepare a written ''qualitative and quantitative assessment'' of any regulation creating a mandate that ''may result in the expenditure by the State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more'' in any one year before promulgating a final rule. OSHA's rule does not place a mandate on State or local governments, for purposes of the UMRA, because OSHA cannot enforce its regulations or standards on State or local governments (29 U.S.C. 652(5)). Under voluntary agreements with OSHA, some States require public sector entities to comply with State standards, and these agreements specify that these State standards must be at least as protective as OSHA standards. The Occupational Safety and Health Act (29 U.S.C. 651 et seq.) does not cover tribal governments in the performance of traditional governmental functions, though it does cover tribal governments when they engage in commercial activity. However, the rule would not require tribal governments to expend, in the aggregate, $100,000,000 or more in any one year for their commercial activities. As noted below, OSHA also reviewed this rule in accordance with Executive Order 13175 on Consultation and Coordination with Indian Tribal Governments (65 FR 67249 (11/9/2000)), and determined that it does not have ''tribal implications'' as defined in that Executive Order.

OSHA concludes that the final rule would impose a Federal mandate on the private sector in excess of $100,000,000 in expenditures in any one year, as documented in the Final Economic Analysis (FEA) (*see* Section VII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis). However, the final rule does not trigger the requirements of UMRA based on its impact on State, local, or tribal governments. The FEA constitutes the written statement containing a qualitative and quantitative assessment of these anticipated costs and benefits required under Section 202(a) of the UMRA (2 U.S.C. 1532(a)).

XII. Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 requires that Federal agencies submitting covered regulatory actions to the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866 must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency (62 FR 19885 (4/23/1997)). Executive Order 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under Executive Order 12866 (*i.e.*, a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely effect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term ''environmental health risks and safety risks'' means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.*, through air, food, water, soil, product use).

The respirable crystalline silica rule is economically significant under Executive Order 12866 (*see* Section VII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis). However, after reviewing the rule, OSHA has determined that the rule would not impose environmental health or safety risks to children as set forth in Executive Order 13045. The rule would require employers to limit employee exposure to respirable crystalline silica and take other precautions to protect employees from adverse health effects associated with exposure to respirable crystalline silica. OSHA is not aware of any studies showing that exposure to respirable crystalline silica disproportionately affects children, that there are a significant number of employees under 18 years of age who may be exposed to respirable crystalline silica, or that employees of that age are disproportionately affected by such exposure.

A few commenters expressed concerns about exposure of children to respirable crystalline silica through their parents' contaminated work clothing (*e.g.*, Document ID 4204, pp. 73–74). The American Federation of Labor and Congress of Industrial Organizations concluded that maintaining OSHA's longstanding hierarchy of controls in the final rule would prevent silica dust from being carried home on work clothing better than would a rule that relies solely on respirators to protect workers (Document ID 4204, pp. 64–65, 72–74). OSHA agrees, and finds that the final rule's primary reliance on engineering and work practice controls to protect workers will result in greater protection to children than either the prior permissible exposure limit for respirable crystalline silica or a rule that places primary reliance on respiratory protection.

Because OSHA does not believe that the health risks of respirable crystalline silica have a disproportionate impact on children, OSHA concludes the respirable crystalline silica rule does not constitute a covered regulatory action as defined by Executive Order 13045. To the extent children are exposed to respirable crystalline silica either as employees or at home as a result of family members' workplace exposures, the final rule offers greater protection than did the previous permissible exposure limits.

XIII. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed this final rule in accordance with Executive Order 13175 on Consultation and Coordination with Indian Tribal Governments (65 FR 67249 (11/9/2000)), and determined that it does not have ''tribal implications'' as defined in that Executive Order. The Occupational Safety and Health Act (29 U.S.C. 651 *et seq.*) does not cover tribal governments in the performance of traditional governmental functions, so the rule will not have substantial direct effects on one or more Indian tribes in their sovereign capacity, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. On the other hand, employees in commercial businesses owned by tribes or tribal members will receive the same protections and benefits of the standard as all other covered employees.

XIV. Environmental Impacts

Introduction

OSHA has reviewed the final rule according to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500 *et seq.*), and the Department of Labor's NEPA procedures (29 CFR part 11). The Agency has determined that the final rule will have no significant impact on air, water, or soil quality; plant or animal life; the use of land; or other aspects of the external environment. Therefore, OSHA concludes that the final standard will

have no significant environmental impacts. This conclusion reaffirms the conclusions set forth in the Preliminary Economic Analysis (PEA).

To reach this conclusion, OSHA examined comments received about the potential environmental impacts posed by the final rule. Comments addressed two main issues: (1) Potential water runoff from construction tasks; and (2) costs associated with federal, state, and local environmental permits employers could be required to obtain as a result of the final rule. There were no specific comments regarding soil quality, plant or animal life, or land use. This section first lays out OSHA's preliminary conclusions regarding environmental impacts and then shows why the best available evidence in the rulemaking record reaffirms those conclusions. SBREFA and Conclusions Contained in the PEA

Pursuant to the recommendations from the Small Business Advocacy Review Panel, the Agency investigated potential environmental impacts and articulated its findings in the PEA. As noted in the SBREFA report (Document ID 0937, p. 77), the Panel requested that OSHA clarify how its silica rulemaking was related to designating silica-containing materials as hazardous wastes. In the PEA, OSHA explained that it did not believe silica wastes are classified as hazardous wastes for purposes of the Environmental Protection Agency (EPA) (Document ID 1720, p. IX–68). And the contents of OSHA's final rule on silica have no direct bearing on whether silica waste is classified as hazardous for EPA purposes.

In addition, some Small Entity Representatives (SERs) raised the possibility that the use of wet methods to limit silica exposures in some areas could violate EPA rules with respect to suspended solids in runoff unless provisions are made for recycling or settling the suspended solids out of the water. The SBAR Panel recommended that OSHA investigate this issue, add appropriate costs if necessary, and solicit comment. In response, the Agency identified six construction tasks where wet methods were utilized and found negligible costs related to controlling excess water because the amount of water used to control silica dust was minimal and typically did not produce runoff. OSHA's estimate of the potential environmental impact of each of these six equipment types was summarized in the PEA as follows:

- Stationary masonry saws: Most stationary saws come equipped with a water basin that typically holds several gallons of water and a pump for recycling water for wet cutting. The water is recirculated and, thus, not continually discharged. When emptied, the amount of water is not sufficient to produce a runoff.
- Hand-held masonry saws: Large quantities of water typically are not required in order to control dust. With these saws, water is supplied from a small capacity water tank. Any slurry residue after cutting could be dealt with by sweeping or vacuuming.
- Walk-behind and other large concrete saws: Larger concrete saws are equipped with a tank to supply water to the blade while cutting. These saws leave a slurry residue, but do not require so much water as to create a runoff.
- Walk-behind concrete grinders and millers: Some tools are equipped with a water-feed system. In these, a water line from a tank, a garden hose, or other water supply leads to the grinding head and delivers water to spray or flood the cutting tool and/or the work surface. When an automatic water feed is not available, a helper can apply water directly to the cutting surface. While such wet methods might generate enough water to create a runoff, these grinding and milling activities are typically done during the finishing stages of structure construction (*e.g.*, parking garages) and are often performed inside the structure. Thus, direct discharges to storm drains or surface waters are unlikely.
- Asphalt millers for pavement resurfacing: A typical asphalt milling machine has a built-in reservoir from which water is applied to the cutting drum. The amount of water used, however, is insufficient to produce a runoff.
- Impact drillers/pavement breakers: Water for dust suppression can be applied manually or by using a semi-automated water-feed device. In the simplest method for suppressing dust, a dedicated helper directs a constant spray of mist at the impact point while another worker operates the jackhammer. The helper can use a hose with a garden-style spray nozzle to maintain a steady and carefully directed mist at the impact point where material is broken and crushed. Jackhammers retrofitted with a focused water mist aimed at the tip of the blade offer a dramatic decrease in silica exposure. Although water-fed jackhammers are not commercially available, it is neither expensive nor difficult to retrofit equipment. Studies suggest that a water flow rate of 1/8 to 1/4 gallon per minute is best for silica dust control. At this rate, about 7.5 to 15 gallons of water per hour would be applied to (*i.e.*, sprayed on) the work area. It is unclear whether this quantity of water applied to a moveable work area at a constant rate would produce a runoff. If the work were in sufficient proximity to a storm drain or surface water, the contractor might need to use a simple barrier to prevent the water from entering the drain, or otherwise filter it. Because the volume of water is relatively small, the costs for such barriers are likely insubstantial and would typically overlap with the contractor's existing obligations for a site-control plan to prevent unwanted runoff from other causes.

In the PEA, OSHA found that employers typically have pre-existing obligations to limit runoff of solid waste, such as from rainfall, into storm drains. The Agency preliminarily concluded that: (1) The use of wet methods for certain construction tasks would not cause significant environmental problems from water runoff; and (2) employers should be able to comply with non-OSHA environmental regulations because runoff from wet methods can be easily controlled. As explained below, in light of the best available evidence contained in the record, OSHA reaffirms its preliminary conclusions.

Potential Water Runoff From Construction Tasks

While the Agency did not receive any comments directly addressing the PEA's discussion of environmental impacts, it did receive several comments on the water runoff issue. Most of the concerns expressed related to construction work, although a few comments came from entities in general industry. The construction and general industry commenters that addressed the issue of water runoff from the use of wet methods to comply with the final PEL included James Hardie Building Products, Inc.; the Unified Abrasives Manufacturers' Association; American Road & Transportation Builders Association; the General Contractors Association of New York; the Masonry & Concrete Saw Manufacturers Institute; and the Fertilizer Institute. None of the commenters to raise this issue provided any evidence to establish that runoff created by wet methods would actually create a problem (Document ID 2322, Attachment G, p. 14; 2243, p. 2; 2245, p. 4; 2314, p. 2; 2316, Attachment 1, pp. 2–3; 2101, pp. 6–7, 11–12). For example, one commenter, the Construction Industry Safety Coalition, advanced a theoretical argument that wet methods would either: (a) Require ''tremendous'' amounts of water; or (b) fail to effectively control silica. It stated:

For employers using wet methods, even attempting to meet this ''no visible dust'' standard will require a tremendous amount of water—many studies discussed in the technological feasibility analysis certainly support this notion. Such large amounts of water run counter to OSHA's contractor's assessment that ''minimal'' water should be used to avoid environmental contamination issues. The Agency contends that construction employers can mitigate any environmental concerns by utilizing as little water as possible to prevent accumulations from occurring or potentially damaging residential or commercial buildings. Even if utilizing only a little water will effectively reduce exposures to below the proposed PEL, the CISC has significant concerns that it will prevent all visible dust from being emitted (Document ID 2320, Attachment 1, pp. 9–10).

In light of the discussion set forth in Chapter VI of the FEA, Technological Feasibility, and evidence in the record, OSHA's preliminary findings regarding water runoff are affirmed. The Agency concludes that the comments it received expressing concerns about the runoff issue are unsubstantiated and theoretical and do not provide a sufficient justification for OSHA to alter its preliminary conclusions. As discussed in the Technological Feasibility section, OSHA finds that appropriate wet methods will typically require only limited application of water, possibly as little as a mist. In such conditions, the water will evaporate before collecting into a body of water. Where a greater water flow is necessary to suppress airborne silica, the runoff, rather than forming a free-flowing stream, will typically consolidate into slurry. In addition, because employers want to keep nearby structures and materials dry, they will typically use as little water as necessary.

OSHA finds support for these findings in the hearing testimony compilation assembled by the Building and Construction Trades Department. That evidence demonstrates the practical reality that water runoff from construction tasks is insignificant (Document ID 4223, pp. 28–30). Indeed, Deven Johnson, of the Operative Plasterers' and Cement Masons' International Association, stated that in her years of experience in using wet methods to control relatively dusty situations involving demolition, she had never had a problem with runoff-related issues. She indicated that runoff tends to create a slurry, which is easily vacuumed up (Document ID 3581, pp. 1695–1696). Gary Fore, a consultant and former Vice President for the American National Asphalt Pavement Association, likewise said that runoff was never a problem. He confirmed the PEA's preliminary conclusion for asphalt milling operations. While there may be a substantial amount of water used in the course of a day, it is applied as an aerosol. Further, although the pavement surface may be temporarily moist, it does not produce runoff from the construction site (Document ID 3583, p. 2209). Finally, Donald Hulk, Safety Director for Manafort, a construction contractor, testified that contrary to hypothetical assertions about potential runoff issues, his company did not find managing potential runoff from wet methods to be a problem. His reasoning confirmed the PEA's finding that the amount of water required for typical silica-containing dust suppression will not create substantial runoff. Moreover, he testified that in the case of demolition related to roadway construction, excess water is typically absorbed into demolition debris or evaporates—which is aided by the fact that most construction activity occurs during the warmer parts of the year (Document ID 3583, Tr. 2384–2385).

Certain industries voiced water runoff concerns specific to their workplaces. For example, the fertilizer industry stated its apprehension about OSHA's ''preference'' for wet methods to control silica exposure and indicated that such methods would be potentially problematic from an environmental standpoint at its facilities (Document ID 2101, pp. 6–7, 11–12). OSHA finds the fertilizer industry's concern misplaced because the final standard does not require the use of wet methods in general industry. Additionally, as discussed in Chapter III, the Agency estimates that exposures to respirable crystalline silica in the fertilizer industry are sufficiently low that most fertilizer-related manufacturing industries will not be affected by the final standard; the mixing-only fertilizer industry, NAICS 325314, was the only one judged to be affected.

The coal-fired electric industry also raised the issue of water runoff in its industry. The Edison Electric Institute and Alabama Power Company indicated a potential for conflict between an EPA rulemaking regarding ash ponds at the site of coal-fired electric utilities and this rulemaking (Document ID 2357, pp. 28–29; 2185, Attachment 1, p. 11). OSHA considered this concern, but has concluded that this will not be a problem in practice. The commenters never explained how the wet methods that might be required in Table 1 for construction activities (*e.g.*, cutting concrete for transmission and distribution) would result in water flowing into fly ash ponds. In any event, the Agency has found that the proper use of wet methods will not result in significant runoff issues for any of the industries covered by the standard.[128]

Air Quality/Permit Concerns

Regulations that will reduce the atmospheric concentration of respirable crystalline silica in the air within industrial and other facilities and workplaces have the potential to affect, either positively or negatively, the amount of respirable crystalline silica emitted by these sources into the ambient (external) environment. In most cases, the change will be small. As discussed in Chapter V of the FEA, Costs of Compliance, most ventilation is needed to reach the preceding PEL rather than the new PEL. The extent to which the reduction in the PEL—and, hence, occupational exposures—under the OSHA standard will impact air quality depends on how employers handle the increased volume of respirable crystalline silica captured by the relevant control technologies. Taking into account the measures employers are already using to comply with the existing silica PEL, and the fact that the baghouses employers are already using capture at least 99 percent of silica emissions (Document ID 3641, p. VII–19), OSHA concludes that the final rule will not have a significant impact on air quality

A number of commenters raised concerns that the final rule would create an onerous and cost-increasing administrative burden because it would necessitate obtaining EPA environmental permits, notably with regard to air quality regulations and related permits and process approvals at the state and local level. The concern was not an adverse environmental impact, per se, but rather the burden of complying with existing environmental rules in the context of the new OSHA standard (*e.g.,* Document ID 2291, Attachment 1, p. 12; 2379, Appendix 1, p. 14; 2380, Attachment 2, p. 19; 2317, pp. 2–3). OSHA's response to these cost concerns is addressed in Chapter V of the FEA in the section on general industry engineering control costs.

A prime concern voiced by the commenters was having to comply with OSHA compliance deadlines while simultaneously meeting deadlines under applicable air quality permitting regulations.

For example, the Asphalt Roofing Manufacturers Association (ARMA) raised the issue of EPA permits related to changes in ventilation systems.

[128] Alabama Power also referred to problems with environmental permits, but did not specify to which environmental permits they were referring. Permit issues are addressed later in this section.

. . . the proposal appears to completely disregard environmental permitting requirements, which will present a significant time demand in almost every case because the standard will require increased dust collection, and releases to outside air will trigger air pollution limitations and permitting requirements for both State and or Federal agencies. Recent experience of ARMA members relating to implementation of the new National Ambient Air Quality Standards (NAAQS) for particulate matter ($PM_{2.5}$) reveals that, even in the case of minor facility modifications which emit particulate matter, authorization to construct or modify a control device can take more than a year to obtain. Even longer permitting times will be experienced in cases requiring complex modeling of nearby sources, or State or Federal approval of modeling methods and protocol inputs. These factors could further delay the issuance of permits by an additional twelve months, assuming the facility is able to develop a passing model. If the model does not pass, further modeling and review by permitting agencies, or additional emissions abatement, may be required to obtain the permits, extending still further this step in the process (Document ID 2291, Attachment 1, p. 12).

As the Agency explains in the Summary & Explanation section of the preamble dealing with paragraph (j), dates, the final rule's effective and enforcement dates have been tailored to allow a sufficient period of time for employers to meet requirements for approval by other regulatory agencies. (A discussion of various state permitting times can be found in ''Examples of State Environmental Agency Permit Turnaround Times,'' ERG, 2015.) The Agency believes providing longer compliance deadlines should address the primary concerns expressed by commenters regarding the time necessary to obtain any required environmental permit approvals. Ultimately, as discussed in the Summary and Explanation, cases that are unusually problematic can be addressed through OSHA's enforcement discretion if the employer can show that it has made good faith efforts to implement engineering controls, but has been unable to implement such controls due to the time needed for environmental permitting.

Some industries raised permit concerns unique to their operations. The Association of American Railroads and American Short Line and Regional Railroad Association stated that it foresaw a need for a permit under the Clean Water Act if a ballast was sprayed with a chemical, which, through run off or by another means, reached a body of water (Document ID 2366, p. 7).

OSHA considers the railroad industry's concern about the threat of significant water contamination from chemical dust suppressant speculative because of the limited amount of water potentially used. Consequently, the Agency does not foresee a significant environmental impact. Additionally, no current OSHA standard governs the use of chemical dust suppressants. While some state or local governments may require a permit, it is not clear this would pose a new issue for the railroads, as OSHA believes it is likely that they already have to deal with such issues in the context of runoff from deicing chemicals, as well as oil and metal particles from normal operations. OSHA notes, however, that the analysis in the railroad section of Chapter IV of the FEA, Technological Feasibility, discusses chemical suppressants merely as a possibility for reducing exposures, but it is not ultimately identified as necessary to enable employers in the industry to meet the PEL of 50 $\mu g/m^3$. Accordingly, the FEA's cost analysis for the railroad industry does not include chemical suppressants, but assumes the industry will use wet methods to reduce exposures, and estimates the costs accordingly. To the extent chemical dust suppressants are more cost-effective than water, the FEA has overestimated the cost to the industry. And to the extent suppressants pose an environmental air quality permitting issue, OSHA notes that suppressants are not required under the final rule and is not including relevant permitting costs in its analysis.

The Shipbuilders Council of America (SCA) stated that if the final silica rule altered blasting technologies and/or facility equipment, the data currently used for shipyard permits in certain states (*e.g.*, state air and water permits) would be invalid, necessitating permit and plan updates and creating additional costs for the industry (Document ID 2255, p. 2). The final rule does not specify engineering control changes in this area; nor does the Agency believe the lower PEL will require a change in engineering controls for abrasive blasting, relative to current standards. As laid out in Chapter V in the FEA, employers complying with the hierarchy of controls under the existing silica PEL and ventilation standards will already be using engineering controls to limit exposures. OSHA has found that the only additional feasible engineering controls employers in shipyards can implement to reduce exposures is the use of HEPA vacuums (in lieu of dry sweeping). Implementation of this control will reduce potential environmental problems because the use of HEPA vacuums raises less dust than dry sweeping.

Positive Environmental Effects

Based on its review of the record, OSHA concludes that the final rule will potentially have a positive environmental impact. At least one industry commenter, in the context of the hydraulic fracturing industry, suggested that its technology, the adoption of which would presumably be hastened by the promulgation and enforcement of the final rule, would reduce potential environmental impacts (Document ID 3589, Tr. 4140). In a similar vein, as discussed in both Chapters IV and V of the FEA, the final standard actually helps construction employers' reduce fugitive and co-generated dust, aiding in their compliance with environmental standards related to the dust. (The issue of controlling fugitive dust overlaps with the issue of existing employer obligations to minimize the runoff of solid waste into public water, discussed previously in this chapter, as well as the general expectation that employers clean up their work sites after their work is completed, as discussed in Chapter V).

Conclusion

As a result of this review, OSHA has reaffirmed its conclusions in the PEA, that the silica final rule will have no significant impact on air, water, or soil quality; plant or animal life; the use of land; or aspects of the external environment. It finds that the final standard is in compliance with NEPA and will have no significant environmental impact.

XV. Summary and Explanation of the Standards

OSHA proposed two standards for occupational exposure to respirable crystalline silica—one for general industry and maritime and a second for construction. Both proposed standards were structured according to OSHA's traditional approach, including separate provisions for a permissible exposure limit (PEL), exposure assessments, and methods of compliance, which includes a requirement to follow the hierarchy of controls. The methods of compliance provision in the proposed construction standard included Table 1, which specified engineering controls, work practices, and respiratory protection for common construction operations (now referred to as tasks). Construction employers who would have chosen to fully implement engineering controls, work practices, and respirators for a task in proposed Table 1 would have been exempted from conducting exposure assessments for employees conducting

that task, but would have been required to comply with the PEL.

The structure of the final standard for general industry and maritime remains generally consistent with other OSHA health standards. The most significant structural change from the proposed general industry and maritime standard is that ''cleaning methods,'' which was under the *Methods of Compliance* paragraph, is now a separate paragraph called *Housekeeping*. The same change regarding *Housekeeping* was made to the standard for construction. In addition both standards include a requirement for a written exposure control plan, which is included under the *Methods of Compliance* paragraph in the standard for general industry and maritime but as a separate paragraph in the standard for construction. Most importantly, the structure for the construction standard is significantly different from OSHA's traditional approach to address stakeholder concerns about compliance in the construction industry.

Many stakeholders thought that construction employers who fully and properly implement the engineering controls, work practices, and respiratory protection specified in Table 1 should be considered to be in compliance with the PEL. As reflected in paragraph (c) of the standard for construction (which includes Table 1), and as discussed in more detail in the summary and explanation, OSHA agrees that construction employers who fully and properly implement the engineering controls, work practices, and respiratory protection for a task on Table 1 do not have to demonstrate compliance with the PEL for that task, because these controls provide a level of protection equivalent to that provided by the alternative approach that includes the 50 μg/m^3 PEL.

OSHA also received many comments about the challenges of conducting exposure assessments in the construction industry. OSHA expects that because of these challenges most construction employers will follow Table 1. Therefore, OSHA made major structural changes to the standard for construction to emphasize Table 1 in paragraph (c) for employers who choose to follow that approach. Paragraph (d) of the standard for construction provides alternative exposure control methods for construction employers who choose not to follow Table 1 or who perform tasks that are not included in Table 1 (*e.g.,* abrasive blasting and underground construction (tunnel boring)). Paragraph (d) of the standard for construction contains requirements, including the PEL, exposure assessments, and methods of compliance, that follow OSHA's traditional approach.

Construction employers who choose to follow Table 1 of paragraph (c) are exempt from following paragraph (d) but must comply with provisions in all other paragraphs of the standard for construction. On the other hand, construction employers who follow the alternate exposure control methods in paragraph (d) are exempt from following the provisions in paragraph (c) but must comply with the provisions in all other paragraphs of the standard for construction.

Although the structure of the standard for general industry and maritime differs from the structure of the standard for construction, many of the requirements are the same or similar in both standards. Therefore the summary and explanation is organized according to the main requirements of the standards. It includes paragraph references to the standard for general industry and maritime, followed by paragraph references for the standard for construction. The summary and explanation uses the term ''rule'' when referring to both standards. Generally, when the summary and explanation refers to the term ''rule,'' it is referring to the final rule. To avoid confusion, the term ''final rule'' is sometimes used when making a comparison to or clarifying a change from the proposed rule.

Scope and Application

Separate standards for general industry/maritime and construction. OSHA proposed two separate standards addressing occupational exposure to respirable crystalline silica: one for exposures in general industry and maritime, and another for exposures in the construction industry. The proposed standards were intended to provide equivalent protection for workers while accounting for the different work activities, anticipated exposures, and other conditions in these sectors.

Commenters representing construction employers, labor unions, and governmental entities noted the intrinsic differences between construction and other industries and were generally supportive of OSHA's decision to propose one standard for general industry and maritime and another for construction (*e.g.,* Document ID 1955, p. 2; 2116, p. 40; 2166, p. 3; 2181, p. 4; 2262, p. 14; 2318, p. 13; 2371, p. 5; 3403, p. 3). However, some stakeholders expressed concerns about differentiation among industries.

The Association of Occupational and Environmental Clinics opposed applying occupational health protection measures differently (Document ID 3399, p. 4). Edison Electric Institute (EEI) argued that differences in the standards may create confusion, administrative burden, and ambiguity, and could ultimately frustrate good-faith compliance efforts. EEI suggested that the easiest solution would be for OSHA to have ''a single regulation applicable to the electric utility industry, rather than separate General Industry and Construction requirements'' (Document ID 2357, p. 17).

Commenters representing utility providers, surface mineral mining, rock crushing, railroad operations, and truck distribution expressed concerns about separate standards creating uncertainty about which requirements would apply to various activities (Document ID 2101, p. 3; 2185, pp. 4–5; 2318, p. 13; 2357, p. 4; 2366, p. 3; 3492, p. 2). Southern Company cited the installation of new power delivery lines versus the repair or maintenance of existing power delivery lines as an example, indicating that once a concrete pole is in the ground the process of mounting hardware is exactly the same, but the applicable standard may be different (Document ID 2185, p. 4).

The International Brotherhood of Teamsters (IBT) also expressed concerns about work activities where it may not be clear whether the general industry or construction standard applies. IBT noted that ready-mix concrete truck drivers frequently travel to more than one work location and may work at many different construction sites on any given day. These workers are typically covered by the general industry standard; however, they may work at construction sites and perform certain tasks that could be considered construction work (Document ID 2318, p. 13).

Several commenters requested that OSHA develop a table listing specified exposure control methods for general industry, comparable to proposed Table 1 for construction, or that OSHA add general industry tasks to Table 1 (Document ID 2116, Attachment 1, p. 3; 2212, p. 2; 2244, p. 4; 2339, p. 8; 2357, p. 1). The American Society of Safety Engineers requested that Table 1 ''be considered for the general industry/maritime standard for commonly performed tasks involving high levels of silica exposure'' (Document ID 2339, p. 8).

After considering the concerns raised by commenters, OSHA is issuing one standard that addresses occupational exposure to respirable crystalline silica in general industry and maritime work and another for construction work. As reflected primarily in paragraph (c) and

Table 1 of the standard for construction, the Agency finds that certain conditions inherent to the construction industry, such as the transient nature of the work, warrant alternatives to protect employees that are somewhat different than those that apply to general industry and maritime work. OSHA has long recognized a distinction between the construction and general industry sectors, and has issued standards specifically applicable to construction work under 29 CFR part 1926. The Agency has provided a definition of the term ''construction work'' at 29 CFR 1910.12(b), has explained the terms used in that definition at 29 CFR 1926.13, and has issued numerous interpretations over the years explaining the classification of activities as either general industry or construction work.

In issuing separate standards for general industry/maritime and construction, OSHA's intent is to ensure that employees exposed to respirable crystalline silica in construction are, to the extent feasible, provided equivalent protection to that afforded employees in general industry and maritime. Specifically, OSHA intends that Table 1 in paragraph (c) of the construction standard, while providing employers with an alternative, flexible approach to addressing exposure to respirable crystalline silica in construction, will provide the same level of protection against exposures to silica for construction employees as is provided to general industry and maritime employees; the same is true for construction employees whose employers are following the traditional exposure assessment and hierarchy of controls approach under paragraph (d) of the construction standard.

OSHA recognizes that in some circumstances, general industry activities and conditions in workplaces where general industry tasks are performed may be indistinguishable from those found in construction work. In some cases, employers whose primary business is classified as general industry may have some employees who perform construction work, and employers whose primary business is classified as construction may have some employees who perform general industry work. Given the wide variety of tasks performed in the workplace, it is inevitable that questions will arise regarding the classification of certain activities, and these questions have been and will continue to be addressed in letters of interpretation and other guidance issued by OSHA. However, the distinction between sectors is generally well understood by both OSHA enforcement personnel and the regulated community, and OSHA concludes that any attempt to create exceptions or to provide different criteria in this final rule would not improve upon the current criteria but would, rather, cause confusion.

In certain circumstances, tasks performed in a general industry setting may be indistinguishable from the tasks listed on Table 1, and, under these circumstances, OSHA intends to treat full compliance with the construction standard as full compliance with the general industry/maritime standard. Accordingly, OSHA has revised the scope provision (*i.e.,* paragraph (a)) in the general industry and maritime standard by adding paragraph (a)(3) to permit employers to follow the construction standard rather than the general industry and maritime standard when the general industry/maritime task performed is indistinguishable from a construction task listed on Table 1 in paragraph (c) of the construction standard, and the task will not be performed regularly in the same environment and conditions.

These indistinguishable tasks should not be merely parallel or complementary to or occurring at the same time and place as the construction tasks listed on Table 1, but rather should be of the same nature and type as those construction tasks. OSHA anticipates that the option in paragraph (a)(3) will apply primarily to maintenance and repair tasks performed in general industry or maritime settings. For example, an employee using a portable masonry saw to cut brick to patch a section of an existing brick wall, which is typically maintenance, would require tools and controls that are the same as those of an employee cutting brick while building a new brick wall, which is construction work. In performing this task, the employer could follow the construction standard, including paragraph (c)(1)(ii) of Table 1, rather than the general industry and maritime standard. Similarly, the installation of new power delivery lines is considered a construction activity, while the repair or maintenance of existing power delivery lines is considered a general industry task, even though a handheld drill may be used to drill a hole in concrete during both activities. In this situation, if the employer complies with the entry on Table 1 for handheld and stand-mounted drills (paragraph (c)(1)(vii) of the construction standard), in addition to all other applicable provisions of the construction standard (*e.g.,* paragraph (g), *Written exposure control plan*), the employer would not be obligated under the general industry and maritime standard to perform an exposure assessment for the employee(s) engaged in the drilling task, or be subject to citation for failure to meet the permissible exposure limit (PEL); instead, the employer would have the same accommodation that Table 1 in paragraph (c) of the construction standard affords a construction employer doing that task and following paragraph (c). However, in the event that the employer fails to fully comply with the construction standard by, for example, failing to fully and properly implement the controls on Table 1 or to fully establish and implement a written exposure control plan (*e.g.,* by not designating a competent person to implement the plan), the employer would be subject to the general industry and maritime standard and could be cited for not having performed an exposure assessment or not having achieved the PEL with respect to the employee(s) engaged in that task.

Paragraph (a)(3)(ii) of the general industry and maritime standard provides that, in order for the employer to be able to avail itself of the option to follow the construction standard, the task must not be performed regularly in the same environment and conditions. For example, an employer that performs sanding or cutting of concrete blocks in a concrete block manufacturing plant may not follow the construction standard, because the task is performed regularly in the same environment and conditions. Likewise, an employer whose business includes chipping out concrete from inside the drums of ready-mixed concrete trucks using pneumatic chipping tools may not follow the construction standard, because that task will be regularly performed in a relatively stable and predictable environment that would not require the accommodation of Table 1, which is intended in part to accommodate situations where the tasks will be performed in different environments and conditions.

Regarding comments that exposure controls should be specified in the general industry and maritime standard in a manner similar to that of Table 1 for construction tasks, OSHA concludes that, for most general industry operations, it is not possible to develop a specification that would broadly apply to facilities that vary widely in size, process design, and complexity while being specific enough to provide reasonably objective criteria against which to judge compliance with the standard. Unlike for construction tasks, the rulemaking record does not provide sufficient information for OSHA to account for the wide variety of potential

tasks across the range of manufacturing and other general industry work. In manufacturing industries such as foundries and pottery production, local exhaust specifications must be custom designed for each establishment considering its manufacturing processes, equipment, and layout. Based on its over forty years of experience in enforcing occupational safety and health standards, OSHA concludes that in general industry and maritime, employee protection is best provided through a performance-oriented standard that permits employers to implement engineering controls and work practices that best fit their situation. In contrast, the task-based operations performed in construction are uniquely suited to a specification approach since the same equipment and dust controls are generally used regardless of the nature of the construction project, making specification of an effective dust control approach possible.

Agriculture. The proposed rule did not cover agricultural employers due to limited data on exposures and control measures in the agriculture sector. OSHA's authority is also restricted in this area; since 1976, an annual rider in the Agency's Congressional appropriations bill has limited OSHA's use of funds with respect to farming operations that employ fewer than ten employees (Consolidated Appropriations Act, 1976, 94, 90 Stat. 1420, 1421 (1976) (and subsequent appropriations acts)). The Agency requested information on agricultural operations that involve respirable crystalline silica exposures in the Notice of Proposed Rulemaking (NPRM), as well as information related to the development of respirable crystalline silica-related adverse health effects and diseases among employees in the agricultural sector (78 FR 56274, 56288 (9/12/13). OSHA did not receive information that would support coverage of agricultural operations. Therefore, agriculture employers and operations are not covered by the rule, as specified in paragraph (a)(1)(ii) of the general industry and maritime standard.

Mine Safety and Health Administration (MSHA) jurisdictional concerns. The Fertilizer Institute (TFI) and Fann Contracting, Inc. requested that OSHA clarify the jurisdictional limits of the silica rule in light of OSHA's memorandum of understanding (MOU) with MSHA (Document ID 2101, p. 3; 2116, p. 31) (citing *Interagency Agreement Between the Mine Safety and Health Administration U.S. Department of Labor and the Occupational Safety and Health Administration U.S. Department of Labor*). The MOU, which has been in effect since March 29, 1979 (Document ID 2101, p. 3), delineates certain areas of respective authority, sets forth factors regarding determinations relating to convenience of administration, provides a procedure for determining general jurisdictional questions, and provides for coordination between MSHA and OSHA in all areas of mutual interest. The respirable crystalline silica rule in no way modifies the existing jurisdictional boundaries set forth in the Interagency Agreement, and any issues related to the rule that may arise between MSHA and OSHA are governed by this agreement. Therefore, the final rule does not necessitate a clarification of the jurisdictional limits.

Federal Railroad Administration (FRA) jurisdictional concerns. The Association of American Railroads (AAR) and the American Short Line and Regional Railroad Association (ASLRRA) raised jurisdictional issues about railroad operations (Document ID 2366, pp. 3–4). The stated concern is that railroad operations are also regulated by FRA. AAR and ASLRRA questioned OSHA's jurisdiction over railroad activities that OSHA considered and costed in its preliminary economic analysis, notably those of ''ballast dumper'' and ''machine operator.'' AAR and ASLRRA disagreed with OSHA's inclusion of these job categories as being ''non-operational,'' which allowed them to be included within the scope of the OSHA silica rule. AAR and ASLRRA asserted that the FRA has developed a special expertise, making the FRA uniquely qualified to play the primary role in the federal government's efforts to assure safe employment and places of employment for railroad employees engaged in activities related to railroad operations (Document ID 2366, pp. 3–4).

Section 4(b)(1) of the OSH Act limits OSHA's authority; the Act does not apply to working conditions of employees with respect to which other Federal agencies exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health. Many of the regulatory boundaries between FRA and OSHA are documented in an FRA policy statement that outlines the respective areas of jurisdiction between FRA and OSHA with regard to the railroad industry, but the FRA has also defined some boundaries through rulemaking (Document ID 0692 (43 FR 10583–10590 (3/14/78))). In 2003, FRA amended the Railroad Workplace Safety regulations, 49 CFR part 214, to require that new and employer-designated existing on-track roadway maintenance machines be equipped with, among other things, positive pressurized ventilation systems, and be capable of protecting employees in the cabs of the machines from exposure to air contaminants, including silica, in accordance with OSHA's air contaminants standard, 29 CFR 1910.1000 (49 CFR 214.505). In that rulemaking, the FRA articulated the overlap of its authority with OSHA's concerning protection from air contaminants: ''when working inside the cab, workers receive protection from FRA; when working outside the cab, workers receive protection from OSHA'' (68 FR 44388, 44393–44394 (7/28/03)). Consequently, this OSHA rule applies only to those railroad activities outside the cab (*e.g.,* ballast dumping outside cabs) over which the FRA has not exercised jurisdiction, and only those activities are included in the final economic analysis. Additional discussion of this jurisdictional issue is included in the section on the technological feasibility of railroads (see Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA)).

Forms of silica covered. OSHA received comments about which forms, or polymorphs, of silica (*e.g.,* quartz, cristobalite, tridymite) to include within the scope of the rule. The Industrial Minerals Association—North America and Ameren Corporation supported including all forms within the scope of the rule (Document ID 1760, p. 2; 2200, p. 2; 2315, p. 2). Other commenters made recommendations regarding specific forms of silica. For example, the National Industrial Sand Association (NISA) suggested including tridymite; however, the National Institute for Occupational Safety and Health (NIOSH) and the North American Insulation Manufacturers Association (NAIMA) did not support inclusion of tridymite due largely to its rarity in the workplace (Document ID 2195, p. 30; 2177, Attachment 2, p. 10; 4213, p. 4). Similarly, Southern Company recommended that neither tridymite nor cristobalite be included within the scope of the rule, due to their rarity in the workplace (Document ID 2185, p. 2, 6). The American Composites Manufacturers Association and Southern Company suggested that OSHA focus exclusively on quartz (Document ID 1732, p. 6; 2185, p. 6). NAIMA suggested OSHA focus on both quartz and cristobalite (Document 4213, p. 4).

As discussed in Section V of this preamble, Health Effects, OSHA has concluded, based on the available scientific evidence, that quartz,

cristobalite, and tridymite have similar toxicity and carcinogenic potency. Including all three forms of crystalline silica in the scope of the rule is therefore protective of the health of employees. Coverage of quartz, cristobalite, and tridymite in the scope of the rule maintains the coverage from OSHA's previous PELs for respirable crystalline silica; to eliminate one or more forms from the scope of the rule would lessen protections, contrary to what the OSH Act contemplates (*see* 29 U.S.C. 655(b)(8)). Therefore, the respirable crystalline silica rule applies to occupational exposure to respirable crystalline silica, as defined in paragraph (b) of each standard to include quartz, cristobalite, and tridymite.

Some commenters contended that OSHA should differentiate between crystalline silica and amorphous silica in the scope of the rule. The Society for Protective Coatings stated that this differentiation would avoid confusion and unnecessary burden, especially for small businesses (Document ID 2120, p. 1; 3544, p. 16). NAIMA stated that NIOSH, IARC (the International Agency for Research on Cancer), EPA (the Environmental Protection Agency), and the California Office of Environmental Health Hazard Assessment all recognize the distinction in potential hazards to workers between amorphous and crystalline silica (Document ID 3544, p. 16). However, OSHA never intended to, and did not, include amorphous silica in the proposed rule. Nor do the final standards apply to amorphous silica. In fact, each standard bears the title, ''Respirable crystalline silica''; only the respirable fraction of crystalline silica, where it exists as quartz, cristobalite, and/or tridymite, is covered.

Requests for exemptions. Commenters requested exemptions from the rule for specific operations or industries, such as auto body operations, cement distribution terminals, floor covering dealers, rural electric distribution cooperatives, and painting operations, arguing that these operations involve low levels of exposure to respirable crystalline silica (*e.g.,* Document ID 2300, p. 4; 2358, p. 15; 2359, pp. 3–7; 2365, p. 2; 3751, p. 2; 2239, pp. 4–5). For example, the National Automobile Dealers Association (NADA) said that the likelihood of worker exposure to significant respirable crystalline silica in dealership auto body operations is de minimis, largely due to product substitution, state-of-the-art work practices, and the use of respiratory protection. NADA requested that OSHA confirm this conclusion through a clear statement in the preamble of its final rule (Document ID 2358, p. 3). Similarly, the World Floor Covering Association requested that OSHA revise the rule to exempt retail flooring dealers and installers from all requirements in the standard based on the intermittent and de minimis exposure of its employees to crystalline silica (Document ID 2359, p. 11). The Portland Cement Association also requested an exemption from the silica rule, arguing that its contemporary inhalation survey and historical data show that there is no probability that respirable crystalline silica exposures can be generated above the proposed action level among employees at cement terminals.

OSHA addresses the concerns of commenters regarding situations where they believe exposures are minimal and represent very little threat to the health of workers by including in the standards' scope and application sections an exception based on the level of exposure to respirable crystalline silica. Therefore, paragraph (a)(2) of the standard for general industry and maritime provides an exception for circumstances where the employer has objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 micrograms per cubic meter of air (25 $\mu g/m^3$) as an 8-hour time-weighted average (TWA) under any foreseeable conditions.

OSHA concludes this approach is sensible policy because providing an exception for situations where airborne exposures are less likely to present significant risk allows employers to focus resources on the exposures of greatest occupational health concern. The Agency has included a definition for ''objective data'' in the rule (discussed with regard to Definitions) to clarify what information and data can be used to satisfy the obligation to demonstrate that respirable crystalline silica exposures will be below 25 $\mu g/m^3$ as an 8-hour TWA under any foreseeable conditions.

When using the phrase ''any foreseeable conditions'' OSHA is referring to situations that can reasonably be anticipated. The Agency considers failure of engineering controls to be a situation that is generally foreseeable. Although engineering controls are usually a reliable means for controlling employee exposures, equipment does occasionally fail. Moreover, OSHA intends the requirements for training on control measures, housekeeping, and other ancillary provisions of the rule to apply where engineering controls are used to limit exposures. Without effective training on use of engineering controls, for example, it is unreasonable to expect that such controls will be used properly and consistently. Thus, the exception does not apply where exposures below 25 $\mu g/m^3$ as an 8-hour TWA are expected or achieved, but only because engineering or other controls are being used to limit exposures; in that circumstance, but for the controls, exposures above 25 $\mu g/m^3$ as an 8-hour TWA would be foreseeable, and are foreseeable in the event of control failure or misuse.

OSHA considers the exclusion from the application of the rule for exposures below the 25 $\mu g/m^3$ action level to be a reasonable point of demarcation. For workplaces or tasks for which exposures are consistently below that threshold, it should be possible for employers to develop or obtain objective data demonstrating that employee exposure will remain below that level under any foreseeable conditions. Other standards have included similar exceptions (*e.g.,* acrylonitrile, 29 CFR 1019.1045; ethylene oxide, 29 CFR 1910.1047; 1,3-butadiene, 29 CFR 1910.1051; chromium (VI), 29 CFR 1910.1026). In order for an employer to take advantage of this exclusion, the employer must have objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 $\mu g/m^3$ as an 8-hour TWA) under any foreseeable conditions, and must provide this data to the Assistant Secretary upon request.

NADA's submission provides an example of data that can be used to meet the requirements of the standard (Document ID 4197; 4198). NADA conducted air monitoring for employees performing a variety of tasks in automobile body shops. NADA selected body shops from a random sample of members, and worked to ensure that those selected were not the most technologically advanced or cleanest in order to ensure that the results of the study were representative of typical operations. The sampling was conducted in accordance with procedures described in OSHA's Technical Manual, and techniques for controlling dust generated during sanding operations were recorded and monitored. NADA retained a consultant to review testing methodology and final results and worked with Maine's OSHA Consultation Program to gather samples. In the body shops sampled, all but one of the samples taken for respirable crystalline silica indicated that exposures were below the limit of detection. For the one sample where the level of exposure was above the limit of detection, the result was below 25 $\mu g/m^3$ as an 8-hour TWA. A body shop

performing tasks in a manner consistent with that described in the NADA submission would be able to rely on these objective data to demonstrate that exposures do not exceed 25 μg/m³ as an 8-hour TWA under any foreseeable conditions.

The construction standard, paragraph (a), also provides an exception where employee exposure will remain below 25 μg/m³ as an 8-hour TWA under any foreseeable conditions, but it does not require the employer to have objective data to support the exception. The data presented in Chapter IV of the FEA indicate that construction tasks can and often do involve exposures that exceed 25 μg/m³ as an 8-hour TWA. However, some construction tasks may involve only minimal exposure to respirable crystalline silica. Some commenters indicated that they believed these tasks were covered under the scope of the proposed construction standard. For example, the Construction Industry Safety Coalition (CISC) and the National Association of Home Builders indicated that they believed that mixing mortar, pouring concrete footers, slab foundation, and foundation walls, and the removal of concrete formwork would be covered by the standard (Document ID 2319, pp. 19–21; 2296, pp. 8–9). OSHA finds that these tasks, when performed in isolation from activities that do generate significant exposures to respirable crystalline silica (*e.g.,* tasks listed on Table 1, abrasive blasting), do not create respirable crystalline silica exposures that exceed 25 μg/m³ as an 8-hour TWA. OSHA's analysis of the rulemaking record also indicates that a substantial number of employees in the construction sector perform tasks involving occasional, brief exposures to respirable crystalline silica that are incidental to their primary work. These employees include carpenters, plumbers, and electricians who occasionally drill holes in concrete or masonry or perform other tasks that involve exposure to respirable crystalline silica. CISC estimated that 1.5 million employees in the construction industry perform such tasks (Document ID 2319, pp. 72–73). Where employees perform tasks that involve exposure to respirable crystalline silica for a very short period of time, OSHA finds that exposures for many tasks will be below 25 μg/m³ as an 8-hour TWA. Short-term respirable crystalline silica exposures must be very high in order for those exposures to exceed 25 μg/m³ as an 8-hour TWA; for example, if an employee is exposed for only 15 minutes, his or her exposure would have to exceed 800 μg/m³ for that 15 minute period before the 8-hour TWA exposure would exceed 25 μg/m³.

When performed without adequate controls, some tasks can generate such high exposures. However, for some construction tasks that may be performed occasionally, for brief periods of time, exposures would not generally be expected to exceed 25 μg/m³ as an 8-hour TWA. For example, for hole drillers using hand-held drills, the highest result identified in OSHA's exposure profile was for a worker performing dry drilling on a wall on the lower level of a concrete parking garage where air circulation was poor (*see* Chapter IV of the FEA). This result showed an exposure of 300 μg/m³ during the sampling period (Document ID 1423, p. 833). If the duration of exposure was 15 minutes, the 8-hour TWA exposure would be 19 μg/m³, and therefore under the 25 μg/m³ threshold (assuming no exposure for the remainder of the shift).

Rather than require construction employers to develop objective data to support an exception from the construction standard for employees who are exposed to minimal levels of respirable crystalline silica, or who are occasionally exposed to respirable crystalline silica for brief periods, OSHA is structuring the scope paragraph (*i.e.,* paragraph (a)) for the construction standard so that the standard applies to all occupational exposures to respirable crystalline silica, except where employee exposure will remain below 25 μg/m³ as an 8-hour TWA under any foreseeable conditions. This approach relieves construction employers of the burden of developing objective data for such situations.

In the NPRM, OSHA asked stakeholders whether the Agency should limit the coverage of the rule to materials that contain a threshold concentration (*e.g.,* 1 percent, 0.1 percent) of crystalline silica (78 FR at 56288). Stakeholders representing industries including cement and concrete, composites manufacturing, fertilizers, and sand and gravel suggested a threshold, commonly presenting concerns regarding requirements for labels and safety data sheets (SDSs) (*e.g.,* Document ID 1785, p. 4; 2116, Attachment 1, p. 45; 2179, pp. 3–4; 2101, pp. 8–9; 2284, p. 10; 2296, p. 44; 2312, p. 3; 2317, p. 3; 2319, p. 120; 2327, Attachment 1, p. 14; 4208, pp. 19–20). For example, TFI supported a percentage-based threshold for crystalline silica containing materials, indicating that such an approach would be consistent with OSHA's past standard-setting experience for asbestos-containing materials. TFI stated that OSHA should not set a threshold at lower than 1 percent, and recommended that OSHA consider a 5 percent threshold, noting challenges in measuring crystalline silica content in bulk materials at concentrations below 1 percent (Document ID 2101, pp. 5–9).

OSHA has not included a threshold concentration exception in these standards. The Agency has concluded that it would not be appropriate to establish a threshold crystalline silica concentration because the evidence in the rulemaking record is not sufficient to lead OSHA to determine that the suggested concentration thresholds would be protective of employee health. The Agency's exposure assessment findings show that exposures to respirable crystalline silica can exceed the action level of 25 mg/m³ or PEL of 50 mg/m³ even at threshold concentrations less than 1 or 0.1 percent, as demonstrated by the abrasive blasting activities investigated in a NIOSH survey report using Staurite XL in containment (Document ID 0212, p. 12). Issues with regard to requirements for labels and SDSs are addressed in the summary and explanation of requirements for *Communication of Respirable Crystalline Silica Hazards to Employees* in this preamble.

The Brick Industry Association (BIA) argued that its members should be exempt from compliance with the respirable crystalline silica rule, indicating that the low toxicity of crystalline silica in the brick and structural clay industry does not cause a material risk of health impairment. BIA noted that OSHA has established specific requirements for certain industries in the past, such as the pulp, paper and paperboard mill industry in 29 CFR 1910.216, and the textile industry in 29 CFR 1910.262. BIA requested that OSHA take a similar approach for the brick industry because, BIA argued, silicosis is essentially non-existent in the brick industry's workers (Document ID 2300, pp. 2–4). OSHA also received comments and testimony from stakeholders in the brick, tile, and fly ash industries who argued that in their industries, crystalline silica was most commonly shrouded or occluded within matrices of aluminosilicates, and therefore the silica was less bioavailable and exhibited reduced toxicity (*e.g.,* Document ID 2085, p. 2; 2123, p. 1; 2267, p. 8; 2343, Attachment 1, p. 30; 3587, Tr. 3628; 3587, Tr. 3704).

As discussed in Section V of this preamble, *Health Effects,* OSHA has reviewed the evidence concerning potential effects on silica-related toxicity of a variety of physical factors,

including the age of fractured surfaces of the crystal particle and clay occlusion of the particle. OSHA recognizes that the risk to employees exposed to a given level of respirable crystalline silica may not be equivalent in different work environments due to differences in physical factors that affect the potency of crystalline silica. OSHA also recognizes that workers in these industries (*e.g.,* brick manufacturing) may experience lower rates of silicosis and other health effects associated with exposure to respirable crystalline silica. However, OSHA finds that these employees are still at significant risk of developing adverse health effects from exposure to respirable crystalline silica. The Agency is therefore is not excluding brick, tile, or fly ash from the scope of the rule based on physical characteristics of crystalline silica.

OSHA also received multiple studies, along with testimony and comments from the Sorptive Minerals Institute (SMI) (Document ID 2377; 4230). SMI stated that sorptive clays are limited to a specific and discreet subset of deposits in the U.S., including specifically: The Monterey formation (California), the Porters Creek formation (Mississippi Valley), the Twiggs and Meigs fullers earth (southeastern U.S.), the Wyoming or Western-type sodium bentonite deposits, the calcium bentonite deposits (north-central Florida), and the fullers earth deposits of eastern Virginia (Document ID 4230, p. 3). As discussed in Section V, Health Effects, SMI contended that silica in sorptive clays exists as either amorphous silica or as geologically ancient, occluded quartz, and that neither form poses the health risk described in OSHA's risk assessment (Document ID 4230, p. 2). After evaluation of the evidence SMI submitted to the record, OSHA finds that quartz originating from bentonite and similar sorptive clays is considerably less toxic than unoccluded quartz, and evidence does not exist that would permit the Agency to evaluate the magnitude of the lifetime risk resulting from exposure to silica in sorptive clay deposits. OSHA is therefore excluding sorptive clays from the scope of the rule, as described in paragraph (a)(1) of the general industry and maritime standard. The PEL in 29 CFR 1910.1000 Table Z–3 (*i.e.,* the formula that is approximately equivalent to 100 μg/m^3) will continue to apply to occupational exposure to respirable crystalline silica from sorptive clays. The exemption covers exposures resulting from the processing, packaging, and distribution of sorptive clays originating from the geological deposits described above (and intended for sorptive clay-specific use such as absorbents for oil, grease, and animal waste, as a carrier for pesticides and fertilizers, or in cosmetics, pharmaceuticals, and animal feeds).

Relationship to other OSHA standards. EEI and the American Iron and Steel Institute (AISI) sought clarification from OSHA regarding how the silica rule would affect the existing coke oven emissions standard or the PEL for coal dust. EEI said that OSHA should expressly exempt coal dust from the rule (Document ID 2357, p. 4). AISI similarly stated that the rule potentially conflicts with the coal dust PEL and is duplicative of existing steel industry standards. AISI stated that OSHA's existing coke oven emissions standard protects employees working in the regulated area around metallurgical coke ovens and metallurgical coke oven batteries where exposures to emissions are of greatest concern. AISI believes that workers covered by OSHA's coke oven emissions standard are therefore already protected adequately from the dangers of crystalline silica exposure and such operations should be exempt from the rule (Document ID 3492, p. 2).

The respirable crystalline silica rule has no effect upon OSHA's standard for coke oven emissions, the existing PEL for coal dust, or any other substance-specific standard. None of these requirements provide the full range of protections afforded by the respirable crystalline silica rule. The PEL for coal dust is only a PEL; it does not provide any additional protections, such as medical surveillance. Other requirements therefore do not provide protection equivalent to the respirable crystalline silica rule. Accordingly, the silica rule applies to these situations to the extent there is silica exposure and the conditions for excluding them from the rule's scope are not met.

Definitions

Paragraph (b) of the standard for general industry and maritime (paragraph (b) of the standard for construction) provides definitions of terms used in the standards.

''Action level'' means a concentration of airborne respirable crystalline silica of 25 micrograms of respirable crystalline silica per meter cubed of air (μg/m^3), calculated as an 8-hour time-weighted average. The action level triggers requirements for exposure assessment and, in the standard for general industry and maritime, medical surveillance. The definition is unchanged from the proposal.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the permissible exposure limit (PEL) on days when no exposure measurements are made. Even when all measurements on a given day fall below the PEL but are above the action level, there is a reasonable chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL (Document ID 1501). The importance of the action level is explained in greater detail in the summary and explanation of *Exposure Assessment* and summary and explanation of *Medical Surveillance*.

The action level in this rule is set at one-half of the PEL. This is the same ratio of action level to PEL that has been used and been effective in other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026).

Following the publication of the proposed rule, OSHA received a number of comments pertaining to the definition of the action level. Some commenters, such as National Council for Occupational Safety and Health (NCOSH), American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), International Brotherhood of Teamsters, United Steelworkers (USW), Center for Effective Government (CEG), American Public Health Association (APHA), American Thoracic Society (ATS), and Cara Evens, a private citizen, supported OSHA's proposal to include an action level of 25 μg/m^3 (*e.g.,* Document ID 1801, p. 2; 2173, pp. 2–3; 2175, p. 5; 2178, Attachment 1, p. 2; 2318, p. 10; 2336, p. 5; 2341, pp. 2–3; 4204, pp. 42–45, 51–52). For example, USW supported the inclusion of an action level that is half the PEL (25 μg/m^3) because:

> This action level will further reduce exposure to respirable crystalline silica by workers and will incentivize employers to implement best-practice controls keeping exposures at a minimum as well as reducing costs of monitoring and assessments. The USW believes measuring airborne concentrations of silica at 25ug/m^3 will prove feasible given current sampling techniques (Document ID 2336, p. 5).

AFL–CIO noted that action levels have long been incorporated into OSHA standards in recognition of the variability of workplace exposures and argued that the inclusion of an action level is particularly important in this

rulemaking because exposures at the PEL pose a significant risk to employees (Document ID 2256, Attachment 2, p. 9). NCOSH and CEG echoed AFL–CIO's concerns about significant risk remaining at the PEL, and NCOSH, further noted that significant risk remains at the action level (Document ID 2173, p. 2; 2341, p. 2).

As discussed in more detail in the summary and explanation of *Medical Surveillance*, some stakeholders, such as APHA, supported an action level trigger for medical surveillance in the standard for general industry because of significant risk of disease remaining at the action level and even below (Document ID 2178, Attachment 1, p. 2).

The National Institute for Occupational Safety and Health (NIOSH) supported an action level that is lower than the PEL because it is consistent with longstanding industrial hygiene practice, and an action level is included in other OSHA standards. NIOSH did not recommend a value for the action level but cited a 1975 study by NIOSH (Leidel *et al.* 1975, Document ID 1501) as demonstrating that an action level provides a high level of confidence that most daily exposures will be below the PEL (Document ID 2177, Attachment B, p. 23).

Other commenters supported having an action level, but advocated a higher level (*e.g.,* Document ID 1963, pp. 1–2; 2196, Attachment 1, pp. 1–2; 2200, pp. 1–2; 2213, p. 3; 2232, p. 1; 2233, p. 1; 2301, Attachment 1, p. 78; 2311, p. 3). For instance, the National Industrial Sand Association (NISA) recommended an action level of 50 μg/m^3, which is one half the value of the PEL they supported (100 μg/m^3). NISA recommended a higher PEL because it disagreed with OSHA that significant risk existed at the proposed PEL of 50 μg/m^3. NISA also argued that a PEL of 50 μg/m^3 would not be technologically or economically feasible. However, NISA's reasons for recommending an action level set at half of its recommended PEL mirrored many of the reasons offered by USW and AFL–CIO, including maintaining consistency with other OSHA standards, accounting for exposure variability, and providing employers with incentives to keep exposures low. In addition, NISA commented that keeping exposures well below the PEL would provide a margin of safety to protect against uncertainties in the toxicology and epidemiology data supporting a PEL (Document ID 2195, pp. 30–35). NISA also recommended that medical surveillance be triggered at the action level (although, as noted above, NISA recommended an action level of 50 μg/m^3); that recommendation is discussed in the summary and explanation of *Medical Surveillance*.

Southern Company asserted that OSHA set the proposed action level too low, because it believed it is difficult to measure based on current laboratory detection limits (Document ID 2185, pp. 5–6). It recommended that OSHA consider setting the action level at an achievable analysis level (though a suggested level for OSHA to consider was not provided) or conduct further cost analyses of additional sampling and ancillary provisions this may trigger. As stated further below, OSHA's conclusion that silica exposures can be measured with reasonable accuracy at the action level is discussed in the Sampling and Analysis discussion of technological feasibility in Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA).

Other commenters supported an action level but argued that the proposed action level was set too high. For example, the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) argued that the action level would need to be set at 12.5 μg/m^3, one-fourth of a 50 μg/m^3 PEL, in order to ensure that fewer than 5 percent of exposures would exceed a PEL of 50 μg/m^3 (Document ID 2282, Attachment 3, p. 14). In support of its recommended action level, UAW cited a study by Rappaport *et al.* (1988), which reported that no more than 12 percent of log-normally distributed exposures are expected to exceed the PEL with an action level set at one half the PEL (Document ID 2282, Attachment 2, pp. 310, 314). Similarly, the BlueGreen Alliance (BGA) supported a lower action level, indicating that the proposed action level was not protective enough. BGA supported an action level of no higher than 25 percent of the PEL ''. . . in order to provide reasonable likelihood that 95% of exposures are below the PEL'' (Document ID 2176, p. 2).

Finally, some commenters opposed having any action level (Document ID 2085, p. 3; 2296, p. 40; 2305, pp. 4, 10; 2312, p. 2; 2317, p. 2; 2327, Attachment 1, pp. 13, 15–17; 2305, pp. 4, 10; 2296, p. 40; 3577, Tr. 707–708). Mercatus Center of George Mason University (Mercatus Center) asserted that OSHA did not provide adequate justification for the proposed action level, arguing that because OSHA found a PEL of 25 μg/m^3 to be infeasible, the Agency has not shown that employers would have sufficient incentives to limit exposures to the action level (Document ID 1819, p. 2). The Fertilizer Institute indicated that the action level will create a de facto 25 μg/m^3 standard because the initial and periodic monitoring requirements will be a time-consuming, expensive endeavor (Document ID 2101, pp. 7–8). The National Concrete Masonry Association and Blue Stone Block Supermarket argued that the best approach would be to remove the action level and only ''require action when the PEL is exceeded'' (Document ID 2279, p. 9; 2384, p. 9). They believed requiring action only when their recommended PEL of 100 μg/m^3 is exceeded would be effective in reducing silica-related illnesses and more cost-effective for industries.

OSHA considered these comments and has decided to retain an action level of 25 μg/m^3. OSHA agrees with CEG and AFL–CIO that that the inclusion of an action level of 25 μg/m^3 is particularly important in this rulemaking because employees exposed at the action level and revised PEL remain at significant risk of developing respirable crystalline silica-related diseases (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk). In addition, as explained in Chapter IV of the FEA, OSHA has found that the revised PEL is technologically and economically feasible. OSHA disagrees with Mercatus Center that an action level of 25 μg/m^3 is not appropriate because that level is not feasible as a PEL, and the Agency does not agree with the Fertilizer Institute that a 25 μg/m^3 action level creates a de facto standard. The action level only triggers certain requirements (*i.e.,* a requirement for exposure assessment in general industry/maritime and construction, and medical surveillance in general industry/maritime only); employers that exceed it but remain at the PEL or below will not be in violation of the rule, so long as they comply with the requirements associated with the action level. The requirements associated with exposures at or above the action level create an incentive—but not a requirement—for employers to reduce exposures below the action level where it is reasonably possible to do so. Although OSHA could not find that engineering controls and work practices are sufficient to reduce and maintain respirable crystalline silica exposures to a level of 25 μg/m^3 or below in most operations most of the time in affected industries, it is likely possible for some employers to reduce exposures to below the action level in some circumstances, without the use of respirators. The Agency also concludes that it is feasible to measure respirable crystalline silica levels at an action level of 25 μg/m^3 with reasonable accuracy (*see* Chapter IV of the FEA). Because employers are not required to reduce

exposures below 25 μg/m³, feasibility concerns are not relevant. Consequently, OSHA does not agree with NISA and Southern Company that feasibility concerns warrant revising the proposed action level upward.

OSHA agrees, however, that maintaining exposures below an action level that is half the PEL provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. OSHA's early standards relied, in part, on a statistical basis for using an action level of one-half the PEL (*e.g.,* acrylonitrile, 29 CFR 1910.1045; ethylene oxide, 29 CFR 1910.1047). OSHA previously determined (based in part on research conducted by Leidel *et al.*, 1975) that where exposure measurements are above one-half the PEL, the employer cannot be reasonably confident that the employee is not exposed above the PEL on days when no measurements are taken (Document ID 1501, pp. 5–6, 29–30, 38). Similarly, Rappaport *et al.* (1988) used monitoring data and applied a statistical method to estimate that no more than 12 percent of lognormally-distributed exposures would be expected to exceed the PEL if mean exposures remain below an action level set at one-half the PEL (Document ID 2282, Attachment 2).

OSHA thus agrees with UAW and BGA that an action level lower than one-half of the PEL would provide a higher degree of confidence that exposures are not likely to exceed the PEL. However, OSHA's policy is to set the action level at a value that effectively encourages employers to reduce exposures below the action level while still providing reasonable assurance that employee exposures are typically below the PEL. The Agency's experience with previous standards also indicates that an action level of one-half the PEL effectively encourages employers, where feasible, to reduce exposures below the action level to avoid the added costs of required compliance with provisions triggered by the action level.

OSHA is convinced, therefore, that an action level is needed and decided to set the action level at one-half of the PEL, based on residual risk at the PEL of 50 μg/m³, the feasibility of measuring exposures at an action level of 25 μg/m³, and the administrative convenience of having the action level set at one-half the PEL, as it is in other OSHA standards. OSHA's risk assessment indicates that significant risk remains at the PEL of 50 μg/m³. OSHA therefore has a duty to impose additional requirements on employers to reduce remaining significant risk when those requirements will afford benefits to employees and are feasible (*Building and Construction Trades Department, AFL–CIO* v. *Brock*, 838 F.2d 1258, 1269 (D.C. Cir 1988)). With significant risk remaining at 50 μg/m³, reducing that risk by incorporating an action level is necessary and appropriate. OSHA concludes that the action level will result in a real and necessary further reduction in risk beyond that provided by the PEL alone.

''Competent person'' means an individual who is capable of identifying existing and foreseeable respirable crystalline silica hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The competent person must also have the knowledge and ability necessary to fulfill the responsibilities set forth in paragraph (g) of the construction standard. OSHA has not included requirements related to a competent person in the general industry and maritime standard. This definition therefore is included only in the construction standard.

In the proposal, OSHA defined competent person as one who is capable of identifying existing and predictable respirable crystalline silica hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them. OSHA received a number of comments related to this definition. Many of these commenters suggested that the definition should be expanded. For example, Building and Construction Trades Department, AFL–CIO (BCTD) recommended that OSHA revise the proposed definition to require that the competent person be capable of identifying the proper methods to control existing and predictable hazards in the surroundings or working conditions. BCTD also asked that the definition specify that the competent person be ''designated by the employer to act on the employer's behalf.'' It proposed specific language that incorporated these suggestions (Document ID 4223, p. 112). International Union of Operating Engineers (IUOE) endorsed the BCTD definition and International Union of Bricklayers and Allied Craftworkers (BAC) agreed with BCTD that OSHA's definition needed to be more fully developed (Document ID 2262, p. 40; 2329, p. 5).

The American Society of Safety Engineers (ASSE) advocated for the following definition, which it based on that of the asbestos standard:

> Competent person means, in addition to the definition in 29 CFR 1926.32(f), one who is capable of identifying existing respirable crystalline silica hazards in the workplace and selecting the appropriate control strategy for such exposure and for developing and overseeing written access control plans, who has the authority to take prompt corrective measures to eliminate such hazards, as specified in 29 CFR 1926.32(f), and who is trained in a manner consistent with OSHA requirements for training (Document ID 4201, pp. 3–4).

Finally, NIOSH noted the American National Standards Institute (ANSI) AIO.38 definition of competent person:

> One who, as a result of specific education, training, and/or experience, is capable of identifying existing and predictable hazards in the surroundings [or] working conditions that are unsanitary, hazardous or dangerous to employees, and who has the authorization and responsibility to take prompt corrective measures to eliminate them [emphasis omitted] (as cited in Document ID 2177, Attachment B, p. 9).

In determining if the proposed definition for competent person needed to be revised, OSHA considered these comments and the definition of competent person in the safety and health regulations for construction (29 CFR 1926.32(f)). Under 29 CFR 1926.32(f), competent person is defined as one capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees and who is authorized to take prompt corrective measures to eliminate them. OSHA concludes that its definition for competent person is consistent with 1926.32(f) but tailored to respirable crystalline silica by specifying ''respirable crystalline silica hazards'' instead of ''unsanitary, hazardous, or dangerous'' conditions. OSHA did make a few minor revisions to its proposed definition. The Agency replaced the word ''one'' with ''individual,'' which is merely an editorial change. The Agency removed the phrase ''in the surroundings or working conditions'' and changed it to ''in the workplace'' to make it specific to the workplace. The Agency removed the phrase ''to eliminate them'' and changed it to ''to eliminate or minimize them'' to denote there may be cases where complete elimination would not be feasible. OSHA also changed ''predicted'' to ''foreseeable'' to make the wording consistent with the scope of the standard (paragraph (a)).

OSHA agrees with ASSE and the ANSI definition highlighted by NIOSH that the definition for competent person must indicate that the competent person has appropriate training, education, or experience. Therefore, OSHA further

revised the proposed definition for competent person to indicate that the competent person must have the knowledge and ability necessary to fulfill the responsibilities set forth in paragraph (g). Comments regarding knowledge or training for a competent person and OSHA's responses to those comments are discussed in the summary and explanation of *Written Exposure Control Plan*.

The requirement that the competent person have the knowledge and ability to fulfill the responsibilities set forth in paragraph (g) addresses BCTD's and ASSE's requests to amend the definition to specify that the competent person be capable of identifying or selecting the proper methods to control hazards in the surroundings or working conditions. It is clear from paragraph (g) that the competent person must be familiar with and also capable of implementing the controls and other protections specified in the written exposure control plan.

ASSE also requested that the definition indicate that the competent person be capable of developing and overseeing the written access control plan, which OSHA had proposed. However, the final rule does not specify a written access control plan, and instead requires a written exposure control plan. Regardless, OSHA does not agree with ASSE's suggestion that the definition should be revised to indicate capability to develop a written plan. OSHA assigns that responsibility to the employer because under paragraph (g)(4), the competent person is someone on the job site who makes frequent and regular inspections, and thus may not be involved in developing the written exposure control plan in an office environment. OSHA also disagrees with BCTD that the definition should specify that the competent person is designated by the employer to act on behalf of the employer. The employer's obligation to designate a competent person is clearly specified in paragraph (g)(4) and the definition clearly states that the competent person has authority to promptly apply corrective measures.

The competent person concept has been broadly used in OSHA construction standards (*e.g.*, 29 CFR 1926.32(f) and 1926.20(b)(2)), particularly in safety standards. This standard does not affect the competent person provisions in these other standards.

''Employee exposure'' means the exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator. This definition clarifies the requirement that employee exposure must be measured as if no respiratory protection is being worn. The definition, which is consistent with OSHA's previous use of the term in other standards, did not generate any comment and is unchanged from the proposal.

''High-efficiency particulate air (HEPA) filter'' means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter. The definition is unchanged from the proposal. HEPA filters are more efficient than membrane filters because they are designed to target much smaller particles. In the housekeeping requirements of paragraph (h)(1) of the standard for general industry and maritime (paragraph (f)(1) of the standard for construction), OSHA refers to HEPA-filtered vacuuming as an example of an appropriate cleaning method, and the Table 1 entry for handheld and stand-mounted drills requires use of a HEPA-filtered vacuum (if a commercially available hole-cleaning kit connected to a dust collector is not being used). OSHA had also proposed HEPA-filtered dust collectors as controls for some tasks listed on Table 1 of the proposed standard for construction.

The Agency received one comment related to HEPA filters from the Occupational and Environmental Health Consulting Services (OEHCS). First, OEHCS recommended that the definition be expanded to indicate that HEPA filters are effective at removing particles in the 0.3-micrometer size range, as measured by a laser particle counter. Second, it requested addition of the term ''Portable High Efficiency Air Filtration (PHEAF)'' device, defined as a portable device equipped with a certified HEPA filter that, when tested as a complete unit, is 99.97 percent effective in removing particles in the 0.3-micrometer size range, as measured by a laser particle counter (Document ID 1953, pp. 4–6). OEHCS advocated for a requirement that portable filtration devices (*e.g.*, HEPA vacuums, dust collectors used on tools, and filter systems for enclosed cabs) meet the definition of PHEAF. It argued that HEPA vacuums or other portable filtration devices might not perform effectively in the field due to inadequate, damaged, or deteriorating sealing surfaces; replacement filters that do not fit correctly; filter cabinets that are damaged; or filters that are punctured. Claiming that damaged filters might not build up enough pressure differential to signal that they should be changed, OEHCS recommended a requirement for field testing the devices using a laser particle counter to ensure that HEPA filters function as intended (Document ID 1953, Attachment 1, pp. 2–4).

OSHA encourages employers to ensure that HEPA filters function in the field according to the specifications of this definition. However, the Agency concludes that it is not appropriate to include requirements for PHEAF devices, as defined by OEHCS, or laser particle counting testing, in the rule due to the lack of documented effectiveness or consistency with the definition and because of the lack of support in the record. As a result, OSHA is retaining its proposed definition for HEPA filter and is not adding PHEAF to the definitions section.

''Objective data'' means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

The proposed definition of ''objective data'' also included ''calculations based on the . . . chemical and physical properties of a substance'' as an example of a type of objective data that might demonstrate employee exposure to respirable crystalline silica. BCTD objected to this example's inclusion in the definition (Document ID 2371, Attachment 1, pp. 11–12). Although BCTD agreed that the chemical and physical properties of a substance are among the factors that may be relevant in determining whether data from one set of circumstances can be used to characterize the exposures in other circumstances, BCTD stated that the proposed definition suggested that the chemical and physical properties of the material could be determinative in every instance. It also maintained that on construction sites the work processes themselves are more consistently a significant predictor of ambient silica exposures than percentage of silica in the material itself. Finally, BCTD argued that it is very important to focus not only on the overall operation, but also the specific silica dust-generating task.

In including this item in the definition, OSHA did not intend to imply that it would be relevant in all circumstances. Nonetheless, OSHA has removed the phrase ''chemical and physical properties'' from the final definition of ''objective data'' because it has concluded that a substance's

chemical and physical properties are not typically relevant for demonstrating exposures to respirable crystalline silica. However, in those instances where a substance's physical and chemical properties demonstrate employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity, an employer may use that information as objective data under this rule.

The proposed rule also stated that objective data is information demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, operation, or activity. Throughout this rule, OSHA has often replaced the word ''operation'' with the word ''task'' (*see* summary and explanation of *Specified Exposure Control Methods* for further discussion). OSHA has made the change to ''task'' (instead of ''operation'') in this definition to remain consistent with that change. This is also consistent with NIOSH's recommendation to add specificity to the definition by including the term ''task'' (Document ID 2177, Attachment B, p. 12).

In addition, the proposal indicated that ''objective data'' needed to reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Dow Chemical Company stated that this requirement is generally appropriate, but argued that when data pertain to a more challenging work environment with higher potential for exposure, those data should be considered objective data (Document ID 2270, p. 2). It explained:

> If data from a more challenging environment demonstrate compliance with the Permissible Exposure Limit, then one may infer with confidence that workers in a less challenging environment (*i.e.*, with less potential for exposure) are also not exposed above the PEL. Even if the two work environments are not ''closely resembling,'' the data are still an objective, valid method of screening workplaces that have a clearly lower risk of exposure (Document ID 2270, p. 2).

OSHA agrees with Dow that data pertaining to an environment with higher exposure potential can be used as objective data for other environments with less potential for exposure. Therefore, OSHA added ''or with a higher exposure potential'' to the definition.

Edison Electric Institute (EEI) requested that OSHA harmonize the definition of ''objective data'' throughout its regulations (Document ID 2357, p. 22). OSHA recognizes that the term has evolved over time based on the Agency's experience implementing those standards. ''Objective data'', as defined in this standard, is based on the record in this rulemaking and reflects an appropriate definition in the context of exposures to respirable crystalline silica. Additionally, OSHA has established a process, the Standards Improvement Project, to improve and streamline OSHA standards, including the revision of individual requirements within rules that are inconsistent. OSHA will consider reviewing the consistency of this definition in the next iteration of this ongoing effort.

Many commenters suggested that OSHA add specificity with regards to what is considered objective data and establish criteria for objective data in the definition (*e.g.*, Document ID 2177, Attachment B, p. 11; 2181, p. 5; 2253, p. 4; 2256, Attachment 2, p. 10; 2339, p. 7; 2371, Attachment 1, p. 12; 2379, Appendix 1, pp. 54–55; 2380, Attachment 2, p. 26; 4223, p. 70). As discussed in the summary and explanation of *Exposure Assessment*, OSHA intends for the performance option to give employers flexibility to accurately characterize exposures using whatever processes or data are most appropriate for their circumstances. The Agency concludes it would be inconsistent to include specifications or criteria in the definition of objective data and thus has not done so here.

Commenters also provided examples of alternative exposure measurement and characterization strategies that could generate objective data, such as: area sampling (Document ID 2195, pp. 36–37); area exposure profile mapping (Document ID 2379, Appendix 1, pp. 48–49); real-time monitoring (Document ID 2256, Attachment 3, p. 12; 2357, pp. 37–38; 2379, Appendix 1, pp. 48–49, 55–56; 3578, Tr. 941–942; 3579, Tr. 161–162; 3588, Tr. 3798–3800; 4204, p. 56); and geotechnical profiling with testing for crystalline silica content (Document ID 2262, p. 13). Trolex LTD pointed to emerging methods and technologies, such as new optical methods for particle counting and identification, which might provide enhanced measurements of real-time employee exposure to respirable crystalline silica in the future (Document ID 1969, p. 2).

In addition, commenters provided specific examples of types of information and information sources that they felt should be considered objective data. For example, the American Foundry Society (AFS) commented that objective data should include data that permits reliable estimation of exposure, such as: data from real-time monitors and area exposure mapping; data from less than full-shift samples where professional judgment can be used to determine exposure levels; and exposure data where the percent of silica is calculated using a historical average for the area or operation involved (Document ID 2379, Appendix 1, pp. 54–55). The National Association of Manufacturers suggested the following as reliable sources of objective data: published scientific reports in the open scientific literature; NIOSH Health Hazard Evaluations; insurance carriers' loss prevention reports; and information that the silica in a process cannot be released because it is bound in a matrix preventing formation of respirable particles (Document ID 2380, Attachment 2, p. 26). ASSE identified industry-wide data, safety data sheets from product manufacturers, prior historical sampling data under comparable conditions, and aggregated company-wide sampling information as reliable sources of objective data (Document ID 3578, Tr. 1036). Commenters also pointed to data collected by a trade association from its members (*e.g.*, Document ID 2181, pp. 5–6, 7; 2371, Attachment 1, Appendix A; 3544, pp. 12–13; 3583, Tr. 2394; 3585, Tr. 2905–2906; 3588, Tr. 3936–3938; 4197, pp. 1–6; 4198, pp. 1–181; 4223, pp. 68–70).

The Agency, while including specific examples in the definition (*i.e.*, air monitoring data from industry-wide surveys and calculations based on the composition of a substance), does not intend to limit the information that can be considered objective data to the information from those sources. OSHA agrees that data developed with alternative exposure measurement and characterization strategies, both those currently available and those that become available in the future, and the types of information and information sources suggested by commenters can be used as objective data where the conditions of the definition are satisfied. Monitoring data obtained prior to the effective date of the rule can also be considered objective data if it demonstrates employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity and reflects workplace conditions closely resembling or with a higher exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operation.

Objective data is further discussed in the summary and explanation of *Scope*

and Application (paragraph (a)(2) for general industry and maritime) and *Exposure Assessment* (paragraph (d) for general industry and maritime standard and paragraph (d)(2) for the construction standard).

''Physician or other licensed health care professional [PLHCP]'' means an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (i) of this section (paragraph (h) of the standard for construction). This definition is unchanged from the proposal, and is included because the standard requires that all medical examinations and procedures be performed by or under the supervision of a PLHCP.

OSHA received two comments on the definition of PHLCP, both of which addressed the scope of the PHLCP's qualifications, from APHA and ATS (Document ID 2175, p. 5; 2178, Attachment 1, p. 5). ATS agreed with OSHA's determination of who is qualified to be a PLHCP (Document ID 2175, p. 5). APHA advocated that the PLHCP:

> . . . should be licensed for independent practice . . . and have training and experience in clinical and in population/preventive health, in managing and interpreting group surveillance information, and in the care and management of respiratory illness (Document ID 2178, Attachment 1, p. 5).

APHA commented that:

> . . . different members of the health team may provide different required services through referral or other arrangements, but the designated PLHCP should have responsibility for program oversight and coordination (Document ID 2178, Attachment 1, p. 5).

As discussed further in the summary and explanation of *Medical Surveillance*, OSHA agrees that different tasks may be performed by various PLHCPs, according to their licenses, but has determined that requiring a license for independent practice and the extra training and responsibilities advocated by APHA are neither necessary nor appropriate for the PLHCP in OSHA standards. Any PLHCP may perform the medical examinations and procedures required under the standard when he or she is licensed, registered, or certified by state law to do so. Who qualifies to be a PLHCP is determined on a state-by-state basis by state licensing bodies. OSHA's broad definition for PLHCP gives the employer the flexibility to retain the services of a variety of qualified licensed health care professionals. Moreover, since the term PHLCP includes more than just physicians, it addresses concerns about the limited availability of medical providers in rural areas (*e.g.*, Document ID 2116, Attachment 1, p. 43; 2365, p. 10).

OSHA has included the same definition for PLHCP in other standards and continues to find that it is appropriate to allow any individual to perform medical examinations and procedures that must be made available under the standard when he or she is appropriately licensed by state law to do so and is therefore operating under his or her legal scope of practice. PLHCP, as defined and used in this standard, is consistent with other recent OSHA standards, such as chromium (VI) (29 CFR 1910.1026), methylene chloride (29 CFR 1910.1052), and respiratory protection (29 CFR 1910.134). OSHA's experience with PLHCPs in these other standards supports the Agency's determination.

''Regulated Area'' means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL. The definition is unchanged from the proposed standard. This definition is consistent with the use of the term in other OSHA standards, including those for chromium (VI) (29 CFR 1910.1026), 1,3-butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

OSHA proposed the inclusion of regulated areas in the standards for both construction and general industry/maritime, but has not included this provision, or the associated definition, in the final standard for construction. Construction industry stakeholders should instead refer to paragraph (g)(1)(iv) for written exposure control plan requirements to describe procedures for restricting access.

Several stakeholders, including the Construction Industry Safety Coalition (CISC) and National Association of Home Builders, requested that OSHA clarify what ''reasonably expected'' means (*e.g.*, Document ID 2296, p. 25; 2319, p. 89). CISC argued that ''[s]uch subjective language is not enforceable and . . . will be fraught with compliance problems . . .'' (Document ID 2296, p. 25; 2319, p. 89).

As noted above, the language in the regulated areas definition has been included in a number of previous OSHA standards. Based on OSHA's experience with these standards, OSHA expects that employers will have little difficulty understanding the meaning of the phrase ''reasonably be expected to exceed.'' One reason OSHA chooses to utilize language that has been used in previous standards, where possible, is to avoid the sort of confusion CISC describes. In addition, the basis for establishing regulated areas in general industry and maritime and the reason for omitting this requirement in the construction standard are discussed in further detail in the summary and explanation of *Regulated Areas*.

''Respirable crystalline silica'' means quartz, cristobalite, and/or tridymite contained in airborne particles that are determined to be respirable by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling. The definition in the rule is very similar to the proposed definition with one modification. OSHA changed the wording from ''means airborne particles that contain quartz, cristobalite, and/or tridymite and whose measurement is determined by a sampling device . . .'' to ''means quartz, cristobalite, and/or tridymite contained in airborne particles that are determined to be respirable by a sampling device . . .'' to make it clear that only that portion of the particles that is composed of quartz, cristobalite, and/or tridymite is considered to be respirable crystalline silica.

The definition for respirable crystalline silica encompasses the forms of silica (*i.e.*, quartz, cristobalite, and tridymite) covered under current OSHA standards and harmonizes the Agency's practice with current aerosol science and the international consensus that the ISO convention represents. The American Conference of Governmental Industrial Hygienists (ACGIH) and the European Committee for Standardization (CEN) have adopted the ISO criteria for respirable particulate collection efficiency, and the criteria are sometimes referred to as the ISO/CEN definition. NIOSH has also adopted the ISO definition in its Manual of Sampling and Analytical Methods (Document ID 0903, p. 2). Adoption of this definition by OSHA allows for workplace sampling for respirable crystalline silica exposures to be conducted using any particulate sampling device that conforms to the ISO criteria (*i.e.*, a device that collects dust according to the particle collection efficiency curve specified in the ISO standard). The relationship between the ISO criteria for respirable particulate collection efficiency and the ACGIH criteria is discussed in greater detail in

the Sampling and Analysis discussion in Chapter IV of the FEA.

The U.S. Chamber of Commerce (the Chamber), Halliburton, and the National Rural Electric Cooperative Association (NRECA) asserted that OSHA's proposed definition of respirable crystalline silica would encompass non-respirable particles (Document ID 2288, p. 15; 2302, p. 7; 2365, p. 12). NRECA stated:

> . . . the proposed definition would include anything that gets collected onto the sampling media from respirable-particle size-selective samplers. Unfortunately, these samplers are not fool-proof and often much larger sized particles do make their way into the sampling media; that is, they collect total crystalline silica dusts rather than just the respirable portions. This definition will include all total dusts that make their way through the cyclone and into the sampling media, thus suggesting a much larger exposure than is otherwise the case . . . (Document ID 2365, p. 12).

As indicated in the discussion of the feasibility of measuring respirable crystalline silica exposures in Chapter IV of the FEA, there is currently no sampling device that precisely matches the ISO criteria in capturing respirable dust. However, available research indicates that many existing devices can achieve good agreement with the ISO criteria. When operated correctly, the sampling devices do not collect total dusts; they collect only the respirable fraction.

The Chamber and NRECA also argued that OSHA's proposed definition of respirable crystalline silica would include substances other than crystalline silica (Document ID 2288, p. 15; 2365, p. 12; 3578, Tr. 1138). NRECA stated:

> An additional concern with the definition is that it states ''any particles that contain quartz, cristobalite, and/or tridymite . . .'' It is possible to interpret this portion of the definition to mean that any other mineral/impurities that were able to be collected into the sampling media will be counted/weighed as opposed to just the silica portions . . . (Document ID 2365, p. 12).

In addition, American Industrial Hygiene Association (AIHA) indicated that the proposed definition would include the entirety of a sample of dust containing any miniscule but detectable quantity of quartz, cristobalite or tridymite, and recommended revising the definition (Document ID 2169, pp. 2–3).

OSHA recognizes that the proposed definition could have been misunderstood to encompass components of respirable dust particles other than quartz, cristobalite, and tridymite. This was not the Agency's intent, and, in response to these comments, OSHA has revised the definition to clarify that only the portion of the particles composed of quartz, cristobalite, or tridymite is considered to be included in the definition of respirable crystalline silica.

Ameren Corporation supported OSHA's inclusion of quartz and cristobalite and allowing the use of a sampling device designed to meet the characteristics for respirable particle size-selective samplers specified in ISO 7708:1995 in the definition, but indicated that the definition should be limited to a ''percentage of 1% or greater'' (Document ID 2315, p. 3). However, it did not provide a rationale for why OSHA should include this in the definition. Including such a limitation in the definition of respirable crystalline silica would have the effect of limiting coverage of the rule to situations where crystalline silica concentrations in a mixture exceed the 1 percent threshold. As discussed in the summary and explanation of *Scope and Application*, OSHA concludes that it is not appropriate to limit coverage of the rule to situations where concentrations of crystalline silica in a mixture exceed a 1 percent threshold.

The Society for Protective Coatings (SSPC) and the National Automobile Dealers Association recommended that OSHA distinguish between amorphous silica and crystalline silica in the definition (Document ID 2120, p. 2; 2358, p. 5). SSPC also provided a link to a Web page (*http://www.crystallinesilica.eu/content/what-respirable-crystalline-silica-rcs*) to guide the Agency on revising the definition. OSHA finds that the term ''crystalline'' is sufficiently descriptive and does not merit further explanation in the definition. However, the Agency affirms here that fused quartz and other forms of amorphous silica are not considered crystalline silica under the rule.

The SEFA Group (formerly the Southeastern Fly Ash Company) suggested adding a definition for ''free respirable crystalline silica'' to describe crystalline silica as an independent structure with varying surface chemistry, as distinguished from crystalline silica that is incorporated into a larger matrix of the parent mineral (Document ID 2123, p. 2). OSHA has revised the definition to clarify that respirable crystalline silica includes only the crystalline silica contained in airborne particles, *i.e.*, the component in dust that is crystalline silica and not some other mineral. The Agency does not agree that defining the term ''free respirable crystalline silica'' will alter the meaning or enhance the clarity of the rule, and has not added this term.

''Specialist'' means an American Board Certified Specialist in Pulmonary Disease or an American Board Certified Specialist in Occupational Medicine. The term is used in paragraph (i) of the standard for general industry and maritime, (paragraph (h) of the standard for construction), which sets forth requirements for medical surveillance. For example, paragraph (i)(7)(i) of the standard for general industry and maritime, (paragraph (h)(7)(i) of the standard for construction) requires that the employer make available a medical examination when specialist referral is indicated in the PLHCP's written medical opinion for the employer.

The proposed rule did not include this term in the Definitions paragraph because it only allowed referral to an American Board Certified Specialist in Pulmonary disease, which was clearly addressed in the *Medical Surveillance* paragraph of the rule. However, several commenters recommended that OSHA expand the types of specialists to whom employees could be referred. For example, Dow Chemical requested that OSHA not require the pulmonary specialist to be board certified to expand availability of specialists and noted that several OSHA standards, such as benzene and 1,3-butadiene, do not require the specialist to be board certified (Document ID 2270, pp. 5–8). The Glass Association of America, Asphalt Roofing Manufacturers Association, North American Insulation Manufacturers Association, ATS, and BCTD requested that OSHA also allow referral to an occupational medicine specialist, with many of them specifying a board certified occupational medicine specialist (Document ID 2215, p. 9; 2291, p. 26; 2348, Attachment 1, p. 40; 3577, Tr. 778; 4223, p. 129).

OSHA is retaining the requirement for board certification to ensure a high level of competency. However, OSHA is persuaded by comments and testimony that individuals who are either American Board Certified in Occupational Medicine or American Board Certified in Pulmonary Disease are recognized specialists qualified to examine patients referred for possible respirable crystalline silica-related diseases. OSHA concludes that both pulmonary disease and occupational medicine specialists are qualified to counsel employees regarding work practices and personal habits that could affect their respiratory health, consistent with recommendations in Section 4.7.2 in ASTM standards E 1132–06, Standard Practice for Health Requirements Relating to Occupational

Exposure to Respirable Crystalline Silica and E 2626–09, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities (Document ID 1466, p. 5; 1504, p. 5). OSHA therefore added the definition to allow referrals to providers who are American Board certified in pulmonary disease or occupational medicine. The addition of the term to definitions also allows OSHA to simply refer to ''specialist'' when referring to American Board certified pulmonary disease and occupational medicine specialists in the medical surveillance paragraph of the rule.

''Assistant Secretary,'' ''Director,'' and ''This section'' are also defined terms. The definitions are consistent with OSHA's previous use of these terms in other health standards and have not changed since the proposal, which elicited no comments.

Finally, stakeholders suggested that OSHA define a number of new terms, including: ''affected employee'' (American Iron and Steel Institute (AISI) (Document ID 2261, p. 4)), ''aged silica'' (the Sorptive Minerals Institute (Document ID 3587, Tr. 3698–3699)), ''asphalt milling'' (IUOE (Document ID 2262, pp. 23–24)), ''chest radiograph'' (NIOSH (Document ID 2177, Comment B, pp. 40–41)), ''controlling employer'' (BAC and BCTD (Document ID 2329, p. 7; 2371, pp. 38–40)), ''each employee'' or ''each affected employee'' (AISI (Document ID 3492, p. 3)), ''earth moving'' (IUOE (Document ID 2262, pp. 6–9, 15)), ''earth moving equipment'' (IUOE (Document ID 3583, Tr. 2356–2360; 2262, pp. 6–9, 15)), ''estimating respirable dust, excessive'' (Industrial Hygiene Specialty Resources (Document ID 2285, p. 7)), ''gross contamination'' or ''grossly contaminated'' (ORCHSE, AFS, and NAHB (Document ID 2277, p. 4; 3584, Tr. 2669–2671; 3487, pp. 21–22; 2296, p. 29; 2379, Attachment B, p. 32)), ''grossly'' (Tile Council of North America (Document ID 2363, p. 6)), ''intermittent work'' (EEI (Document ID 2357, p. 14)), ''respirable dust'' (AFS (Document ID 2379, Attachment B, pp. 16, 28)), ''safety and health professional technician'' (Dr. Bird of the Chamber (Document ID 3578, Tr. 1176–1177)), ''short duration'' (EEI (Document ID 2357, p. 14)), and ''silica exposure'' (AIHA (Document ID 2169, p. 5)).

OSHA has concluded that these terms do not need to be defined in the rule. Many of the terms were part of the proposal or were included in stakeholder's comments on the proposal, but do not appear in the rule. For example, the proposed rule contained a provision related to protective work clothing in regulated areas that would have been triggered where there is potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica. As discussed in summary and explanation of *Regulated Areas*, OSHA has not included a requirement for employers to provide protective work clothing or other means of removing silica dust from clothing in the rule, and the rule does not otherwise use the terms ''grossly,'' ''gross contamination,'' or ''grossly contaminated.'' Therefore, there is no reason to define these terms.

OSHA concludes that many of the other terms that stakeholders asked the Agency to define are sufficiently explained in the preamble or their meanings are clear. For example, OSHA explains the term ''affected employee'' in the summary and explanation of *Exposure Assessment.* Because the term only appears in paragraphs (d)(6) and (7) of the standard for general industry and maritime (paragraphs (d)(2)(vi) and (vii) for construction) and is thoroughly explained in the summary and explanation, OSHA concludes that it need not be defined in this section.

Specified Exposure Control Methods. OSHA's standard requires employers engaged in construction to control their employees' exposure to respirable crystalline silica. Paragraph (c) of the standard for construction describes the specified exposure control methods approach. This approach includes ''Table 1: Specified Exposure Control Methods When Working With Materials Containing Crystalline Silica,'' a table identifying common construction tasks known to generate high exposures to respirable crystalline silica and specifying appropriate and effective engineering controls, work practices, and respiratory protection for each identified task. For each employee engaged in a task identified on Table 1, the employer is required to fully and properly implement the engineering controls, work practices, and respiratory protection specified for the task on Table 1, unless the employer assesses and limits the exposure of the employee to respirable crystalline silica in accordance with paragraph (d) of the standard for construction. If the employer fully and properly implements the engineering controls, work practices, and respiratory protection specified for each employee engaged in a task identified on Table 1, the employer is not required to conduct exposure assessments or otherwise comply with a PEL for those employees. If the employer does not follow Table 1 for employees engaged in identified tasks or if the respirable crystalline silica-generating task is not identified on Table 1, the employer must assess and limit the exposure of employees in accordance with paragraph (d) of the standard for construction. Paragraph (d) of the standard for construction imposes requirements similar to OSHA's traditional approach of requiring employers to demonstrate compliance with a PEL through required exposure assessments and controlling employee exposures through the use of feasible engineering controls and work practices (*i.e.*, the hierarchy of controls) (*see* the summary and explanation of *Alternative Exposure Control Methods* for further discussion of this approach).

The concept for the specified exposure control methods approach was included in the proposed rule. OSHA also included a version of Table 1 in the proposed rule for construction employers, identifying specific engineering controls, work practices, and respiratory protection for common construction tasks that employers could use to meet the requirement to implement engineering and work practice controls. Employers fully implementing the engineering controls, work practices, and respiratory protection on Table 1 would not have been required to conduct exposure assessments for employees performing a listed task, but would have been required to comply with the 50 $\mu g/m^3$ PEL for those employees. For tasks where respirator use was to be required, employees were presumed to be exposed above the PEL, and thus the proposed standard would have required the employer to comply with all provisions that would be triggered by exposure above the PEL (*e.g.*, regulated areas, medical surveillance), except for exposure monitoring.

Prior to the NPRM, OSHA included this alternative compliance approach in the Preliminary Initial Regulatory Flexibility Analysis (PIRFA) provided to small business representatives during the Small Business Regulatory Enforcement Fairness Act (SBREFA) process (Document ID 0938, pp. 16–17). Participants in the SBREFA process generally supported the approach and their comments further informed the Agency in developing the proposed rule (Document ID 0937, pp. 37–39). An alternative compliance approach similar to that developed by OSHA for the SBREFA process was also included in ASTM E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, a consensus standard issued in May

2009 developed by a committee consisting of both labor and industry representatives for crystalline silica exposures in construction (Document ID 1504). Following this, on December 10, 2009, the Advisory Committee on Construction Safety and Health (ACCSH) recommended that OSHA include the specified exposure control methods approach in its proposed rule (Document ID 1500, p. 13).

The approach of specifying a list of tasks with a corresponding list of controls to simplify compliance in the construction industry received wide support from representatives in government, including the National Institute for Occupational Safety and Health (NIOSH); professional organizations, including the American Industrial Hygiene Association (AIHA) and the American Society of Safety Engineers (ASSE); labor, including the International Union of Operating Engineers (IUOE), the Building and Construction Trades Department of the AFL–CIO (BCTD), the Laborers' Health and Safety Fund of North America (LHSFNA), and the International Union of Bricklayers and Allied Craftworkers (BAC); and industry groups, including the Associated General Contractors of New York State, the Edison Electric Institute (EEI), and the National Asphalt Pavement Association (NAPA) (*e.g.*, Document ID 2177, Attachment B, p. 23; 3578, Tr. 1028; 2339, p. 8; 3583, Tr. 2337–2338; 2371, Attachment 1, p. 22–23; 3589, Tr. 4192–4193; 2329, pp. 5–6; 2145, pp. 4–5; 3583, Tr. 2171; 2357, p. 26). Walter Jones, an industrial hygienist representing LHSFNA, testified that the approach ''not only makes compliance . . . easier to determine, enforce, and teach, it also assures acceptable levels of healthfulness'' (Document ID 3589, Tr. 4193).

Industry trade associations, such as the Construction Industry Safety Coalition (CISC), Leading Builders of America (LBA), the Mechanical Contractors Association of America, and individual construction employers, including Atlantic Concrete Cutting, Inc. and Holes Incorporated, generally supported the overall approach while being critical of the specifics of Table 1 (*e.g.*, Document ID 4217, p. 20; 2367, p. 2; 2338, p. 3; 2269, pp. 21–22; 2143, pp. 2–3). CISC stated that its group of employers ''continues to be appreciative of OSHA's efforts to try to make a simple compliance option . . . for construction employers'' (Document ID 4217, p. 20).

One commenter, Francisco Trujillo, safety director for Miller and Long, Inc., suggested that the specified exposure control methods approach to compliance in the construction industry is not a substitute for safety professionals and industrial hygienists conducting exposure assessments and selecting the appropriate engineering controls, work practices, and respiratory protection for each task based on the results. He commented that ''[t]he implication that if Table 1 is followed everything will be fine is unrealistic . . .'' and recommended that Table 1 be at most non-mandatory guidance (Document ID 2345, p. 4).

OSHA agrees that safety professionals and industrial hygienists play a key role in ensuring the safety of employees exposed to silica during certain activities, including those not listed on Table 1, and can also help ensure that the engineering controls, work practices, and respiratory protection specified on Table 1 are fully and properly implemented. However, as discussed below, the Agency is not persuaded that construction employees will always be better protected by the traditional performance approach of establishing a PEL and requiring periodic exposure assessments, particularly when the tasks and tools that cause high exposures to respirable crystalline silica, and the dust control technologies available to address such exposures, can be readily identified.

Although there was general agreement among commenters that an alternative approach was needed to simplify compliance for the construction industry, commenters provided various opinions on how such an alternative compliance approach should be structured to ensure that it was workable in practice. Several commenters, including BCTD, LHSFNA, EEI, LBA, Fann Contracting, Inc., CISC, ASSE, the National Association of Home Builders (NAHB), the Associated Builders and Contractors (ABC), and Holes Incorporated, urged OSHA to exempt employers complying with Table 1 from also complying with the PEL (*e.g.*, Document ID 2371, Attachment 1, p. 26; 4223, p. 92–94; 4207, p. 3; 2357, p. 26; 2269, pp. 21–22; 2116, Attachment 1, p. 29; 2319, pp. 123–124; 2339, pp. 8–9; 2296, p. 41; 2289, p. 7; 3580, Tr. 1364). Holes Incorporated and ABC suggested that employers would not use an approach that required compliance with both the PEL and specified engineering controls (Document ID 3580, Tr. 1364; 2289, p. 7). The National Utility Contractors Association (NUCA) argued that not linking the actions on Table 1 directly to compliance with the regulation was confusing and would make it difficult for contactors to be certain they are in compliance (Document ID 2171, p. 2). ASSE suggested that Table 1 should constitute compliance with the PEL because the listed controls ''can be viewed as akin to implementing all technologically feasible controls'' (Document ID 2339, pp. 8–9). BCTD commented that the focus of OSHA's enforcement efforts should be on ensuring that employers have fully and properly implemented the controls listed on Table 1 (Document ID 2371, Attachment 1, p. 26).

Similarly, commenters from both industry and labor, including the American Federation of State, County, and Municipal Employees, Mechanical Contractors Association of America, the American Federation of Labor and Congress of Industrial Organizations, BAC, BCTD, and LHSFNA, also argued that exposure assessments should not be required where employers implement control measures specified on Table 1 for construction tasks (*e.g.*, Document ID 2106, p. 3; 2143, pp. 2–3; 2256, Attachment 2, p. 10; 2329, pp. 5–6; 2371, Attachment 1, pp. 6–7; 4207, p. 2). LHSFNA stated that:

> . . . air monitoring is less practical in construction, where the jobsite and work is constantly changing, than in general industry where work exposures are more stable. In construction, air monitoring results often come back from the lab after the task has ended and thus are of little value . . . (Document ID 2253, p. 2).

On the other hand, other commenters, including NIOSH, argued that fully implementing the controls described on Table 1 would not automatically provide a sufficient level of confidence that exposures are adequately controlled; employers would also need to ensure that the exposures of employees performing Table 1 tasks would not exceed the revised PEL (*e.g.*, Document ID 2177, Attachment B, p. 17). Mr. Trujillo's comment emphasizing the role of safety professionals and recommending that Table 1 be at most non-mandatory guidance was to the same effect (Document ID 2345, p. 4).

Several commenters, including Fann Contracting, IUOE, LBA, CISC, Charles Gordon, a retired occupational safety and health attorney, Arch Masonry, Inc., and NUCA argued that as proposed, the alternative compliance option would not necessarily simplify compliance for some employers, as they would still need to do exposure assessments for a variety of reasons, such as monitoring employees working in the vicinity of Table 1 tasks, complying with the PEL, providing monitoring data to controlling employers on multi-employer worksites, and complying with the rule for tasks

that are not listed on Table 1 (Document ID 2116, Attachment 1, p. 3; 2262, pp. 44–45; 2269, pp. 21–22; 2319, p. 6; 3538, p. 16; 3580, Tr. 1473–1474; 3587, Tr. 3677–3679; 3583, Tr. 2243).

Other commenters supported the inclusion of exposure assessment requirements for employees performing tasks on Table 1 even where employers implement the specified engineering controls, work practices, and respiratory protection to best protect employees in the construction industry. The Center for Progressive Reform commented that:

> [t]he same principles that weigh in favor of a requirement to monitor silica exposure in other industries holds for the construction industry—monitoring gives workers, employers, OSHA, and researchers valuable information that can be used to reduce workplace hazards (Document ID 2351, p. 11).

The International Safety Equipment Association (ISEA) opined that the most protective approach for employees is for employers to take air samples of respirable crystalline silica (Document ID 2212, p. 1). AIHA argued that there remained a need for exposure monitoring to verify that the controls in place for Table 1 tasks actually reduce exposures (Document ID 2169, p. 3). NIOSH recommended periodic exposure monitoring requirements for these tasks to provide a sufficient level of confidence that exposures are adequately controlled and that the employers' selection of equipment, maintenance practices, and employee training were effective (Document ID 2177, Attachment B, pp. 17, 26). Charles Gordon proposed that when performing a Table 1 task, employers should be required to semi-annually monitor each task and keep records of that monitoring to ensure that workers are not exposed to high levels of respirable crystalline silica (Document ID 3539; 3588, Tr. 3801).

After reviewing the comments on this issue, OSHA concludes that the best approach for protecting employees exposed to respirable crystalline silica in the construction industry is to provide a set of effective, easy to understand, and readily implemented controls for the common equipment and tasks that are the predominant sources of exposure to respirable crystalline silica. OSHA is persuaded by comments and data in the record that requiring specific engineering controls, work practices, and respiratory protection for construction tasks, in lieu of a performance-oriented approach involving a PEL and exposure assessment, is justified for several reasons so long as employers fully and properly implement the engineering controls, work practices, and respiratory protection specified on Table 1.

First, the controls listed on Table 1 represent the feasible controls identified in the record for each listed task, and there is substantial evidence that demonstrates that, for most of the Table 1 tasks, exposure to respirable crystalline silica can be consistently controlled below 50 μg/m^3 using those controls (*see* Chapter IV of the Final Economic and Regulatory Flexibility Analysis (FEA)). As such, Table 1 provides a less burdensome means of achieving protection at least equivalent to that provided by the alternative exposure control methods that include the 50 μg/m^3 PEL, which OSHA has determined to be the lowest feasible exposure level that could be achieved most of the time for most of the tasks listed on Table 1. For example, as discussed in Section 5.7 of Chapter IV of the FEA, exposure data demonstrates that the engineering controls and work practices specified on Table 1 for stationary masonry saws (wet cutting) significantly reduce employees' exposures to respirable crystalline silica from a mean of 329 μg/m^3, when cutting masonry dry, to a mean of 41 μg/m^3. Additionally, the record developed during the rulemaking process has contributed greatly to the Agency's understanding of the effectiveness of the prescribed controls. Based on the record, OSHA is confident that exposures will be adequately controlled using the specified methods supplemented with appropriate respiratory protection for those few tasks that are very difficult to control using engineering controls and work practices alone.

Second, this approach recognizes and avoids the challenges of characterizing employee exposures to crystalline silica accurately in many construction tasks while also ensuring that employees are protected. In manufacturing settings and other more stable environments subject to the general industry standard, exposure assessment can provide an accurate depiction of the silica exposure that could be typically expected for employees in normal operating conditions. In general, such assessments need not be repeated frequently, costs are therefore minimized, and the results will be timely even if there is a delay for lab processing. In contrast, the frequent changes in workplace conditions that are common in construction work (*e.g.*, environment, location), along with potential time-lags in the exposure assessment process, provide a compelling argument for the specified exposure control methods approach that emphasizes clear and timely guidance capable of protecting the employees during their shifts instead of relying on a minimum exposure assessment requirement to characterize employee exposures.

Third, requiring employers to implement specified dust controls absent an additional PEL requirement simplifies compliance for employers who fully and properly implement the engineering controls, work practices, and respiratory protection listed on Table 1. Simplifying compliance will also encourage employers performing tasks listed on Table 1 to use this approach, rather than the alternative of performing exposure assessments and implementing dust controls, as required by paragraph (d) of the standard for construction, and thus, will also reduce regulatory burden on construction employers of all sizes. For this reason, OSHA expects that the vast majority of construction employers will choose to follow Table 1 for all Table 1 tasks.

Fourth, this approach will also create greater awareness of appropriate controls, which may in turn facilitate better implementation and compliance, by making it far easier for employees to understand what controls are effective for a given task and what controls the employer must provide. Employees can locate the task they are performing on Table 1 and immediately see what controls are required, along with any specifications for those controls. It will, further, be clear if an employer is not providing the correct controls or ensuring that they are being used appropriately.

''Fully and properly'' implementing the specified exposure control methods. In order for employers to comply with paragraph (c) of the standard for construction, they must ''fully and properly'' implement the engineering controls, work practices, and respiratory protection for each employee engaged in a task identified on Table 1. While several commenters, including BAC and BCTD, supported this requirement (*e.g.*, Document ID 2329, p. 6; 2371, Attachment 1, p. 24), BCTD also urged OSHA to clarify the meaning of ''fully and properly'' implementing the specified engineering controls and work practices on Table 1 to ensure that employers know what is required of them and how the standard will be enforced (Document ID 4223, p. 92; 2371, Attachment 1, p. 27–29).

Other commenters provided suggestions for what they believed should be considered ''fully and properly implementing'' the controls specified on Table 1. NIOSH recommended that OSHA provide checklists and require a daily evaluation

of engineering controls to determine if the controls are performing as designed and to ensure that employees using the controls are trained and have the appropriate materials to operate the controls properly (Document ID 2177, Attachment B, pp. 21–22). IUOE recommended that regular inspections of engineering controls in enclosed cabs should be required (Document ID 2262, p. 29). Anthony Bodway, Special Projects Manager at Payne & Dolan, Inc., representing NAPA, testified that his paving company uses a daily maintenance checklist to ensure that the controls are functioning properly and meeting the standards set by the equipment manufacturers (Document ID 3583, Tr. 2194–2197). AIHA suggested that OSHA require employers to follow the manufacturer's user instructions for installation, use, and maintenance of engineering controls, unless there is a written variance from the manufacturer (Document ID 2169, p. 5). Charles Gordon argued that OSHA should require a competent person to evaluate the use of the controls specified on Table 1 initially and periodically in order to ensure that they are fully and properly implemented (Document ID 4236, p. 4). In general disagreement with these comments, the National Stone, Sand, and Gravel Association (NSSGA) argued that, while employers should conduct routine maintenance of the controls, OSHA should not require an employer to complete an evaluation or inspection checklist of controls or work practices at a certain frequency (Document ID 2327, Attachment 1, p. 21).

Although the specified exposure control methods approach affords compliance flexibility for the employer, OSHA sees value in reminding employers and employees that this option will only be protective if they take steps to ensure that the engineering controls, work practices, and respiratory protection are as effective as possible. Thus, the Agency is requiring employers to fully and properly implement the specified engineering controls, work practices, and respiratory protection for each employee performing a task described on Table 1 in order to be in compliance with paragraph (c)(1) of the standard for construction. To do otherwise would undermine the entire basis for this compliance approach.

Merely having the specified controls present is not sufficient to constitute ''fully and properly'' implementing those controls. Employees will not be protected from exposure to respirable crystalline silica if the specified engineering controls, work practices, and respiratory protection are not also implemented effectively. In order to be in compliance with paragraph (c)(1) of the standard for construction, employers are required to ensure that the controls are present and maintained and that employees understand the proper use of those controls and use them accordingly.

While OSHA has decided not to further define ''fully and properly'' by providing specific checklists for employers or requiring employers to conduct inspections at set intervals, there are several readily identifiable indicators that dust controls are or are not being fully and properly implemented, many of which are discussed with regard to specific equipment and tasks in Chapter IV of the FEA and in the discussions of specific controls that appear further below in the section. For example, for dust collection systems, the shroud or cowling must be intact and installed in accordance with the manufacturer's instructions; the hose connecting the tool to the vacuum must be intact and without kinks or tight bends that would prevent the vacuum from providing the air flow recommended by the tool manufacturer; the filter(s) on the vacuum must be cleaned or changed as frequently as necessary in order to ensure they remain effective (it may be necessary to activate a back-pulse filter cleaning mechanism several times during the course of a shift); and dust collection bags must be emptied as frequently as necessary to avoid overfilling, which would inhibit the vacuum system from operating effectively. For water-based dust suppression systems, an adequate supply of water for dust suppression must be available on site. For worksites without access to a water main, a portable water tank or water truck having enough water for the task must be provided. The spray nozzles must be working properly to produce a spray pattern that applies water at the point of dust generation and inspected at regular intervals to ensure they are not clogged or damaged. All hoses and connections must be inspected as necessary for leaks that could signal that an inadequate flow rate is being delivered.

Manufacturer's instructions can also provide information about how to fully and properly implement and maintain controls. For example, the operator's instruction manual for EDCO concrete/asphalt saws provides a pre-start checklist that includes information about the proper functioning of wet-cutting equipment (Document ID 1676, p. 5). In some cases, industry associations and employers, in collaboration with equipment manufacturers, have also developed best practices with regard to the full and proper implementation of engineering controls, work practices, and respiratory protection for their particular industry or operation. For example, NAPA and the Association of Equipment Manufacturers (AEM) provided operational guidance for water systems during milling operations that includes pre-operation inspection activities, preparations for safe operation, and other operation considerations (Document ID 2181, p. 52).

In addition, paragraph (g) of the standard for construction requires employers to establish and implement a written exposure control plan, which includes provisions for a competent person to make frequent and regular inspection of job sites, materials, and equipment in order to implement the plan (*see* the summary and explanation of *Written Exposure Control Plan* for discussion about this requirement). Thus, the requirement for a written exposure control plan and the competent person, which was added to the final standard for construction, provides additional safeguards for ensuring that employers fully and properly implement Table 1.

OSHA expects that in most instances it will be straightforward for a designated competent person to identify whether the controls have been fully and properly implemented. For example, a significant amount of visible dust being frequently or continuously emitted from the material being worked on can serve as an indication that controls are not fully and properly implemented. A small amount of dust can be expected even with new equipment that is operating as intended by the manufacturer. The amount of visible dust associated with the new dust controls should be noted when equipment is put into service and checked periodically. A noticeable increase in dust emissions would indicate that the dust control system is not operating as intended.

Employees engaged in Table 1 tasks. Commenters expressed concerns about the lack of requirements in the proposed rule to protect employees assisting with Table 1 tasks or working in the vicinity of others engaged in Table 1 tasks (*e.g.*, Document ID 2116, Attachment 1, pp. 2–3). In response, OSHA has clarified the language in paragraph (c)(1) of the standard for construction to encompass all employees ''engaged in a task identified on Table 1.'' This phrasing is intended to include not only the equipment operator, but also laborers and other employees who are assisting with the task or have some

responsibility for the completion of the task, even if they are not directly operating the equipment. For example, where an employee is assisting another employee operating a walk-behind saw indoors by guiding the saw and making sure that the cutting is precise, that employee would be considered to be engaged in the task and would need to wear a respirator. Similarly, employees assisting a jackhammer task would be considered to be engaged in the task and would also be required to wear a respirator if they engaged in the task outdoors for more than four hours in a work shift.

It is not OSHA's intent, however, for all employees who are in the vicinity of a listed task to be considered ''engaged in the task.'' To protect the other employees in the vicinity of a listed task, the employer must account for the potential exposures of these employees to respirable crystalline silica as part of its written exposure control plan. As discussed in the summary and explanation of *Written Exposure Control Plan*, paragraph (g)(1)(iv) of the standard for construction requires a description of the procedures used to restrict access to work areas, when necessary, to limit the number of employees exposed and their exposure levels. Employers must develop procedures to restrict or limit access when employees in the vicinity of silica-generating tasks are exposed to excessive respirable crystalline silica levels. Such a situation might occur in a variety of circumstances, including when an employee who is not engaged in the task, but is working in the vicinity of another employee performing a Table 1 task requiring respiratory protection, is exposed to clearly visible dust emissions (*e.g.*, an employee directing traffic around another employee jackhammering for more than four hours in a shift). In that case, the competent person, as required under paragraph (g)(4) of the standard for construction, would assess the situation in accordance with the employer's procedures to determine if it presents a recognized hazard, and if it does, take immediate and effective steps to protect employees by implementing the procedures described in the written exposure control plan. For the above example, this could include positioning the employee directing traffic at a safe distance upwind from the dust-generating activity.

Table 1. As discussed above, paragraph (c)(1) of the standard for construction includes ''Table 1: Specified Exposure Control Methods When Working With Materials Containing Crystalline Silica,'' which identifies 18 common construction equipment/tasks known to generate high exposures to respirable crystalline silica. For each equipment/task identified, Table 1 specifies appropriate and effective engineering and work practice control methods. Some entries contain multiple engineering controls and work practices. In those instances, OSHA has determined that the specified combination of engineering controls and work practices is necessary for reducing exposures and requires employers to implement all of the listed engineering controls and work practices in order to be in compliance. Some entries contain multiple compliance options denoted with an ''OR'' (*e.g.*, (c)(1)(ix), (c)(1)(x), (c)(1)(xii), (c)(1)(xiii), (c)(1)(xv), and (c)(1)(xviii) of the standard for construction). For those entries, OSHA has determined that more than one control strategy could effectively reduce exposures and permits the employer to decide which option could be best implemented on the worksite. Table 1 also specifies respiratory protection for those entries where OSHA has determined from its analysis of technological feasibility it is needed to ensure employees are protected from exposures to respirable crystalline silica. These respirator requirements are divided by task duration (*i.e.*, ''less than or equal to four-hours-per-shift'' and ''greater than four-hours-per-shift'').

Table 1 in the final standard differs from Table 1 in the proposed standard in a number of respects. As proposed, ''Table 1—Exposure Control Methods for Selected Construction Operations,'' listed 13 construction operations that expose employees to respirable crystalline silica, as well as control strategies and respiratory protection that reduce those exposures. In developing Table 1 for the proposed standard, OSHA reviewed the industrial hygiene literature across the full range of construction activities and focused on tasks where silica-containing materials were most likely to be fractured or abraded and where control measures existed to offer protection against a variety of working conditions. OSHA also included additional specifications on proposed Table 1 to ensure that the strategies listed were properly implemented and remained effective.

Table 1 was the subject of many comments in the rulemaking record. Commenters, such as BCTD, urged OSHA to reconsider its use of the proposed term ''operation'' to describe the activities listed on Table 1 (Document ID 2371, Attachment 1, p. 23). Kellie Vazquez, on behalf of Holes Incorporated and CISC, suggested that it would be helpful to include more specifically-defined tasks, rather than broader operations (Document ID 2320, pp. 8–9). In the same vein, BCTD suggested that OSHA ''revise [Table 1] to make clear that its focus is on particular silica dust-generating *tasks*, not more broadly-defined *operations*'' as ''there is an important distinction between specific tasks that may generate silica dust and the employer's overall operation, which may include different silica dust-generating tasks, requiring different controls'' (Document ID 2371, Attachment 1, p. 23). BCTD also recommended that, to avoid confusion, Table 1 should specify that each task is being performed on or with a material that contains silica (Document ID 2371, Attachment 1, p. 24). Responding to both suggestions, OSHA has changed the terminology used in Table 1 from ''Operation'' to ''Equipment/Task'' to clarify that the controls apply to silica-generating activities done by employees and silica exposure generated by equipment, and has revised the title of Table 1 accordingly to ''Specified Exposure Control Methods When Working with Materials Containing Crystalline Silica.''

Other commenters requested that OSHA include additional activities on Table 1. The Sheet Metal Air Conditioning Contractors National Association (SMACNA) commented that using powder-actuated tools should be added (Document ID 2226, p. 2), and the Interlocking Concrete Pavement Institute (ICPI) suggested that OSHA include compacting pavers, sweeping sand into paver joints, and compacting the aggregate base (Document ID 2246, pp. 2, 11). NAHB noted that Table 1 failed to cover hand-mixing concrete (Document ID 2334, p. 4). OSHA did not receive data showing that employees engaged in many of these additional minor tasks (pulling concrete forms, mixing concrete for post holes, etc.) experience significant routine exposure to respirable crystalline silica above the action level that would require their employers to comply with provisions of this rule. Because OSHA does not currently have data indicating that additional controls for these tasks would be needed on a regular basis or would be effective, it has determined not to include them on Table 1.

OSHA recognizes the possibility that employers may later discover that there are tasks that are not covered by Table 1 where they may have difficulty meeting the PEL. If such cases arise, OSHA can address them in several ways, including: considering technological or economic infeasibility defenses, and applying its variance process—either temporary or permanent, pursuant to which an

employer can apply to exclude an industry or process from enforcement of the standard based principally on a showing that it is providing equivalent protection for its workers.

Several commenters requested that OSHA add tasks or activities and equipment to Table 1 that are associated with general industry operations such as asphalt plant operations, shale gas fracturing, and artificial stone and granite countertop work (Document ID 2212, p. 2; 2116, Attachment 1, p. 28; 2244, p. 4). OSHA is not including these in the construction standard for the reasons discussed in the summary and explanation of Scope.

NUCA requested that OSHA add underground construction, specifically excavation, onto Table 1, stating:

> The nature of excavation underground construction is continuously mobile. Exposure assessments take time to evaluate by a lab, and in that time, the jobsite conditions will change or crews will move to other sites. Test results simply could not be available in enough time to be relevant to a particular jobsite. This not only makes costly lab assessments irrelevant to particular sites, it also does nothing to protect the workers on those sites (Document ID 2171, p. 2).

OSHA's technological feasibility analysis for underground operations (Section 5.12 of Chapter IV of the FEA) indicates that employees performing activities not specific to tunneling, such as grinding, hole drilling, or chipping, receive similar exposures from their equipment as employees performing those same activities aboveground in enclosed environments (*e.g.*, indoors). As a result, employers can comply with the dust control requirements of the standard by fully and properly implementing the dust controls specified on Table 1 of the final standard for construction for those tasks. However, as explained in the technological feasibility analysis cited above, OSHA determined that it was not possible to develop a clear control specification that would prove effective for most situations where tunnel boring machines, road headers, and similar kinds of equipment are used. Effective dust control for operations that use these kinds of equipment consists of a combination of water sprays at the tunnel face and along the conveyors that remove material from the face, general dilution ventilation through the tunnel, local exhaust ventilation for excavating equipment and conveyor transfer points, and enclosed cabs for the operators. Dust control may also require enclosures for conveyors and belt cleaning mechanisms. Designing effective and efficient dust control systems must take into account specific factors of the tunnel project and equipment being used, and are analogous to dust control strategies used in underground mines, as described in NIOSH's *Handbook for Dust Control in Mining* (Document ID 0887). Given the degree of complexity and project-specific considerations that should be taken into account, OSHA determined that it was not possible to devise an effective specification applicable to all tunnel projects and thus has not added an entry for tunnel boring in underground construction to Table 1.

Likewise, although abrasive blasting is a common source of silica exposure in construction, OSHA does not include an entry for abrasive blasting on Table 1 for reasons explained more fully below. As described in the Introduction to Chapter IV of the FEA, the tasks included on Table 1 of the final rule are those that have been widely recognized as high-exposure tasks in construction, and for which there has been considerable research performed on the effectiveness of dust control strategies. The record indicates that the tasks reflected in Table 1, with few exceptions such as underground construction and abrasive blasting, are the tasks that employers will most frequently need to address to ensure employee protection from crystalline silica hazards. For tasks not included on Table 1 that foreseeably generate silica exposures above the action level, construction employers will, in accordance with paragraph (d) of the standard for construction, need to conduct an exposure assessment and maintain exposures at or below the PEL through use of the traditional hierarchy of controls.

Commenters also weighed in on OSHA's general approach to selecting the engineering controls and work practices for each task. LBA argued that there was a disconnect between the feasibility evidence and the controls and work practices included on Table 1 (Document ID 2269, p. 17). NAHB urged OSHA to ensure that the protection methods included on Table 1 are based on verifiable studies that show effective solutions (Document ID 2296, p. 28). BCTD also opined that only ''control measures supported by good quality evidence should be listed on Table 1'' (Document ID 2371, Attachment 1, p. 24).

OSHA agrees that the engineering controls, work practices, and respiratory protection specified on Table 1 need to be consistent with the evidence presented in its technological feasibility analyses (*see* Chapter IV of the FEA). To that end, OSHA has based the specifications on Table 1 on extensive exposure data collected from a variety of sources including NIOSH reports, data submitted to the record, OSHA's compliance case files, and published literature.

Requirements for water delivery systems and dust collection systems. OSHA is requiring the use of an integrated water delivery system supplied by the equipment manufacturer for several types of equipment listed on Table 1: Stationary masonry saws; handheld power saws (any blade diameter); walk-behind saws; drivable saws; rig-mounted core saws or drills; handheld grinders for uses other than mortar removal; and walk-behind milling machines and floor grinders. OSHA is requiring the use of systems that are developed in conjunction with the tool because they are more likely to control dust emissions effectively by applying water at the appropriate dust emission points based on tool configuration and not interfere with other tool components or safety devices.

CISC commented that the requirement for an integrated water system limited options for employers and may reduce the use of the table, stating ''. . . if a construction employer finds a way to effectively deliver water through another mechanism, in the CISC's view that should be encouraged'' (Document ID 2319, p. 103; 2320, p. 16). OSHA expects that most employers will use integrated water systems, as provided by manufacturers, and will follow Table 1 but its intent is not to prohibit the use of other dust suppression methods during cutting. Employers may implement other controls or wet method configurations if they determine that the alternative control is more appropriate for their intended use. However, employers who choose to use controls not listed on Table 1 will be required to conduct exposure assessments and comply with the PEL in accordance with paragraph (d) of the standard for construction.

CISC also questioned the appropriateness of requiring an integrated water delivery system when most integrated systems are intended to keep the blade cool and are not designed for dust suppression (Document ID 2319, p. 103; 2320, p. 16). In written testimony, Rashod Johnson of the Mason Contractors Association of America stated that

> the vast majority of masonry saws provide water on the blade itself. This is solely for the purpose of keeping the blade cool during cutting. A side effect, just happens to be dust suppression. Now, manufacturers of these saws are starting to explicitly state that the water used is for cooling the blade only and

should not be used to suppress dust (Document ID 2286, p. 2).

However, product literature from five major saw manufacturers (Andreas Stihl, Husqvarna, Hilti, Makita USA, and Wacker Group) highlights the use of water application equipment to suppress dust in addition to blade cooling (Document ID 3998, Attachment 12a, pp. 9, 15–16; 3998, Attachment 12e, p. 3; 3998, Attachment 12f; 3998, Attachment 12g, p. 5; 3998, Attachment 12h, p. 8). For example, Stihl's manual for the model 410 and 420 cut-off machines (handheld masonry saws) specifically recommends a water flow rate for dust suppression (Document ID 3998, Attachment 12a, pp. 9, 15–16). Furthermore, Stihl is not the only cut-off saw manufacturer to state that water used with its product is intended to suppress dust emissions. Husqvarna's product literature for the K 3000 Wet describes the product as a power cutter for wet applications that is equipped with a dust extinguisher system (Document ID 3998, Attachment 12f, p. 1). Hilti also recognizes that water suppresses dust and recommends the use of wet cutting to reduce dust in its instruction manual for the Hilti DSH 700/DSH 900 model handheld masonry saws (Document ID 3998, Attachment 12e, p. 3).

CISC asked that OSHA clarify whether there needs to be a separate integrated water delivery system in addition to the system provided by the manufacturer to keep the blade cool (Document ID 2319, p. 104). Beamer *et al.* (2005) conducted experiments to observe the differences in the various wet cutting methods available and found that the greatest improvement in dust reduction occurred with freely flowing water applied at a rate of 48 gallons per hour (0.8 gallons per minute), resulting in dust reduction of about 93 percent and confirming the benefits of water flowing over the stationary saw cutting blade compared with other misting systems (Document ID 1555, p. 509). That, in addition to the manufacturer information submitted to the record, indicates that the existing water systems for blade cooling are effective at respirable dust capture and will satisfy the requirements under paragraphs (c)(1)(i) through (c)(1)(xviii) of the standard for construction where integrated water systems are required. Therefore, OSHA has determined that, where water-based dust suppression can be used with tools and equipment, those that are equipped with an integrated water delivery system are effective and the best available technology for controlling respirable crystalline silica. A separate integrated water delivery system in addition to the system provided by the manufacturer to keep the blade cool is not required.

OSHA is requiring the use of a commercially available dust collection system (*i.e.,* local exhaust ventilation (LEV)) for several types of equipment listed on Table 1, including: handheld power saws for fiber cement board (with a blade diameter of 8 inches or less), handheld and stand-mounted drills (including impact and rotary hammer drills), jackhammers and handheld power chipping tools (as an alternative to a water delivery system), handheld grinders for mortar removal, and handheld grinders for uses other than mortar removal (as an alternative to a water delivery system). OSHA's intent is to ensure that employers use equipment that is appropriately designed for the tool being used and that will be effective in capturing dust generated from using the tool.

CISC opposed OSHA's requirement for commercially available systems, stating ''[t]his specification eliminates specialty manufactured products that may be equally effective'' (Document ID 2320, p. 11). However, CISC did not provide examples or describe what is meant by ''specialty manufactured products.'' It is not OSHA's intent to prevent employers from using products that are custom made by aftermarket manufacturers (*i.e.,* made by someone other than the original tool manufacturer) which are intended to fit the make and model of the tool and designed to meet the particular needs and specifications of the employer purchasing the product. These systems are designed to work effectively with the equipment and not introduce new hazards such as obstructing or interfering with safety mechanisms. The ''commercially available'' limitation is meant only to eliminate do-it-yourself on-site improvisations by the employer. An employer is free to improvise and use controls that are not commercially available. However, those systems would not meet the requirements of Table 1 and the employer will be required to conduct exposure assessments and comply with the PEL in accordance with paragraph (d) of the standard for construction.

In Table 1 of the proposed rule, OSHA would have required dust collection systems be equipped with High-Efficiency Particulate Air (HEPA) filters, which are 99.97 percent efficient in capturing particles having an aerodynamic diameter of 0.3 μm or larger. In the final standard, OSHA is not requiring the use of HEPA filters and instead is requiring the use of filters with a capture efficiency of 99 percent or greater for respirable particulate. Although OSHA received comments and testimony in support of using HEPA filters to capture silica dust (Document ID 1953, pp. 3–4; 1973, pp. 2–3), extensive comments were submitted to the record expressing concern regarding this requirement.

Occupational and Environmental Health Consulting Services, Inc. (OEHCS) noted the numerous deficiencies found with HEPA filtration from ineffective seals, deterioration of the filter, and inadequate testing prior to use, which often results in employee exposure to potentially-hazardous particles and possible recontamination of the work environment (Document ID 1953, Attachment 1). The Precast/Prestressed Concrete Institute (PCI), NUCA, and LBA noted that HEPA filters do not work well in the construction environment because filters will clog up quickly and must be changed often (Document ID 2276, p. 10; 3729, p. 3; 2269, p. 23). CISC noted that HEPA filters will typically not last an entire shift, stating that they clog up quickly and need to be monitored and changed frequently (Document ID 2320, p. 114). Consequently, CISC asserted, HEPA filters are not effective at filtering respirable dust or at reducing exposures to respirable silica (Document ID 2319, p. 95).

OSHA reached the same conclusion in its technological feasibility finding for mortar and concrete grinding as well (*see* Section 5.11 of Chapter IV of the FEA). Finding that best practices may counsel toward the use of HEPA-rated filters in the case of grinding, and particularly mortar grinding, OSHA nonetheless determined that under field conditions HEPA filters may rapidly clog, leading to an increase in static pressure drop and loss of the airflow needed for LEV to effectively capture silica dust at the point of generation (Document ID 0731, pp. 375, 384).

OSHA is persuaded that it should not require that dust collection systems be equipped with HEPA filters because HEPA filters in some applications will result in loss of airflow and concomitant degradation of dust-capture efficiency. In examining manufacturers' specifications for many commercially-available dust collectors, OSHA finds that most offer, in addition to HEPA filters, other filters with a 99 percent efficiency or better in the respirable-particle-size range. Many examples of products equipped with filters that do not meet HEPA specifications but nevertheless meet the requirement for 99 percent efficiency in the respirable-particle-size range were submitted to the

record and include the EDCO Vortex 2000 (captures 99 percent of 0.5 μm or larger particles) (Document ID 4073, Attachment 4a, Row 55), the iQ 360x stationary saw (99.5 percent, particle size unspecified) (Document ID 4073, Attachment 4a, Row 58), a Porter-Cable vacuum (99.85 percent, particle size unspecified) (Document ID 3998, Attachment 13p), the Bosch 3931A (99.93 percent of 3 μm particles) (Document ID 3998, Attachment 10, p. 29), the CS Unitec (99.93 percent of 0.3 μm particles) (Document ID 4073, Attachment 4a, Row 99), and the Dustless 16-gallon collector (''almost HEPA,'' filters to 0.5 μm particles) (Document ID 4073, Attachment 4a, Row 211). A filter efficiency of at least 99 percent allows for longer tool usage, compared to one with a HEPA filter, before significant drops in airflow of the dust collection system. Furthermore, as explained above, requiring that dust collectors be equipped with HEPA filters can cause rapid airflow drop, reducing dust capture efficiency at the shroud or hood and exposing employees to high respirable dust and silica concentrations. Therefore, OSHA has decided not to require HEPA filters on Table 1 for dust collection systems and instead requires that dust collectors have a filter with 99 percent or greater particle capture efficiency. Employers should consult with their suppliers to determine the dust collection equipment that will best suit their needs for a given application.

OSHA also received many specific comments about particular changes to the notes and additional specifications, associated with the entries on Table 1, and on the specified engineering and work practice control methods identified for each entry, which are further discussed later in this section.

Notes and additional specifications on Table 1. Several commenters responded to the appropriateness of including the notes and additional specifications in the individual entries on Table 1. OSHA included these in the proposed rule to ensure that the strategies listed were properly implemented and remained effective.

Some commenters stated that the notes were too detailed, while others argued that the notes were not detailed enough (Document ID 2319, p. 6; 2262, p. 29; 3581, Tr. 1631–1632; 3585, Tr. 2924–2925, 3052–3053; 4223, pp. 95–97). Several commenters expressed concern that certain notes were unrealistic or too confusing for an employer to comply with. CISC stated that the inclusion of the notes left Table 1 ''unworkable'' for most employers in the construction industry (Document 2319, p. 6). Others questioned whether these additional specifications were a mandatory component of Table 1 or simply suggested guidelines to help determine the efficacy of the control (Document ID 2296, p. 28; 3441, pp. 4–5). On the other hand, some commenters asserted that the additional specifications were needed on Table 1 to ensure that controls are properly operated and effective (Document ID 3589, Tr. 4286–4287; 3581, Tr. 1631–1632; 4223, pp. 95–97).

To balance the need to clarify how the specifications apply to make Table 1 workable with the need to provide more specific information about the controls in order to ensure that they are effective, OSHA has removed most of the notes and additional specifications from the individual entries on Table 1 and has instead included revised specifications for the controls in paragraph (c)(2) of the standard for construction. This approach has the added benefit of making Table 1 more readable because specifications that apply to multiple rows can now be addressed in a single subparagraph.

Paragraph (c)(2)(i) of the standard for construction requires employers to provide a means of exhaust as needed to minimize the accumulation of visible airborne dust for tasks performed indoors or in enclosed areas. When tasks are performed indoors or in enclosed areas, the dispersal of dust can be impeded such that concentrations can build up without the aid of forced ventilation. Flanagan et al. (2006) concluded that the degree to which a work area is enclosed is an important determinant of employee exposure based on data demonstrating increased exposures to respirable crystalline silica for enclosed environments (those with two to four walls, as well as those having walls, a roof, and windows), as compared to outdoor environments (Document ID 0677, pp. 148–149). Increased exposures to respirable crystalline silica were also demonstrated for tasks listed on Table 1 in enclosed areas, such as jackhammering inside a large pool area (Document ID 3958, Rows 1064, 1065, 1066) and handheld sawing in a large garage building open in front and closed on three sides (Document ID 3777, p. 65).

Sufficient air circulation in enclosed or indoor environments is important to ensure the effectiveness of the control strategies included on Table 1 and to prevent the accumulation of airborne dust. The ''means of exhaust'' necessary to minimize the accumulation of visible airborne dust could include dilution ventilation through the use of portable fans that increase air movement and assist in the removal and dispersion of airborne dust, which would otherwise remain in the enclosure and contribute to elevated exposures. To be effective, the ventilation must be implemented so that movements of employees, or the opening of doors and windows, will not adversely affect the airflow.

Paragraph (c)(2)(ii) of the standard for construction requires employers, for tasks performed using wet methods, to apply water at flow rates sufficient to minimize release of visible dust generated by the task. BCTD and LHSFNA encouraged OSHA to specify minimum flow rates for water where there are data or studies to support such a recommendation (Document ID 3581, Tr. 1632; 3589, Tr. 4286–4287). NIOSH recommended a flow rate of 0.5 L/min for handheld power saws based on experimental data and recommended that OSHA specify a minimum water flow rate of 300 mL/minute for jackhammers based on a field study of control equipment fabricated specifically for the study (Document ID 2177, Attachment B, pp. 19, 33; 0867, p. 6). Water has been proven an efficient engineering control method to reduce exposures to airborne crystalline silica-containing dust. Adequate dust capture is dependent on a variety of factors such as dust particle size, velocity, spray nozzle size and location, use of surfactants or other binders, and environmental factors (water hardness, humidity, weather, etc.) that must be considered when implementing wet methods. Water flow rates suggested by various studies, while perhaps instructive, may not be applicable to all of the different types of equipment that could be used or the conditions that may be encountered by employers following Table 1. Because the appropriate water flow rates for controlling silica dust emissions can vary, OSHA is not establishing a required flow rate for wet suppression systems or specifying a flow rate for individual Table 1 entries.

Paragraphs (c)(2)(iii)(A)–(F) of the standard for construction require employers implementing measures that include an enclosed cab or booth to ensure that the enclosed cab or booth is maintained as free as practicable from settled dust, has door seals and closing mechanisms that work properly, has gaskets and seals that are in good condition and work properly, is under positive pressure maintained through continuous delivery of fresh air, has intake air that is filtered through a pre-filter that is 95 percent efficient in the 0.3–10.0 μm range (*e.g.,* MERV–16 or

better), and has heating and cooling capabilities.

Dust can be unintentionally carried into enclosed cabs or booths through a number of routes, including on employees' boots, during the opening of doors when accessing or exiting the cab, through leaks in the system, or when employees roll down windows. IUOE, recommending that OSHA add specificity to the cab requirements (*e.g.,* heating and air conditioning, housekeeping), argued that without greater specificity ''there is a grave danger that intended safeguards become counterproductive as dust is re-circulated within the enclosures'' (Document ID 2262, pp. 29–33).

Direct-reading instruments show that fine particle (0.3 micron (μm) in size) concentrations inside operator cabs can be reduced by an average of 93 percent when cabs are clean, sealed, and have a functionally adequate filtration and pressurization system (Document ID 1563, p. 1). Cecala *et al.* (2005) studied modifications designed to lower respirable dust levels in an enclosed cab on a 20-year-old surface drill at a silica sand operation. The study found that effective filtration and cab integrity (*e.g.,* new gaskets, sealed cracks to maintain a positive-pressure environment) are the two key components necessary for dust control in an enclosed cab (Document ID 1563, p. 1).

OSHA determined that the requirements specified in paragraphs (c)(2)(iii)(A)–(F) of the standard for construction reduce the likelihood of respirable crystalline silica exposure in enclosed cabs or booths when employees are present by lowering the potential for dust to be re-suspended inside the enclosure, promoting the ability of the enclosed cab or booth to keep dust from entering through cracks or openings (*e.g.,* seals, gaskets, and closing mechanisms are present, in good condition, and work properly), ensuring that the working conditions in the cab are comfortable so that employees are less likely to open the window of the cab, and ensuring that the fresh air provided to the employee does not contain silica particles.

IUOE also suggested that OSHA require employers to provide boot brushes or mudflingers to minimize the dust brought into the cab, to equip cabs with dust-resistant materials, and to affix warning labels to the interior of the cab (Document ID 2262, p. 30; 4025, p. 17). The Agency has not included these additional requirements since it expects that the specifications in paragraphs (c)(2)(iii)(A)–(F) of the standard for construction combined with frequent inspections by the competent person will be sufficient to protect employees against the potential respirable crystalline silica exposures within the enclosure.

OSHA has not included more specific requirements in paragraphs (c)(2)(i)–(c)(2)(iii) of the standard for construction (*e.g.,* establishing a minimum face velocity, volumetric flow rate for air movement, or a required number of air changes; flow rate for wet suppression systems; or a frequency for the cleaning of cabs or booths). However, as discussed in the summary and explanation of *Written Exposure Control Plan,* paragraph (g)(1)(ii) of the standard for construction requires the employer to establish and implement a written exposure control plan that describes the engineering controls and work practices used to limit employee exposure to respirable crystalline silica. This description should include details such as the appropriate means of exhaust needed to minimize the accumulation of visible airborne dust for a particular task, the appropriate flow rate and droplet size needed for wet suppression systems to minimize release of visible dust, and the procedures for maintaining and cleaning an enclosed cab or booth. Paragraph (g)(4) of the standard for construction also requires a competent person to make frequent and regular inspections of the jobsite, materials, and equipment (including engineering controls) to implement the written exposure control plan.

OSHA did not include specifications on visible dust and wet slurry, included as notes in individual entries on proposed Table 1, in the standard. The Agency has determined that these issues are best addressed by other provisions of the standard, rather than as a note or additional specification included in each relevant Table 1 entry. Further discussion about these specifications is also included below.

Many commenters expressed concern with the note, contained in proposed Table 1 for all but two entries, requiring employers to operate equipment such that no visible dust is emitted from the process. Industry commenters, including the Power Tool Institute (PTI), Western Construction Group, SMACNA, the Independent Electrical Contractors, the Distribution Contractors Association, CISC, the Utility and Transportation Contractors Association of New Jersey, Atlantic Concrete Cutting, ABC, LBA, Holes Incorporated, and N.S. Giles Foundations objected to this note, stating that it was an unrealistic requirement which made Table 1 unworkable (*e.g.,* Document ID 1973, pp. 2–9; 2183, p. 3; 2226, p. 2; 2250, p. 2; 2309, p. 4; 2319, pp. 97–98; 4217, p. 6; 2356, p. 2; 2367, p. 2; 2289, p. 7; 2269, p. 21; 3441, p. 5; 3598, pp. 1–2).

Some industry commenters asserted that it is impossible to perform tasks, such as sawing, grinding, and drilling, without generating any visible dust (Document ID 2357, pp. 27–28; 3441, p. 6; 4073, Attachment 9e, p. 1). Holes Incorporated noted that when grinding or using other hand-held pieces of equipment, the work cannot be performed with the tool flush against the impacted surface, and at times, there will be a gap and visible dust will be emitted even when local exhaust ventilation or wet methods are utilized (Document ID 3441, p. 6).

Other commenters expressed concern that there is no true dustless system, clarifying that even those tools marketed as ''dustless'' produce some level of airborne dust (Document ID 2345, p. 4; 3585, Tr. 2960; 4216, pp. 2–3). Francisco Trujillo, safety director for Miller and Long, stated that:

> Every ''dustless'' system I have ever witnessed has produced some level of airborne dust. This fact alone should show that Table 1 sets criteria that are impossible to achieve . . . (Document ID 2345, p. 4).

On the other hand, commenters, including NAPA and BAC, noted that in their experience there is no visible dust generated when certain equipment, such as asphalt machines for milling or stationary masonry saws, is used with available dust controls (Document ID 3583, Tr. 2216; 3585, Tr. 3072). They did not, however, provide any indication that the same results could be achieved with all of the other equipment listed on Table 1.

Several commenters provided a different rationale for their objections to this note. AIHA opined that the requirement to operate equipment such that no visible dust is emitted from the process is a subjective determination and recommended it be removed from Table 1 entries (Document ID 3578, Tr. 1029–1030; 2169, p. 5). The Masonry and Concrete Saw Manufacturers Institute (SMI) noted that ''[a]dding requirements for . . . avoiding *visible* dust have not been researched specific to respirable silica dust and may have no beneficial impact'' (Document ID 2316, p. 2). NAHB and Holes Incorporated expressed concern that the requirement was a general dust rule, rather than regulating crystalline silica since Table 1 doesn't specify whether ''no visible dust'' refers to visible silica dust or just dust in general (Document ID 2296, p. 29; 3580, Tr. 1355–1356).

Not all industry commenters objected to the note on visible dust contained in the proposed Table 1. ICPI supported a version of Table 1 that included the no-visible-dust requirement for nearly all of the operations listed (Document ID 2352, pp. 4–8).

Commenters from both industry and labor suggested revisions to clarify the note and make it workable. LHSFNA believed the note was needed to ensure the effective use of controls and was not too vague, but acknowledged that the language could be clarified to say something like ''visible dust should be minimized'' (Document ID 4207, p. 2). BCTD also provided significantly revised language for the no-visible-dust requirement. For those operations that involve cutting and grinding on silica-containing substrate, BCTD suggested that, for wet systems, Table 1 of the standard should require that water flow be ''sufficient to control the dust generated so that no visible dust . . . is emitted from the process once the blade has entered the substrate being cut'' and that the relevant note on Table 1 be revised to read:

> A small amount of visible dust may be present when the blade or tool initially enters the substrate and when it is being removed at the end of a task. However, if visible dust is present after the blade or tool has entered the work surface/substrate, this is a sign that the control is not working properly. The operation should be stopped and the equipment and/or workers' cutting technique checked and fixed (Document ID 4223, Appendix 1, p. 14).

PTI's suggested revisions to Table 1 include a note for many of the entries specifying that ''during operation, if excessive visible dust is emitted from the process, immediately stop work and verify that the dust control system is functioning properly'' (Document ID 1973, pp. 2–9).

While opinions varied widely on the utility of a no-visible-dust requirement, no commenters suggested that excessive visible dust generated from tasks abrading silica-containing materials (sawing, grinding, etc.) does not present a risk of significant employee exposure to silica. As noted above, BCTD confirmed that the presence of visible dust after the blade or tool has entered the work surface/substrate is a sign that the control method is not working properly (Document ID 4223, Appendix 1, p. 14). PTI recommended that, when excessive visible dust was present, work stop immediately until the employer could verify the proper functioning of the control (Document ID 1973, pp. 2–9).

OSHA agrees that excessive visible dust is an indication that a control's effectiveness may be compromised, but, after reviewing the entire record on this point, has decided not to include a no-visible-dust requirement for the Table 1 entries. Instead, it has concluded that the purpose of such a requirement is best achieved by bolstering other requirements in the rule, as it applies to construction. First, OSHA considers the written exposure control plan to be centrally important and expects employers to address signs that controls may not be working effectively (*e.g.,* dust is visible) as part of their written exposure control plans required under paragraph (g) of the standard for construction (*see* summary and explanation of *Written Exposure Control Plan* for further discussion). Second, during the designated competent person's frequent and regular inspections of job sites, materials, and equipment to implement the written exposure control plan, as required under paragraph (g)(4) of the standard for construction, OSHA expects that person to make routine observations of dust generated from tasks being conducted. Where increases in visible dust occur, the competent person's assigned role is to take prompt corrective action (*e.g.,* make corrections or adjustments as needed).

OSHA finds that the difference between the small amount of dust generated when control measures are operated effectively and the large amount of dust generated during tasks when control measures are not used or not operated effectively can readily be observed. Several videos presented in the record support this conclusion (*e.g.,* Document ID 4073, Attachment 4b). These videos demonstrate that when a task is uncontrolled or inadequately controlled, a large dust plume can be seen. When controls such as water or vacuum-based ventilation are used, little dust is observable. These significant differences in the observable dust generated during controlled and inadequately-controlled tasks provide an opportunity for employers to readily detect poorly-performing equipment and address these problems quickly. The principle concern, however, is with a lot of visible dust, rather than any visible dust, which is a concern for which the appropriate corrective action is difficult to quantify or state in objective terms. Instead, the presence of significant visible dust lends itself to a more process-oriented control approach, as exemplified by the written exposure control plan and competent person requirements. OSHA thus concludes that the issue of visible dust is best addressed by the requirement to fully and properly implement the controls specified on Table 1, and the written exposure control plan and competent person requirements, rather than as a note or additional specification included in each Table 1 entry.

Commenters also objected to the specification to prevent wet slurry from accumulating and drying when implementing wet methods, as proposed for several Table 1 entries. Both Holes Incorporated and NAHB objected to the ambiguity of the requirement and presented concerns about how employers on a construction site would comply with such a requirement (Document ID 3441, p. 9; 2296, p. 28).

Other commenters expressed concern regarding the disposal of silica slurry (Document ID 2246, pp. 9–10; 3585, Tr. 2886; 2319, p. 94). ICPI noted that employers have to expend extra effort to locate a place to dispose of dust-filled slurry, which is not possible in some conditions or locations (Document ID 2246, pp. 9–10). CISC described how slurry created using wet-cutting methods outside can flow into storm drains, potentially violating environmental regulations (Document ID 2319, p. 94). The Mason Contractors Association of America explained that in California, silica slurry produced from wet cutting is classified as a hazardous material, requiring contractors working in the state to follow hazmat procedures for its disposal (Document ID 3585, Tr. 2886).

However, NIOSH argued that since the vast majority of masonry saws provide water on the blade itself to cool and lubricate the blade and suppress dust, employers already have to deal with slurry when cutting masonry and concrete (Document ID 4233, Attachment 1, p. 6). OSHA agrees that the standard does not pose any new requirements regarding the disposal of slurry on employers who already use wet methods for sawing masonry products.

OSHA concludes that any measures necessary to manage slurry in order limit employee exposure to respirable crystalline silica (*i.e.,* exposure that results from slurry drying and dust particles becoming airborne) are best addressed through the employer's written exposure control plan and competent person requirements, rather than as a note or additional specification included in each Table 1 entry. These requirements are discussed above and in the summary and explanation of *Written Exposure Control Plan.*

In several Table 1 entries, OSHA has included a requirement to operate and maintain tools in accordance with

manufacturer's instructions to minimize dust emissions. This requirement is intended to ensure that the controls are implemented effectively to reduce exposures to respirable crystalline silica. Manufacturer's instructions that influence the effectiveness of the tool and controls with regard to minimizing dust emissions may include, but are not limited to, additional specifications for water flow rates, air flow rates, vacuum equipment, rotation of the blade, maintaining and changing blades, and frequencies for changing water.

Respiratory protection specified on Table 1. Industry associations, including the American Subcontractors Association (ASA), the Institute of Makers of Explosives (IME), the General Contractors Association of New York (GCANY), and CISC, commented on the appropriateness of the respirators that OSHA proposed for Table 1 (*e.g.,* Document ID 2213, p. 2; 2187, p. 3; 2314, p. 2; 2319, p. 102). For example, ASA stated:

> OSHA's proposed Table 1 for construction would seem to suggest that the Agency believes a construction employer can achieve the PEL with engineering and work practice controls. Yet the Agency then requires respiratory protection for 60 percent of the operations listed in Table 1. This failure is even more perplexing since OSHA failed to identify, obtain and/or cite sufficient data for its conclusions with respect to the 13 operations addressed in Table 1 (Document ID 2187, p. 3).

GCANY explained in their comments that ''[c]urrent respiratory protective equipment is cumbersome to wear and to work in and would expose the worker to other hazards on a job site'' (Document ID 2314, p. 2). CISC urged OSHA to ''eliminate the heavy use of respiratory protection,'' arguing that:

> OSHA's reliance on respiratory protection is analytically inconsistent with its position that it is technologically feasible to reach the proposed PEL in most construction operations most of the time, and particularly when the control measures specified in Table 1 are used. Requiring such heavy use of respirators . . . will serve as a significant barrier to effective use of [Table 1] (Document ID 2319, p. 102).

Respirator requirements on Table 1 of the final rule are based on a review of all the evidence pertaining to exposure profiles and available controls in the rulemaking record, including an evaluation of the updated exposure profiles and evidence on available controls submitted to the rulemaking record, as described in Chapter IV of the FEA. A primary purpose of such evaluation was for OSHA to better identify those situations where exposures above the PEL are likely to persist despite full and proper implementation of the specified engineering and work practice controls and supplemental respiratory protection will therefore be necessary to ensure employees are protected from silica-related health risks. As documented in its analyses of technological feasibility for each Table 1 task, OSHA finds that most of the time employees are performing tasks on Table 1, respiratory protection will not be required. For most of the tasks or equipment on Table 1, OSHA expects that work will be performed for four hours or less and/or outdoors (*see* Chapter IV of the FEA). For certain tasks listed on Table 1, OSHA was able to distinguish indoor environments, where exposures are typically above 50 μg/m^3 even with the use of engineering controls and work practices, from outdoor environments, where engineering controls can typically maintain exposures below 50 μg/m^3, in order to eliminate requirements for respiratory protection where tasks are performed outdoors (*e.g.,* using handheld grinders for uses other than mortar removal (c)(1)(xii)). Elsewhere, OSHA was able to further refine the equipment or tasks listed on Table 1 (*e.g.,* handheld power saws (c)(1)(ii)–(iii); walk-behind and drivable masonry saws (c)(iv)–(v); milling machines (c)(1)(xiii)–(xv)) in order to eliminate previously proposed requirements for respiratory protection. In other cases, OSHA found engineering controls and work practices specified on Table 1 sufficient to maintain employee exposures at or below 50 μg/m^3 when fully and properly implemented (*e.g.,* (c)(1)(i), (c)(1)(ix), (c)(1)(xiv)), and thus determined that a respiratory protection requirement was not necessary. Specific changes to the respiratory protection requirements for each task listed on Table 1 are discussed in more detail below.

Consequently, required respiratory protection under Table 1 is limited to situations in which OSHA has determined that exposures over 50 μg/m^3 will often occur. For example, OSHA is not requiring the use of respiratory protection when handheld power saws (any blade diameter) are used outdoors, for less than four hours, with water-based dust suppression systems because OSHA's exposure profile indicates that exposures will be below 50 μg/m^3 TWA most of the time that saws are used, given typical work patterns (*e.g.,* outdoors for less than four hours per shift) (*see* Section 5.6 of Chapter IV of the FEA). Data submitted to the record by the Concrete Sawing and Drilling Association (CSDA) (Document ID 3497) also show that wet sawing produces exposures below 50 μg/m^3 TWA with typical use patterns during the work shift. In contrast, indoor use of handheld wet power saws generates frequent exposures in excess of 50 μg/m^3 TWA with typical use patterns during the work shift; from OSHA's exposure profile, half of the exposure samples associated with using handheld power saws indoors exceed 50 μg/m^3 TWA, and two indoor samples included in the data submitted by CSDA were above a TWA of 50 μg/m^3 (Document ID 3497, p. 5). As a result, Table 1 requires supplemental respirator use when handheld power saws are used indoors or in an enclosed area with water-based dust suppression systems.

OSHA has also used the terms ''indoors or in an enclosed area'' rather than ''indoors or within a partially sheltered area'' in order to clarify that any requirement to use respiratory protection when the task is performed under these conditions is limited to those areas where the dispersal of dust can be impeded such that concentrations can build up without the aid of forced ventilation. For example, a work area with only a roof that does not impede the dispersal of dust would not be considered ''enclosed,'' while it may have been considered by some to be a ''partially sheltered area.''

As a result of these modifications, OSHA expects that many fewer employees will need to use respiratory protection than was the case for the proposed rule, and respiratory protection will not be necessary for the most commonly encountered work situations and environments specified on Table 1.

ISEA suggested that OSHA make the respirator requirements on Table 1 more user-friendly and performance-oriented by listing only an APF and recommending that users consult the APF table found in the respiratory protection standard, rather than listing generic respirator types (Document ID 2212, p. 2). In response to this comment, OSHA has maintained certain requirements for respiratory protection, but has eliminated specific requirements for the type of respirator that must be used (*e.g.,* half-mask respirator, powered air-purifying respirator (PAPR) with loose-fitting helmet or negative pressure full facepiece). Instead, OSHA includes on Table 1 only the minimum Assigned Protection Factor (APF) required. This change from the proposal provides the employer with the option of determining which respirator offers the best protection for its employees in the multitude of construction environments

that may be encountered. However, this is only the minimum protection factor required for the respirator, and employers have the flexibility to provide a more protective respirator to those employees who request one or require a more protective respirator based on the employer's evaluation of the worksite. As discussed in the summary and explanation of *Respiratory Protection*, paragraph (d)(3)(i)(A) of the respiratory protection standard (29 CFR 1910.134), which includes a table that can be used to determine the type or class of respirator that is expected to provide employees with a particular APF, can help employers determine the type of respirator that would meet the required minimum APF specified by Table 1. In order to reflect this change to the respirator requirements, the Agency has modified the heading on Table 1 to ''Required Respiratory Protection and Minimum Assigned Protection Factor (APF).''

The respirator requirements on Table 1 are divided by task duration: ''less than or equal to four hours/shift'' and ''greater than four hours/shift.'' AIHA recommended that OSHA clarify what time is included when determining less than or greater than four hours (Document ID 2169, p. 6). OSHA has determined that time starts when the operator begins using the tool, and continues to be counted until he or she completes the task. This time includes intermittent breaks in tool usage and clean-up. For example, an employee cuts and places bricks, one at a time, for three hours consecutively. The employee then spends 30 minutes cleaning up the saw and empting slurry or dust collectors. All three hours spent cutting and laying bricks along with the 30 minutes for clean-up count. Tasks that are performed multiple times per day, during distinct time periods, should be counted as separate tasks, and times should be combined. For example, an employee cuts multiple bricks for 15 minutes, lays bricks for two hours and returns to cut more bricks for another 30 minutes. The two hours spent laying bricks do not count towards the total time for compliance with Table 1.

The duration of a task that generates respirable crystalline silica influences the extent of employee exposure and, in some cases, requirements for use of respirators. Some commenters suggested that OSHA modify the time breakdown for activities and respirator usage, such as BCTD's suggestion to divide tasks on Table 1 into two hours, four hours, and eight hours. Other commenters such as CISC, Holes Incorporated, and the Mason Contractors Association of America, suggested that OSHA exclude short duration tasks (*e.g.,* 90 minutes or less) from Table 1, and NUCA suggested that the four hour cutoff is arbitrary and had no data to support it (Document ID 4073, Attachment 14f, p. 2; 2319, pp. 100–102; 3580, Tr. 1453; 3585, Tr. 2882; 3729, p. 3).

After reviewing these comments, OSHA has decided to maintain this division in the standard. OSHA selected four hours as an appropriate division point for respirator usage because it finds that employers and employees can anticipate whether a task will take less than half of a shift or more than half of a shift (as opposed to smaller time intervals), and so can plan accordingly on the need for respirator use on a given job. In addition, OSHA selected only a single durational division for respirator tasks in all of the relevant Table 1 tasks to avoid the confusion that could result from triggering mandatory respirator use at different times for different tasks. OSHA also determined that excluding short duration tasks from Table 1, although included in the ASTM E 2625–09 consensus standard, was inappropriate, given that employees engaged in a task listed on Table 1 are best protected using the available engineering controls, work practices, and respiratory protection specified for the task and are only exempt from complying with the standard where employee exposure will remain below 25 $\mu g/m^3$ as a time-weighted average under any foreseeable conditions (*see* summary and explanation of Scope for further discussion of this exclusion).

Table 1 of the proposed rule used the phrase ''4 hours per day'' to indicate when respirators were required, but Table 1 of the final standard uses ''4 hours per shift.'' OSHA's exposure data is largely drawn from samples of employee exposure averaged over an 8-hour period, which is a typical time for a shift. The proposed rule referred to a time period of four hours ''per day'' for the purpose of limiting employee's exposure during the normal 8-hour shift that most employees work during a single day. OSHA recognizes, however, that some common tasks such as jackhammering during nighttime highway construction may occur during an 8-hour period that spans two calendar days (*e.g.,* 8 p.m. until 4 a.m.). OSHA did not intend to allow employees to be exposed to respirable crystalline silica without respiratory protection for longer than four hours in that scenario, so OSHA has specified four hours ''per shift'' in the final rule.

OSHA also recognizes that the form and length of a shift may vary such that an employee may have a break between work periods (*e.g.,* four hours on, two hours off, four hours on), work shifts may be longer than eight hours, or employees may work double shifts within a single day. The work periods in each of those examples constitutes a ''shift'' for purposes of determining the maximum amount of time that an employee may spend on one of the applicable Table 1 tasks without respiratory protection. OSHA's exposure data is not sufficient to support the conclusion that a longer duration of exposure without respiratory protection would be safe just because that exposure is spread out over a period that is longer than the normal 8-hour shift. Thus, an employee who works a 12-hour shift from 8 p.m. to 10 a.m. with a 2-hour rest break in the middle would have to wear a respirator if engaged in an applicable Table 1 task such as jackhammering outdoors if the employee will be jackhammering from 8 p.m. to 11 p.m., taking a break from 11 p.m. until 2 a.m., and then jackhammering again from 2 a.m. until 4 a.m. for a total of five hours of jackhammering. However, assuming no other silica exposure, the employee would not require respiratory protection if the jackhammering is limited to 8 p.m. until 11 p.m. and 2 a.m. until 3 a.m. for a total of four hours, even if the employee repeats the same shift and jackhammering times every day of the week. Accordingly, the change from ''per day'' to ''per shift'' clarifies OSHA's original intention regarding when respirator use is required for Table 1 tasks.

The requirement to provide respirators for Table 1 tasks is based on the anticipated duration of the task. Some commenters, such as EEI, expressed confusion about how this requirement would apply to non-continuous work (*e.g.,* Document ID 2357, p. 27). EEI opined that:

> The nature of non-continuous work can also make it hard to anticipate when a certain task may exceed four hours per day. Suppose, for example, a job task using a stationary masonry saw is not anticipated to last beyond four hours, so all controls listed in Table 1 are followed, and the employee does not wear a respirator. Then, due to unforeseen complications, the job lasts beyond four hours. Simply following the regulations as proposed, it is unclear whether the employee would be allowed to put on a half-mask after four hours, or if OSHA will not allow the employer to use the Table 1 option because the employee was not in a half-mask for the first four hours (Document ID 2357, p. 27).

In contrast, other commenters suggested that, despite the variable nature of the work, employers and employees generally know how long it will take to complete a particular task (*e.g.,*

Document ID 3581, Tr. 1684, 1686). OSHA recognizes, based on the comments above and the nature of construction work in general, that application of this requirement warrants some flexibility. For several Table 1 tasks, respiratory protection with the appropriate APF is required if the duration of a task is anticipated to exceed four hours, but is not required if the duration of a task is less than or equal to four hours (*e.g.,* (c)(1)(ii), (c)(1)(x), (c)(1)(xii)). For these tasks, the Agency does not expect employers to know exactly how long it will take to perform a task. Rather, OSHA expects employers to make a good-faith judgment of the task's anticipated duration over the work shift based on previous experience and all other available information. If the employer anticipates that an employee will be engaged in a task for more than four hours, the employer must provide respirators (if required by Table 1) to the employee at the beginning of the shift. For example, in the case of an employee grinding concrete walls indoors, the employer should know, in advance, the area of surface that is to be worked on in the course of a shift. If, based on the employer's experience, the time needed to grind that area is typically less than four hours, the employer would not be required to provide respirators to the employee. If, however, using the same example, the employer experiences unforeseen difficulties that extend the task duration beyond four hours, the employer would be required under Table 1 to provide the listed respiratory protection as soon as it becomes evident that the duration of the grinding task may exceed the 4-hour limit, measured from the beginning of the task rather than the point when the need for extra time becomes evident.

Commenters, including BCTD, Fann Contracting, and IUOE, expressed confusion about whether an employee must wear a respirator for the entire duration of a task when that task is expected to last more than four hours, or rather wear the respirator for only the portion of the task that exceeds four hours (*e.g.,* Document ID 3581, Tr. 1681; 2116, Attachment 1, p. 28; 2262, p. 27). OSHA hereby clarifies that the intent is to require respirator use throughout the duration of the task.

The objective of the silica standard is to limit an employee's average exposure over a work shift. In each of OSHA's health standards, this is accomplished by establishing a PEL expressed as an 8-hour TWA. Because a PEL is a time-weighted average, the Agency has traditionally required employees to use respirators throughout a shift when employees work on a task or in an area where exposure to a hazardous substance contributes significantly to an employee's exposure in excess of the PEL at any point during that shift. This same reasoning applies to wearing a respirator from the beginning of a shift where respirators are required on Table 1. Thus, OSHA is continuing the same approach to respirator use for tasks listed on Table 1 of the standard for construction as it has for other OSHA health standards. Under Table 1 of the final standard for construction, when a respirator is required only when a task is performed for more than four hours per shift and when the employer estimates that the duration of the task will exceed four hours, the employer must provide and ensure that a respirator is used the entire time that task is performed over the shift, not just during the time beyond the first four hours that the task is performed. For example, if an employer anticipates that an employee will operate a jackhammer outdoors for more than four hours, the employer must provide respiratory protection with an APF of 10 and require that it be used for the entire duration of the task. For tasks that are typically intermittent, employers are required to estimate at the outset the total time during the shift that the task itself will be performed and provide respirators required by Table 1 based on that estimate. If an employer knows from experience that an employee will perform a single task listed on Table 1 for four hours or less during a single shift, then the employer must ensure that the employee uses whichever respirator is specified in the ''≤ 4 hr/shift'' column on Table 1 (or need not provide a respirator if no respirator is required on Table 1 for that duration). As another example, if a contractor needs to cut four concrete walls using a handheld power saw (outdoors), and cutting each wall typically takes 45 minutes to complete, for a total time of 3 hours, the employer would not be required by Table 1 to provide a respirator. But if cutting each wall typically takes in excess of 60 minutes, the employer should expect that the total duration of the task will exceed four hours and provide respirators as required under Table 1. The employer is required to provide respirators as soon as it becomes evident that the duration of the task will exceed four hours. Thus, in most situations an employee will be protected by a respirator for all or the majority of a task that exceeds four hours because the rate of progress on the task will become apparent to the employer early on. An employee cannot be allowed to work more than four hours without a respirator when one is required under Table 1 because the employer will have certainty at that point that the task is exceeding four hours.

The above examples assume that employees are engaged in only one task covered by Table 1 each shift. Paragraph (c)(3) of the standard for construction requires that, where employees perform more than one task on Table 1 during the course of a shift for a combined total of more than four hours, employers must provide, for the entire duration of each task performed, respiratory protection that is consistent with that specified in the ''> 4 hr/shift'' column of Table 1, even if the individual duration of each task is less than four hours. If no respirator is specified for a task in the ''> 4 hr/shift'' column of Table 1, then respirator use would not be required for that part of the employee's shift. For example, if an employer plans to have his employee use a handheld grinder outdoors on a concrete wall for three hours and then use a chipping hammer for two additional hours, the employer would not be required to ensure that his employee uses a respirator for the three hours the employee is using the grinder, since respiratory protection is not specified on Table 1 for the use of a grinder outdoors for more than four hours per shift; however, the employer would be required to ensure that his employee uses a respirator with an APF of 10 for the two hours the employee is using the chipping hammer. This is so even though use of the chipping hammer, if performed with no grinding beforehand, would not have required a respirator for the duration that the tool was used. If the employee will be engaged in two activities that both have ''None'' specified for respiratory protection in both the ''≤ 4hr/shift'' and the ''> 4 hr/shift'' columns, such as driving a half-lane milling machine and then operating a walk-behind milling machine equipped with an integrated water delivery system, then respirator use would not be required for any part of an employee's shift even if the employer knows that the cumulative total of that work will exceed four hours.

When an employee performs multiple tasks that do not exceed a combined total of more than four hours, employers must provide the respiratory protection specified in the ''≤ 4 hr/shift'' column of Table 1 for each task. For example, if an employer plans to have his employee use a handheld grinder for mortar removal for one hour and a stationary masonry saw for an

additional two hours, the employer is required to ensure that his employee uses a respirator with an APF of 10 for the one hour the employee is using the grinder. The employer would not be required to ensure that his employee uses a respirator for the two hours the employee is using the stationary masonry saw, since respiratory protection is not specified on Table 1 for the use of a stationary masonry saw.

Thus, whatever permutations may arise, the employer must estimate the duration of the task(s) to determine whether Table 1 will trigger the requirement for respiratory protection. If unforeseen conditions arise that cause the estimated duration to be revised for any of the tasks, the employer is required to provide the required respiratory protection as soon as it becomes evident that the employee will be engaged in the task for more than four hours during the shift.

Updating Table 1. Commenters, including LHSFNA, BAC, BCTD, Charles Gordon, and James Hardie Building Products, Inc., suggested that the utility of Table 1 will diminish over time if OSHA has no mechanism to include new control methods that may be developed (*e.g.,* Document ID 4207, pp. 2–3; 4219, pp. 20–21; 4223, pp. 98–102; 3588, Tr. 3792–3793; 2322, pp. 21–23).

Commenters also provided specific recommendations for the frequency at which OSHA should update Table 1 and the process by which OSHA should do so. James Hardie Building Products, Inc. commented that additional controls demonstrated to maintain or increase employee protection should be incorporated by reference whenever they become available ''without the need to undergo a formal rulemaking process'' (Document ID 2322, pp. 21–22). The National Consumers League and the American Public Health Association suggested that OSHA consider updating Table 1 periodically (*e.g.,* every five years) and publish a direct final rule to adopt a revised Table 1 when NIOSH deemed new dust control technology effective and feasible (Document ID 2373, p. 3; 2178, p. 3). Similarly, the Center for Effective Government urged OSHA to review Table 1 every five years and make revisions when new control technologies are found to be technologically and economically feasible (Document ID 3586, Tr. 3319).

Other commenters urged OSHA to consider mechanisms to update Table 1 without going through the rulemaking process. NIOSH suggested that the Agency develop a database of control technologies to supplement those on Table 1, rather than initiate rulemaking to update Table 1 (Document ID 2177, Attachment B, pp. 20–21). LHSFNA suggested that OSHA post enforcement decisions based on objective data online and permit employers performing similar tasks to use the controls specified in those decisions to meet their obligations under Table 1 (Document ID 4207, pp. 2–3). Holes Incorporated argued that Table 1 should be amendable by employers when testing proves that using such controls would ensure compliance with the PEL (Document ID 3441, p. 12; 3580, Tr. 1491).

IUOE, BCTD, and BAC argued that Table 1 should be an appendix to the rule so that it can be more easily updated (Document ID 2262, pp. 48–49; 2329, p. 6; 2371, Attachment 1, pp. 30–31). BCTD offered an approach for updating Table 1 that relied on the Agency establishing a mechanism for employers, equipment manufacturers, and others to submit data to the Agency for evaluation and subsequent inclusion in future versions of Table 1. BCTD proposed:

> OSHA could publish the criteria in a non-mandatory appendix to the standard, so employers, manufacturers and researchers would have a clear understanding of what they will have to demonstrate to get their proposed controls onto the table.
>
> Interested parties could then request that OSHA evaluate a control option, supporting their request with objective data, peer-reviewed studies, reports by NIOSH or other governmental agencies, or other reputable sources. If OSHA determined, based on the supporting data, that the technology meets its criteria for inclusion on Table 1, OSHA would issue an interpretative letter to that effect and/or issue a compliance directive advising its compliance officers that employers that fully and properly implement the particular control should be treated as if they were in compliance with the requirements of Table 1. This approach would enable OSHA to continually add to the options employers can utilize as new technologies come on-line, while at the same time ensuring that these additional controls meet the Agency's criteria (Document ID 4223, p. 100).

Charles Gordon also provided a detailed suggestion for the addition of regulatory text to address the issue of updating Table 1:

> Updating controls. (i) Three years from the effective date of this standard and every 3 years thereafter, OSHA shall request comments on new or improved engineering controls which can achieve the PEL or Action Level without supplementary respirator use for operations specified in Table 1 or other operations not in Table 1 that have crystalline silica exposure over the Action Level.
>
> (ii) If OSHA concludes that a new control will achieve the PEL without supplementary respirator use, it shall publish a notice permitting that control to be used for that Table 1 operation along with the other permitted controls or publish a direct final rule including that other operation in Table I and permitting the use of that control.
>
> (iii) If a commenter submits to OSHA an engineering control for an operation in Table 1, which can achieve the action level without supplementary respirator use based on valid studies and cost data showing it is feasible, then no later than the date specified in paragraph (f)(6)(i), OSHA shall publish a proposal, proposing that that engineering control be the required engineering control for that operation (Document ID 4236, Appendix 1, p. 1).

Based on the comments and perspective reflected in the rulemaking record, OSHA sees the value in periodically updating Table 1 and is concerned that a static Table 1 may discourage innovation in the development of control technologies for reducing silica exposure. However, while OSHA may certainly consider future updates or adjustments to Table 1 if warranted, it will likely need to accomplish substantive changes through additional rulemaking. In any event, it has no intention to bind a future Administration to such rulemaking, whether to update Table 1 in particular or the entire rule in general, according to a schedule built into this rule. Meanwhile, the need to revise Table 1 in the future should be limited since the controls specified—primarily wetting the dust or ventilating and collecting the dust—are stated in general terms that will not be rendered obsolete by, for example, design improvements to water spraying or vacuuming equipment.

Even if the proposed mechanisms are consistent with the law governing rulemaking, OSHA is unwilling to specify a mechanism for updating Table 1 for several reasons. First, the procedures outlined by BCTD and Charles Gordon would commit the Agency to spend future resources to accept a large volume of information from interested parties, evaluate it in a timely manner, and prepare the needed economic and technological feasibility analysis and other rulemaking documents. OSHA may have higher rulemaking priorities and demands on its resources at that time, however. Second, Table 1 cannot both contain enforceable means of compliance and also be contained in a non-mandatory appendix. To ensure that employers who do not conduct exposure monitoring comply fully with the Table 1 provisions, OSHA must include the control specifications of Table 1 in the final standard for construction as requirements rather than as non-mandatory recommendations. Third, the

controls specified on Table 1 are flexible and not tied to existing technology. The controls specified on Table 1 provide for the use of wet methods, ventilation, and in some cases, isolation. OSHA did not provide specific criteria for ventilation systems (size, air flow rate, etc.) or water flow rates. Instead, OSHA specifies that employers must operate the tools with integrated dust controls in accordance with the manufacturer's instructions. These instructions provide flexibility to take advantage of advances in technology. For example, as manufacturers develop effective surfactants to be used with water to further reduce silica exposure, there will be no need for OSHA to update Table 1 to specifically allow employers to use them. The requirement to use wet methods would still be satisfied.

Thus, OSHA rejects the suggestions to establish a specific mechanism for updating Table 1 in the future. If significant technological advances occur that require OSHA to initiate rulemaking in order to incorporate emerging technology not already encompassed by this rule, it will do so in the context of its rulemaking priorities at that time. Of course, interested parties may petition the Agency at any time to modify the dust control specifications on Table 1 of the standard for construction, and OSHA will consider such petitions based on the likely benefit that will accrue to workers and the Agency's available resources at the time.

Comparison with consensus standards. The requirements in paragraph (c) of the standard for construction are generally consistent with ASTM E 2625–09, the national consensus standard for controlling occupational exposure to respirable crystalline silica in construction. The ASTM standard provides a task-based control strategy, including five tables that specify control measures and respiratory protection for common construction equipment and tasks. While the ASTM standard provides this task-based control strategy, it also applies the PEL and exposure assessment to these tasks, as OSHA did in its proposal. However, OSHA's final standard for construction, as discussed above, takes a different approach by requiring specific engineering controls, work practices, and respiratory protection for construction tasks on Table 1; where employers fully and properly implement the engineering controls, work practices, and respiratory protection specified on Table 1, compliance with Table 1 is in lieu of the performance-oriented approach involving a PEL and exposure assessment, as provided as an alternative exposure control method in paragraph (d) of the standard for construction. Additionally, there are numerous differences between the tasks listed and the engineering controls, work practices, and respiratory protection specified on OSHA's Table 1 and those included on ASTM's tables. The ASTM standard also does not divide tasks according to duration and does not apply the approach to tasks limited to 90 minutes total time. The differences between OSHA's standard and the consensus standard, including those in the overall approach to compliance and in the format of Table 1, the tasks listed, and the engineering controls, work practices, and respiratory protection specified, best reflect the evidence received into the rulemaking record and the realities of the construction industry. These differences will also enhance compliance with OSHA's standard in the construction industry and, in doing so, better effectuate the purposes of the OSH Act and protect employees in the construction industry from the significant risks posed by exposures to respirable crystalline silica.

Table 1 entries. Table 1 identifies 18 common construction equipment/tasks known to generate high exposures to respirable crystalline silica. For each kind of equipment/task identified, Table 1 specifies appropriate and effective engineering controls, work practices, and, when necessary, respiratory protection. As proposed, Table 1 listed 13 construction operations that expose employees to respirable crystalline silica and identified control strategies and respiratory protection that reduce those exposures. OSHA received many specific comments about particular entries on Table 1 and on the specified engineering controls, work practices, and respiratory protection included for each entry. The additional equipment/tasks included on Table 1 of the final rule for construction are handheld power saws for cutting fiber-cement board (with blade diameter of 8 inches or less) and rig-mounted core saws and drills. Other entries on Table 1 of the final standard for construction were broken out from those proposed and added as separate entries. These include dowel drilling rigs for concrete (included under ''Operating Vehicle-Mounted Drilling Rigs for Concrete'' on proposed Table 1), walk-behind milling machines and floor grinders (included under ''Milling'' on proposed Table 1), small drivable milling machines (included under ''Milling'' on proposed Table 1), large drivable milling machines (included under ''Milling'' on proposed Table 1), heavy equipment and utility vehicles used to abrade or fracture silica-containing materials or used during demolition activities involving silica-containing materials (included under ''Heavy Equipment During Earthmoving'' on proposed Table 1), and heavy equipment and utility vehicles for tasks such as grading and excavating, but not demolishing, abrading, or fracturing silica-containing materials (included under ''Heavy Equipment During Earthmoving'' on proposed Table 1). One entry on Table 1 of the final standard for construction, vehicle-mounted drilling rigs for rock and concrete, is the result of combining two entries from proposed Table 1 (''Operating Vehicle-Mounted Drilling Rigs for Rock'' and ''Operating Vehicle-Mounted Drilling Rigs for Concrete''). One proposed entry, ''Drywall Finishing,'' was not included on Table 1 of the final standard for construction. A discussion of each of the 18 Table 1 entries in the construction standard, including the comments received and the changes made from the proposed Table 1 entries, follows below in the order in which they appear on Table 1.

Stationary masonry saws. Stationary masonry saws are used in the construction industry to cut silica-containing masonry materials such as bricks, concrete blocks, stone, and tile (see Section 5.7 of Chapter IV of the FEA). They are mounted either on a table-top or a stand, and include a flat platform where the work piece (*e.g.,* a brick) sits before the worker brings a rotating circular abrasive blade into contact with the work piece by either pressing a swing arm mounted blade onto the piece or by moving the piece on a sliding platform into contact with a fixed blade (Document ID 4073, Attachment 4a, Rows 42–48, 55–63, 179–188, 288–297, 343–351). The cutting surface is about waist-high and at arm's length from the worker's breathing zone. A nozzle for spraying water is usually attached near the blade, and is connected to a water basin of some kind via a hose.

When using stationary masonry saws, paragraph (c)(1)(i) of the standard for construction requires that saws be equipped with an integrated water delivery system that continuously feeds water to the blade and that the tool be operated and maintained in accordance with manufacturer's instructions to minimize dust emissions. Saw designs vary between manufacturers and, as with other operating parameters, manufacturer's recommendations for optimizing wet methods are likely to vary somewhat with the saw size and

design. OSHA is not specifying a minimum flow rate; based on the evidence in the record, OSHA anticipates that the water flow rate specified by the manufacturer will optimize dust reduction. OSHA recognizes that the employer's best available information for reducing dust with a specific control comes from the manufacturer's operating instructions. This is why OSHA is requiring the saw be operated and maintained according to the manufacturer's instruction to minimize dust.

The language describing the required control for stationary masonry saws was revised from the proposed rule to clarify that water must be continuously applied to the blade, and language was added to require that manufacturer's instructions be followed. This reflects OSHA's intent that employers use a saw with integrated water delivery system supplied by the saw manufacturer. OSHA finds that systems that are developed in conjunction with the tool are more likely to control dust emission effectively by applying water at the appropriate dust emission points based on tool configuration, and not interfere with other tool components or safety devices. These include free-flowing water systems, with or without a pump and basin, that are designed for blade cooling, as well as manufacturer systems designed for dust suppression alone (Document ID 1555, p. 509; 3998, Attachment 12a, pp. 9, 15–16; 3998, Attachment 12e, p. 3).

The proposed entry for stationary masonry saws also included a note requiring that water be changed frequently to avoid silt build-up in water and that the blade not be excessively worn. CISC commented that terms such as these were too ambiguous and would thus prevent the table from being a realistic compliance option (Document 2319, p. 98). OSHA understands that these notes could be subject to interpretation and in response, has removed the notes from Table 1. However, these practices are often included in manufacturer's instructions, and OSHA considers these type of instructions to be part of fully and properly implementing engineering controls (*e.g.,* Document ID 4073, Attachment 4a, Rows 59–61).

In the FEA, OSHA's exposure profile for stationary masonry saws shows that wet cutting is an effective dust control. The median 8-hour TWA exposure in the profile is 34 μg/m^3 for workers using saws with water delivery systems (Table IV–5.7–B in Section 5.7 of Chapter IV of the FEA) and the mean exposure for wet cutting is 41 μg/m^3, substantially lower than the mean of 329 μg/m^3 for dry cutting operations, a disparity that affirms that use of water on stationary saws significantly reduces exposure to respirable crystalline silica. Additional field data also show the effectiveness of water to control respirable crystalline silica exposures during cutting. Flanagan *et al.*, in their 2006 study and 2009 data set, found that wet cutting methods (details not available) were associated with markedly lower exposure levels than were reported for all workers using table-mounted saws (Document ID 0677; 0677, Attachment 2). The silica concentrations reported by Flanagan *et al.* over the sampling period (ranging from 12 to 505 minutes) when wet cutting ranged from 6 μg/m^3 to 316 μg/m^3, with a mean of 73 μg/m^3 and median of 46 μg/m^3 (Document ID 0677; 0677, Attachment 2). Since most of the sample durations in this dataset were less than 360 minutes, workers' 8-hour TWA exposures were even lower. These data also included indoor work.

In addition to these field results, the record includes experimental studies that examined the effectiveness of wet dust control systems. Meeker *et al.* (2009) compared intensive masonry cutting done without controls to exposures while using saws with integrated water delivery systems and maximum flow rates of 2.3 and 2.4 liters per minute (0.6 and 0.63 gallons per minute) and found that wet saws were associated with a 91 percent reduction in exposure to respirable quartz (Document ID 803, p. 1; 2177, Reference 11, pp. 104, 107–108). Carlo *et al.* (2010) found reduction rates of 99 percent in the respirable dust exposure when water was applied at the manufacturer-recommended water flow rate, compared to dry cutting (Document ID 3612, pp. 246–247, 249). While respirable dust reductions do not always translate to exactly the same percent reduction in respirable silica levels, OSHA finds that respirable dust reductions are a reliable indicator of the capability of the control to reduce respirable silica. Therefore, OSHA anticipates that the control discussed in Carlo *et al.* (2010) would result in significant reductions to silica exposures.

CISC questioned the appropriateness of requiring an integrated water delivery system when most integrated systems are intended to keep the blade cool and are not designed for dust suppression (Document ID 2319, p. 109). However product literature submitted to the docket from five major saw manufacturers (Andreas Stihl, Husqvarna, Hilti, Makita USA, and Wacker Group) highlights the use of water application equipment to suppress dust in addition to blade cooling (Document ID 3620, pp. 6, 10, 24, 30; 3998, Attachment 12a, pp. 9, 15–16; 3998, Attachment 12e, p. 3; 3998, Attachment 12f; 3998, Attachment 12h; 4233, Attachment 1, p. 6). Beamer *et al.* (2005) conducted experiments to observe the differences in the various wet cutting methods available and found that the greatest improvement in dust reduction occurred with freely flowing water applied at a rate of 48 gallons per hour (0.8 gallons per minute), resulting in dust reduction of about 93 percent and confirming the benefits of water flowing over the stationary saw cutting blade compared with other misting systems (Document ID 1555, p. 509). Therefore, based on the evidence in the record, OSHA has determined that stationary masonry saws equipped with an integrated water delivery system are effective and the best available technology for controlling respirable crystalline silica.

Several commenters suggested that OSHA include an option for dry cutting on Table 1 (*i.e.*, using LEV or other non-wet methods to control dust) because wet methods were not always available and certain materials are required to be cut dry. Commenters explained that freezing temperatures, lack of available water sources on new construction sites, concerns of water damage to surrounding areas during indoor work and problems with discoloration or water staining materials were all reasons why an employer may elect to cut without water (Document ID 0861, p. iv; 1431, pp. 1–6–1–9; 2296, p. 31; 2319, p. 94; 2320, pp. 6–7; 3587, Tr. 3609–3610; 4220, p. 5).

OSHA addresses the issue of freezing temperatures and availability of water in the technological feasibility analysis (Chapter IV of the FEA) and has determined that these barriers can be overcome in most instances, for example by wrapping gutter heat tape around drums of water or adding environmentally-friendly antifreeze additives to water (*e.g.,* Document ID 3589, Tr. 4214, 4230). Moreover, evidence in the record indicates that LEV is not as effective as wet methods for controlling silica dust emissions from stationary saws. In the only study available to OSHA that directly compared wet dust suppression with LEV under the same experimental conditions, Carlo *et al.* (2010) determined that, even though the use of LEV resulted in substantial respirable dust capture, the water application system reduced the dust to a greater extent, reducing respirable dust levels by a factor of 10 more than the LEV systems tested (Document ID 3612, pp.

247–250). Unlike for wet dust control systems, there is little evidence in the record that LEV systems have proven effective in actual field use; the database compiled by Flanagan *et al.* contains no sample results from using stationary saws with LEV (Document ID 0677, Attachment 2).

OSHA finds that the study by Carlo *et al.* indicates that LEV systems on stationary saws are not as effective as water-based dust suppression systems and that respiratory protection will likely be needed. In the PEA, OSHA acknowledged that there was some evidence that exposures could be reduced to or below 50 μg/m^3 with LEV when saws were used for typical cutting periods (15 to 30 percent of the shift) but that the effectiveness of LEV systems for stationary saws had not been widely evaluated. However, no evidence came into the record after the PEA that would allow OSHA to have greater confidence in the use of LEV when dry cutting or to consider it to be as effective as wet cutting in reducing silica dust exposure. Therefore, OSHA has not included a control alternative for the use of dry cutting with LEV in Table 1, and is only allowing integrated water systems for compliance with Table 1.

OSHA understands that there may be limited situations where the use of wet systems is not feasible for a given application. For those situations, the employer may use other means of dust control such as LEV systems, but the employer must then follow paragraph (d) rather than paragraph (c) of the standard for construction, *i.e.*, comply with the 50 μg/m^3 PEL, perform exposure assessments to determine compliance with the PEL, and supplement the engineering and work practice controls with respiratory protection where the PEL is not being met.

Stationary masonry saws with integrated water systems are readily available from several manufacturers including EDCO, Andreas Stihl, Hilti, Makita USA, Husqvarna, Wacker Group, MK Diamond, and Bosch (for tile cutting) and are effective and the best control option available (Document ID 4073, Attachment 4a, Rows 59–63, 183–188, 292–297, 347–351, 417–419; 4073, Attachment 4b, pp. 10–12, 21; 3998, Attachment 12a; 3998, Attachment 12e; 3998, Attachment 12f; 3998, Attachment 12g; 3998, Attachment 12h). Therefore, OSHA has determined that an integrated water delivery system is the appropriate control for inclusion on Table 1.

In the proposed rule, OSHA required the use of a half-mask respirator for employees who operated stationary masonry saws for more than four hours. OSHA made this determination based on the highest exposure results included in its exposure profile. OSHA has since determined that when fully and properly implementing all of the provisions under paragraph (c), employees can operate stationary masonry saws without the use of respirators. This is supported by the exposure profile contained in Table 5.7–B in Section 5.7 of Chapter IV of the FEA, which shows a mean exposure of 41 μg/m^3, a median of 34 μg/m^3 and 75 percent of the sample results below 50 μg/m^3. Flanagan *et al.* reported similar exposures with a mean exposure of 48 μg/m^3 crystalline silica from four exposure samples taken while workers operated saws indoors or in enclosed areas (Document ID 0677, Attachment 2). While water use was not described in any detail, these data show that exposures can be consistently maintained at a level where respiratory protection is not needed. Therefore, the final rule does not require the use of respiratory protection when employers are using wet stationary saws in accordance with Table 1, even when stationary masonry saws are used indoors or in otherwise enclosed areas (situations which are the most likely to generate high exposures).

Handheld power saws (any blade diameter). In the proposed rule, this entry was listed as ''Using Handheld Masonry Saws.'' OSHA has changed the title of this entry in the final rule to clarify that the requirements in Table 1 apply to any use of handheld power saws, not just those involving masonry materials. However, the tools included under this entry have not changed and include cut-off, chop, quickie, and handheld masonry saws.

Handheld power saws are used in the construction industry for cutting a variety of materials (*see* Section 5.6 of Chapter IV of the FEA). They usually consist of a semi-enclosed circular blade, directly adjacent to or in front of two handle grips which are perpendicular to each other. The blade enclosure covers the half (or more) of the blade directly facing the worker. A worker typically will use the blade to cut a work piece (*e.g.*, a brick) placed on the ground by starting the device and slowly lowering the entire handheld saw with both hands to the work piece until the rotating blade makes contact and begins to cut, at which point the worker applies pressure to the work piece and cuts appropriately (Document ID 4073, Attachment 4a, Row 47). A nozzle for spraying water is usually located near the blade, and a water source is usually connected to the saw from a water source via a hose (Document ID 3998, Attachment 12e; 3998, Attachment 12f; 3998, Attachment 12h, pp. 10–11).

When using handheld power saws with any blade diameter (except saws used to cut fiber-cement board), paragraph (c)(1)(ii) of the standard for construction requires that saws be equipped with an integrated water delivery system that continuously feeds water to the blade and that it be operated and maintained in accordance with manufacturer's instructions to minimize dust emissions. Like stationary saws, designs vary between manufacturers and, as with other operating parameters, recommendations for optimizing wet methods are likely to vary somewhat with the saw size and design. In light of these variables, OSHA is not specifying a minimum flow rate. In addition, OSHA is recognizing that the employer's best available information for reducing dust with a specific control comes from the manufacturer's operating instructions, which is why OSHA is requiring the saw be operated and maintained according to the manufacturer's instructions to minimize dust. Water-fed handheld saws are commercially available from a variety of sources (Document ID 0615; 0737; 3998, Attachment 12e; 3998, Attachment 12a; 3998, Attachment 12f; 3998, Attachment 12g; 3998, Attachment 12h).

The data in the record and the studies reviewed by OSHA demonstrate that water spray suppression systems reduce respirable crystalline silica exposures substantially where the system was well designed and properly implemented and maintained (Document ID 0868; 1181; 3497; 3610; 3777; 4073, Attachment 8a). Use of an integrated water delivery system on the cut-off, chop, quickie or masonry saws has been shown to reduce respirable dust exposures by 78–96 percent (Document ID 0868, p. v; 1181, p. 443; 3610, p. 157; 3777, p. 67). Data compiled by the CSDA from member jobsites as well as NIOSH documents showed that all outdoor hand sawing using a saw equipped with a water supply produced exposure levels below a TWA of 50 μg/m^3 (Document ID 3497, p. 5).

In a laboratory study, Thorpe *et al.* (1999) evaluated the effectiveness of two types of water supplies commonly used with handheld saws: (1) A pressurized portable water supply and (2) a constant water supply (Document ID 1181, pp. 443, 445–447). During this evaluation, 15-minute PBZ samples were collected during uncontrolled and controlled (*i.e.*, water-fed) cutting of concrete slabs containing 20 percent to 40 percent

silica (*i.e.*, worst-case conditions) (Document ID 1181, p. 447). The study protocol involved short sampling durations because handheld saws are typically used intermittently to make short cuts. The uncontrolled mean silica concentration during multiple 15-minute trials of intensive cutting ranged from 1,700 μg/m^3 to 4,800 μg/m^3 (reported as 1.7 to 4.8 mg/m^3) (Document ID 1181, p. 448). Reductions in exposure to respirable silica dust when cutting concrete slabs using wet methods compared with no controls were 75 percent for diamond blades and 94 percent for resin blades when using water supplied by mains, and 75 percent for diamond blades and 77 percent for resin blades when using water supplied by a portable tank. Both sources of water were effective at reducing respirable dust, however, the portable tank needed to be periodically re-pressurized to maintain the necessary flow rate, while the water supplied from the mains provided a more constant flow rate. Both types of systems used to supply water to an integrated water delivery system would be acceptable under the table.

NIOSH also evaluated the performance of a commercially available water backpack and spray attachment, pre-set by the attachment manufacturer to provide 1.4 liters per minute water consumption (0.36 gallons per minute) for handheld saws during concrete block cutting (Document ID 0868, pp. 8, 11). The handheld electric abrasive cutter was used outdoors to make cuts through concrete blocks laid lengthwise on a plank 17 inches above the ground. During the 5- to 10-minute trials with water-fed saws, the water spray attachment reduced quartz exposures by an average of 90 percent from uncontrolled levels (Document ID 0868, p. 10). Middaugh *et al.* (2012) conducted a workplace field study to evaluate the effectiveness of dust controls on cut-off saws (Document ID 3610, p. 158). Air sampling was conducted for 10 days at 5 job sites on 4 experienced operators using gas-powered cutoff saws with 14 inch (35.6mm) diameter blades to cut concrete curbs (Document ID 3610, p. 159). Air sampling was conducted both with and without wet methods; sampling ranged from 4 to 16 minutes and corresponded to the entire duration of the task (Document ID 3610, pp. 159–161). With wet suppression, the concentration of respirable silica levels was reduced 78 percent to 210 μg/m^3 (Document ID 3610, p. 162).

Based on the information in the record, OSHA concludes that most of the time, handheld power saw operators use the saw for two hours or less over the course of a workshift, typically using handheld saws for brief, intermittent periods repeated numerous times over the course of a shift (Document ID 1431, p. 3–63). The Mason Contractors Association of America stated that ''90 minutes is actually a really long time to be cutting something. The vast majority of [cutting tasks] are under 15 minutes [total] in any given day'' (Document ID 3585, Tr. 2911). The Bay Area Roofers Waterproofers Training Center agreed, clarifying that when cutting is performed as part of its work it is usually half an hour to 45 minutes a day (Document ID 3581, Tr. 1598). Information contained in research supports this as well. Thorpe *et al.* (1999) used 15-minute sampling durations in the study protocol because handheld saws are typically used intermittently to make short cuts (Document ID 1181, pp. 447–448). Middaugh *et al.* (2012) explained that concrete cutting in roadway construction is frequently performed with a handheld saw, noting that ''although some applications may require cutting for an entire 8-hour workday, typical cutting is performed for less than two hours per day'' (Document ID 3610, p. 162). Sample times from the Flanagan *et al.* database support this; the median time for using handheld portable saws was 101 minutes and the range of cutting times was from 9 to 447 minutes, indicating that saws are typically used for only a portion of the shift, although some workers cut for longer durations (Document ID 0677, Attachment 2).

Estimated TWA exposures (*i.e.*, averaged over eight hours) using task measurements from field studies may exceed 50 μg/m^3 when workers cut with water for two or more hours per day (Document ID 3610; 4073, Attachment 8a, p. 1; 0868). Shepherd and Woskie (2013) estimated that if typical cutting conditions (intensive cutting) were performed outdoors with wet methods for two hours and no other exposure occurred for the remainder of the day, 83 percent (88 out of 106) of the saw operators' 8-hour TWA exposures would be 50 μg/m^3 or less (Document ID 4073, Attachment 8a, p. 1). In further analysis, the authors considered what would happen if operators used the water-fed saws outdoors at this same level of intensity for a full 6 hours of the shift, in which case 61 percent of operators would have 8-hr TWA exposures of 50 μg/m^3 or less (Document ID 4073, Attachment 8a, p. 1).

In the proposal, OSHA based its requirement to use respiratory protection for operating saws more than four hours per shift on the few higher exposure values in its exposure profile, which indicated that exposures would exceed 50 μg/m^3 occasionally when wet cutting with portable saws. However, OSHA concludes that the study by Shepherd and Woskie (Document ID 4073, Attachment 8a) as well as other material contained in the record and discussed above provide a better basis on which to determine the need for respiratory protection. Based on these studies, OSHA determined that outdoor wet cutting for more than four hours could result in more frequent exposures over 50 μg/m^3 than are experienced with shorter task durations. Therefore, paragraph (c)(1)(ii) of the standard for construction requires use of respiratory protection having an APF of at least 10 for employees using a handheld power saw of any blade diameter equipped with an integrated water delivery system for more than four hours per shift. When cutting for four hours or less outdoors, no respiratory protection is required.

The vast majority of samples reviewed by OSHA involve the use of handheld saws outdoors. However, employees may occasionally use handheld saws indoors. When an employee uses a water-based system indoors or within enclosed areas, elevated exposures can still occur (Document ID 0675; 0177; 0846; 3497; 3777). Data submitted by CSDA shows that almost all indoor hand sawing using wet methods produced exposure levels above 50 μg/m^3 (Document ID 3497, pp. 1–4, 6, 8). Additionally, a field study of wet sawing found that an enclosed location (in a large garage building open in front and closed on 3 sides) resulted in significantly higher exposures than when the work was done outdoors (Document ID 3777, p. 1); a separate study found levels as high as 240 and 260 μg/m^3 during indoor wet sawing (Document ID 0675, p. 1098). OSHA's exposure profile contained in Section 5.6 of Chapter IV of the FEA shows that using wet methods indoors results in higher exposures when compared to outdoor cutting with only 50 percent of the exposures in indoor environments being 50 μg/m^3 or less, compared to 80 percent of the outdoor wet sawing samples. Although wet methods substantially reduce operator exposures compared to uncontrolled dry cutting indoors, elevated exposures still occur routinely. To reduce these exposures, OSHA is requiring that work done indoors or in enclosed areas have

additional general ventilation such as exhaust trunks, fans, air ducts or other means of forced air ventilation to prevent the accumulation of dust in the work area. Accordingly, for indoor work, paragraph (c)(1)(ii) requires the use respiratory protection with an APF of 10 regardless of task duration.

Representatives from the roofing industry expressed concern regarding the use of wet methods in their industry, citing primarily the potential increase in slips and falls from introducing water to elevated worksites (Document ID 2320, p. 116; 2192, p. 4; 3526, p. 7). The Tile Roofing Institute stated that in California and Arizona, rooftop operations with roofing tiles or pavers are given an exemption from the requirement to use a dust reduction system because there is no way to address both the silica and fall protection hazard (Document ID 3587, Tr. 3595). Conversely, testimony from the public hearings indicates that wet dust control systems can be used to reduce exposures to silica during cutting of roofing tiles and pavers. Dan Smith, director of training for the Bay Area Roofers and Waterproofers Training Center, testified that the roofing industry in California is starting to voluntarily cut roofing tiles and pavers wet (Document ID 3581, Tr. 1600–1601; 1638) and that use of controls may actually increase visibility, thereby reducing a potential fall hazard (Document ID 3581, Tr. 1603–1604). He also explained that dry cutting of roofing tiles is prohibited in the U.K., and that the contractors association (the National Federation of Roofing Contractors), ''. . . provides guidance and training. They use wet saws on scaffolding at the roof level . . . they use a [water] mister on the tile saw. They use a system like the hytile . . . which is a tile breaking tool'' (Document ID 3581, Tr. 1601).

OSHA understands the concerns expressed by representatives from the roofing industry regarding the use of wet methods and increased risk for falls; however, OSHA concludes that alternate project planning can enable employers to use wet methods by implementing some of the measures described above.

In the proposed rule, OSHA included an option under Table 1 for the use of LEV when using portable masonry saws. While including LEV as an alternative to wet methods in the table was supported by both labor and industry groups (Document ID 2296, p. 32; 4223, p. 140; 4233, Attachment 1, p. 1), OSHA has removed this option from Table 1 based on information contained in the record indicating that LEV cannot consistently maintain exposure at or below a TWA exposure level of 50 μg/m^3 (*see* Section 5.6 of Chapter IV of the FEA). OSHA is not prohibiting use of LEV for dry cutting, as LEV may be effective in reducing exposure to or below 50 μg/m^3 in situations where, for example, saw use is intermittent. Employers who choose to do so may still use LEV in lieu of an integrated water system; however, those employers would be required to comply with the PEL and exposure assessment requirements under paragraph (d) of the standard for construction.

Handheld power saws for cutting fiber-cement board (with blade diameter of 8 inches or less). These specialized saw configurations consist of blades (with four to eight teeth) specifically designed for cutting fiber-cement board (*see* Section 5.6 of Chapter IV of the FEA) (Document ID 2322, p. 9; 2322, Attachment B, p. 8). The blades are fitted to a circular saw (or occasionally to other saws) with dust reduction systems (Document ID 2322, p. 9; 2322, Attachment B, p. 36). These saws have been specifically designed and tested by a member of the fiber-cement siding industry and by NIOSH for controlling the silica exposure of installers who perform cutting in that industry, and the saw is intended specifically for use on fiber-cement board (Document ID 2322, pp. 5, 9; 2322 Attachment B, pp. 33, 36).

When using handheld power saws with a blade diameter of 8 inches or less for cutting fiber-cement board outdoors, paragraph (c)(1)(iii) of the standard for construction requires saws to be equipped with a commercially available dust collection system that provides the air flow recommended by the manufacturer and a filter with a 99 percent or greater efficiency, operated in accordance with the manufacturer's instructions to minimize dust emissions. OSHA is not providing an entry for use of these saws indoors on Table 1 because fiber-cement board, used as siding and fascia applied to the exterior of buildings, is usually cut outdoors and the record lacks information on exposures to silica that would result from cutting fiber-cement board indoors. Therefore, employers who choose to operate saws to cut fiber-cement board indoors must conduct exposure assessments and comply with the PEL in accordance with paragraph (d) of the standard for construction.

This entry was added to Table 1 of the final standard for construction in response to comments NIOSH and the fiber-cement board industry submitted to the rulemaking record. These submissions provided substantial data on control technology (a specially configured saw) for controlling silica exposure when saw operators cut fiber-cement board (Document ID 2177, Attachment B, pp. 17–19; 2322, Attachment B–E and H).

The James Hardie Building company submitted 75 samples for workers using specially configured circular saws (with specialty blades of less than 8 inches) for cutting fiber-cement board with LEV (Document ID 2322, pp. 19–20). These saws were all fitted with cutting blades designed for the fiber-cement board product and some form of dust collector (but not always designed with vacuum suction). Workers using these saws had a mean 8-hour TWA exposure of 11 μg/m^3 (median 7 μg/m^3), although elevated exposures (maximum exposure of 76 μg/m^3) occurred with some saw/control configurations that proved less reliable (for example, saws attached to a dust receptacle, without the benefit of a vacuum dust collection device) (Document ID 2322, pp. 19–20). Although the cutters sawed fiber-cement board products containing 15 to 50 percent silica, the respirable dust collected in the samples was 0 to 12 percent silica and percentages in the lower half of that range were most typical (Document ID 2322, Attachment D, pp. 5–10; 2322, Attachment E, pp. 5–9; 2322, Attachment F, pp. 5–10). Most of the sawyers for whom exposures were elevated cut siding for approximately half the shift (four to five hours), a duration representative of typical cutting activities during a normal day of fiber-cement siding installation (Document ID 2322, Attachment D, p. 16; 2322, Attachment E, p. 16; 2322, Attachment F, p. 18). Several NIOSH reports demonstrate that this and other saw configurations are effective in achieving exposures of 50 μg/m^3 or below when the saw is used with a vacuum dust collector (Document ID 4138; 4139, p. 11; 3998, Attachment 4a; 3998, Attachment 4b; 3998, Attachment 4c).

Based on the evidence in the record, commercially available dust collection systems for handheld power saws with a blade diameter of 8 inches or less and a dust collection device providing the air flow recommended by the manufacturer have been demonstrated to be particularly effective in controlling silica during outdoor cutting of fiber-cement board. One type of saw evaluated was a handheld, dust collecting model equipped with dust collection device rated at 200 cfm over a 7.25-inch-diameter blade (27.5 cfm per inch); however, the measured flow rate was reported to be 69 to 106 cfm. Using this configuration, all 21 exposure

samples taken for siding cutters on construction sites were 41 μg/m³ TWA or less (20 sample results were less than 25 μg/m³) while cutting a variety of fiber-cement board siding products containing up to 50 percent silica (Document ID 3998, Attachment 4a; 3998, Attachment 4b; 3998, Attachment 4c; 4138; 4139). Accordingly, OSHA is requiring in paragraph (c)(1)(iii) that dust collectors be used with saws when cutting fiber-cement board.

Based on the evidence in the record, OSHA is not requiring the use of respiratory protection when employees are using handheld power saws with a blade diameter of 8 inches or less, for cutting fiber-cement board outdoors in accordance with Table 1 for any task duration. OSHA has determined that in such circumstances, employee exposures will be reduced to 50 μg/m³ or less when the controls specified for this task on Table 1 are fully and properly implemented.

Walk-behind saws. When using walk-behind saws (*see* Section 5.6 of Chapter IV of the FEA), paragraph (c)(1)(iv) of the standard for construction requires that saws be equipped with an integrated water delivery system that continuously feeds water to the blade and that the tool be operated and maintained in accordance with manufacturer's instructions to minimize dust emissions. OSHA is specifying that the saws be used with an integrated water feed system because the Agency has identified this as the most effective means of reducing exposures to respirable crystalline silica. This requirement is essentially the same as was proposed for the entry ''Using Portable Walk-Behind and Drivable Masonry Saws.'' As explained below, requirements in the final rule for drivable saws have been separated from those for walk-behind saws.

Saw designs vary among manufacturers, and as with other operating parameters, recommendations for optimizing wet methods are likely to vary somewhat with the saw size and design. As with other saws, OSHA is not specifying a minimum flow rate, but rather anticipates that the water flow rates specified by the manufacturer will optimize dust reduction. OSHA recognizes that the employer's best available information for reducing dust with a specific control comes from the manufacturer's operating instructions, which is why OSHA is requiring the saw be operated and maintained according to the manufacturer's instructions to minimize dust. Water-fed walk-behind saws (manual and self-propelled) are widely available from many manufacturers and construction tool distributors, such as Grainger, EDCO, MK Diamond, and CS Unitec (Document ID 0715; 1676; 1185; 0643; 0615).

CSDA stated that ''nearly 100% of CSDA contractors use water on each and every job and this has to do with extending the life of the expensive diamond tools. The use of water has an additional benefit of containing silica particles that could become airborne'' (Document ID 3496, p. 3). This was supported by others during the public hearings (Document ID 3580, Tr. 1438; 3585, Tr. 2885) and in written comments (Document ID 2316, p. 3). Disagreeing, both SMI and the Mason Contractors Association of America commented that most water-fed systems are designed to keep the blade cool, and their ability to suppress dust has not been sufficiently researched (Document ID 2316, p. 3; 3585, Tr. 2885). CISC similarly asked whether an additional water feed is needed for these saws or whether the one currently integrated for the purpose of cooling the saw will suffice (Document ID 2319, p. 104).

OSHA finds that considerable evidence in the record shows that water application reduces dust emissions, and several saw manufacturers state that using wet cutting will suppress dust (*see* discussion about requirements for water delivery systems above). Furthermore, the water delivery system described in Linch (2002) was for the purpose of cooling or protecting the blade, but was effective in suppressing respirable silica levels to below 50 μg/m³ (Document ID 0784, p. 216). CSDA submitted exposure data collected during slab sawing with saws ''equipped with water supply,'' presumably for blade cooling. Those data show that of 26 measurements of silica concentrations taken during outdoor work, 21 (80 percent) were less than 25 μg/m³, and only one sample (65 μg/m³) exceeded 50 μg/m³ (Document ID 3497, pp. 2–4). Therefore, OSHA concludes water provided as coolant can also control silica exposure.

CISC questioned the feasibility of using wet methods in situations where there is no established water main on site (Document ID 2319, p. 112). OSHA finds that water tanks, which were used to provide water to the walk-behind saws in Linch (2002), are already commonly available on many construction sites and could provide water for a walk-behind saw (Document ID 0784, pp. 216–217).

Data contained in the record show that none of the respirable silica results associated with wet cutting outdoors using walk-behind saws exceeds 50 μg/m³, with the majority of these results being less than or equal to the limit of detection (Document ID 0784, pp. 216–217). These results were obtained using the saw's normal water feed system intended for cooling the blade. Therefore, OSHA has determined that no respiratory protection is required when working outdoors with a walk-behind saw for any task duration.

Since walk-behind saws are used to cut pavement, they are most commonly used outdoors, though they can also be used indoors (Document ID 1431, pp. 3–63). Although the data are limited, water-fed walk-behind saws used indoors or in enclosed areas may result in higher exposures than those measured outdoors. Studies by both NIOSH and Flanagan *et al.* (2001) noted the potential for elevated exposure when walk-behind saws with continuous water application are used indoors, with Flanagan *et al.* reporting four 8-hour TWA sample results between 65 to 350 μg/m³ for four to seven hours of work (Document ID 4233, Attachment 1, p. 10; 0675, pp. 1098–1099). Additionally, the CSDA report submitted to the record shows the only exposure result from indoor slab sawing exceeded 50 μg/m³ despite the use of equipment with water supply (Document ID 3497, pp. 2–4). These results indicate that the source for the elevated exposure is likely due to the build-up of respirable aerosol within the enclosed space, rather than direct exposure to slurry spray (Document ID 0675, p. 1099). While OSHA anticipates that the results for indoor sawing can be reduced by minimizing the build-up of dust with supplemental ventilation as required under paragraph (c)(2)(i) of the rule, OSHA is unable to conclude that exposures can be consistently reduced to 50 μg/m³ or less for this task when performed indoors. Therefore, when used indoors or in an enclosed area, OSHA is requiring the use of respiratory protection with an APF of 10 regardless of task duration.

Drivable saws. Paragraph (c)(1)(v) of the standard for construction requires that, when using drivable saws to cut silica-containing materials, the saw must be equipped with an integrated water delivery system that continuously feeds water to the blade and that the tool be operated and maintained in accordance with the manufacturer's instructions to minimize dust emissions. Drivable saws include those where the operator typically sits in a cab (open or enclosed) away from the pavement cut point, guiding the saw to make long cuts such as are common for utility installation along roadways. These saws are cumbersome to move and are typically only used when

making long cuts. The blade housed by the vehicle can be large (*e.g.*, 8 feet in diameter and 2 inches thick) and is usually equipped with a water-fed system to cool the blade (Document ID 1431, pp. 3–63—3–64). The requirement to use integrated water systems on drivable saws is unchanged substantively from the proposal.

In its Technological Feasibility analysis (see Section 5.6 of Chapter IV of the FEA), OSHA analyzes exposures for workers using drivable saws. The exposure profile includes three samples, two using wet methods as required by Table 1 and one operating under other conditions. The two samples taken on workers using wet saws showed TWA silica exposures of 12 μg/m^3 (*i.e.*, below the limit of detection (LOD)) and 33 μg/m^3 over sampling times of 70 and 125 minutes, respectively. OSHA considers these exposure results to reflect typical work patterns in that operators will often operate the saw for one or two hours before moving the saw to another location. CISC questioned OSHA's use of short term samples and the assumption of zero exposure during the unsampled portion of the shift and noted that this could underestimate the exposures for these workers (Document ID 2319, pp. 51–52). While OSHA acknowledges that this situation may occur at times, there is no evidence that this is the case for these drivable saws samples. These samples were collected by OSHA inspectors, who are instructed to sample for the entire duration of silica exposure. Accordingly, OSHA concludes that these samples accurately characterize the sampled workers' exposure.

In the proposed rule, dust control requirements were specified for drivable and walk-behind saws together, and the proposed rule would have required respirator use when operating either saw in indoor or enclosed environments. In the final standard for construction, the requirements for these kinds of saws are separated on Table 1 because, unlike walk-behind saws, drivable saws are rarely, if ever, used in indoor environments. Because the requirements of Table 1 only apply to outdoor use of drivable saws, and the data available to OSHA demonstrate that the wet methods described above can consistently control exposures in that environment, Table 1 does not require the use of respiratory protection when these controls are implemented, regardless of task duration.

SMI and CISC commented that currently drivable saws use water to cool the cutting tool, and the effectiveness of cooling water for respirable crystalline silica dust mitigation has not been comprehensively researched (Document ID 2316, Attachment 1, p. 3; 2319, p. 112). SMI stated specifically that ''parameters such as flow rate, volume, flow delivery characteristics, velocity, and delivery location have not been evaluated or compared'' (Document ID 2316, p. 3). However, Atlantic Concrete Cutting agreed that all of its cutting services were performed with water (Document ID 2367, p. 2), and that the application of water minimized and most likely eliminated exposure to respirable crystalline silica. Atlantic Concrete Cutting also stated that the use of a ''water-fed system that delivers water continuously at the cut point'' would be an appropriate silica dust control for drivable saws and that respirators would not be needed to further protect employees (Document ID 2367, pp. 2–4). In light of this testimony, OSHA concludes that it is appropriate to permit employers to fully and properly implement water-based systems on drivable saws in compliance with Table 1, eliminating their need to conduct exposure assessments for employees engaged in a task using drivable saws. Moreover, as reflected in Table 1, OSHA concludes that full and proper implementation of this control will not require the use of respirators for this task even if performed for more than four hours in a shift and so has not included respiratory protection for this task.

Rig-mounted core saws or drills. Paragraph (c)(1)(vi) of the standard for construction, an entry for rig-mounted core saws or drills, was not included in proposed Table 1. Core saws or drills are used to perform core cutting (also called core drilling, boring, or concrete coring) to create round holes for pipes, ducts and conduits to pass through walls, ceilings and floor slabs made of concrete, masonry or other materials that may contain silica (*see* Section 5.6 of Chapter IV of the FEA). Core cutting machines (also called core drills) use a thin continuous round cutting surface on the round end of a cylindrical coring tool (''bit'') (Document ID 0679, pp. 18–20). The machine is typically attached to the surface being drilled (bolted on via a rig for stability) (Document ID 3998, Attachment 13e, pp. 4, 9). When the rotating diamond core cutting bit is applied to solid material, the bit cuts away a thin circle of material. The cut separates the central ''core'' of material, within the circumference of the bit, from its surroundings, leaving the core generally intact as it is removed from the hole (Document ID 3501, p. 6). The cylindrical bit can range in size; for example NIOSH described a coring operation used to produce holes 2 to 31 inches in diameter in large sections of concrete conduit (Document ID 0898, p. 6).

For rig-mounted core drills, there is one specified control that consists of using a tool equipped with an integrated water delivery system that supplies water to the cutting surface, operated and maintained in accordance with manufacturer's instructions to minimize dust emissions. Based on evidence in the record, OSHA has determined that baseline conditions for core cutting involve using wet methods and that most core cutting machines are provided with and intended to be used with a water feed system (*e.g.*, Document ID 0675, p. 1097; 0679, pp. 18–21; 0898, p. 6; 3580, Tr. 1415, 1435; 3581, Tr. 1584; 3585, Tr. 2902). Like other saws included in Table 1, these existing systems will fulfill the requirements of Table 1.

Comments submitted by SMI expressed confusion as to whether or not core drilling was included on the table under the entry for drills and the appropriateness of using LEV as required under the proposed table during core cutting (Document ID 2316, p. 2). In the proposed rule, OSHA specifically excluded core cutters from hole drillers using handheld drills (*see* PEA, p. IV–403). OSHA did not include this information because OSHA lacked specific information on exposures to silica that result from core drilling or from industry's practice of using water during coring operations. Upon OSHA's review of core cutter/driller operator exposures and hearing testimony from industry, OSHA determined that there is the potential for silica exposure when employing core saws and that these saws are different enough from other drills and cutting tools to warrant the inclusion of its own separate entry on Table 1.

Kellie Vasquez of Holes Incorporated testified that the process of core drilling is much different than other types of drilling due to the different drill bits used, resulting in much less silica exposure (Document ID 3580, Tr. 1484). This is supported by OSHA's review of record data on core cutting/drilling, which shows that operators generally experience little or no silica exposure during this low-speed process, which is already performed using water-fed equipment as a standard practice (Document ID 0675, pp. 1097–1098; 0898, p. 15).

Additional exposure data compiled by CSDA from member jobsites (Document ID 3497) and other studies (Document ID 0675; 0679; 0898) show that using a

core drill with wet methods results in exposure levels of less than 50 μg/m³ (Document ID 3497). During hearing testimony, BCTD commented that core drills are always used with wet methods (Document ID 3581, Tr. 1584). This was supported by Kellie Vasquez of Holes Incorporated who stated that her concrete cutting operations employ water 100 percent of the time (Document ID 3580, Tr. 1483). Accordingly, OSHA added dust control specifications for core sawing and drilling to Table 1 of the final standard for construction. Because the available evidence described above demonstrates that using wet dust suppression systems for core cutting does not result in silica exposures exceeding 50 μg/m³, the final standard for construction does not require the use of respiratory protection.

Handheld and stand-mounted drills (including impact and rotary hammer drills). Handheld drills are used to, among other tasks, create holes for attachments and small openings in concrete and other silica containing materials (see Section 5.4 of Chapter IV of the FEA). These drills can: (1) Be electric, pneumatic, or gas-powered; (2) use rotary hammers or percussion hammers; and (3) be free-standing or stand-mounted. Handheld drills consist of a handle with a trigger button to begin drilling, a motor compartment above and perpendicular to the handle, and a socket to insert drill bits of varying lengths and styles at the end of the motor compartment. Impact and rotary hammer drills appear the same, but provide the ability to drill with extra motor-generated impacts and/or torque. The drills may have a second handle in front of the main handle for a worker to grasp with the off hand. To control dust, they may contain attachable dust collection systems where the end of the drill bit is surrounded by a vacuuming compartment which connects to the rest of the drill, allowing for dust to be removed while drilling (Document ID 4073, Attachment 4a, Row 68). Handheld drills can also be stand-mounted, in which case a drill is turned on its side and mounted to an adjustable stand, allowing the worker to drill directly into a work product with precision (Document ID 4073, Attachment 4a, Row 72).

Paragraph (c)(1)(vii) of the standard for construction requires that handheld and stand-mounted drills be equipped with a commercially available shroud or cowling with dust collection system that provides at least the minimum air flow recommended by the manufacturer. The dust collection system must include a filter cleaning mechanism and be equipped with a filter with 99 percent or greater efficiency. The dust collection system must be operated in accordance with the manufacturer's instructions to minimize dust emissions. In addition, OSHA is requiring that a HEPA-filtered vacuum be used when cleaning debris from drill holes.

The proposed Table 1 labeled this category of tools ''Using rotary hammers or drills (except overhead).'' In response to several comments, OSHA has revised this description to make clear that drills mounted on stands are also included and also removed the exclusion for overhead drilling. For example, SMACNA recommended expanding the entry for rotary hammers and drills to include overhead drilling, contending that overhead drilling would be just a safe as other drilling if done as directed on the table (Document ID 2226, p. 2). The Mechanical Contractors Association of America commented that overhead drilling should be included in Table 1 since overhead drilling is a common operation in several trades (Document ID 2143, p. 2). OSHA received testimony that overhead drilling along with a drill stand with a vacuum attachment addresses both ergonomic and silica exposure hazards. After review of the evidence in the record, OSHA has determined that it is appropriate to remove the exclusion for overhead drilling in the Table 1 entry for handheld and stand-mounted drills.

As proposed, Table 1 had separate entries for ''Rotary Hammers or Drills'' and ''Jackhammers and Other Impact Drillers.'' OSHA received comments from PTI suggesting that impact drills be covered by the entry for ''Rotary Hammers or Drills,'' rather than by the ''Jackhammers and Other Impact Tools'' entry (Document ID 1973, Attachment 1, p. 4). NIOSH also commented on the potential for confusion, noting that a rotary hammer or drill is technically an impact driller (Document ID 2177, Attachment B, pp. 32–33). Therefore, the entry for handheld or stand-mounted drills in final Table 1 covers activities related to the use of impact and rotary hammer drills. Chipping and breaking activities, which are associated with more intense silica exposures, are covered by the entry for jackhammers and handheld power chipping tools.

CISC commented that OSHA did not state in the proposed rule that the dust collection system needs to be ''commercially available'' (Document ID 2320, p. 112). In the final standard for construction, OSHA has clarified that Table 1 requires that the handheld or stand-mounted drill be equipped with a commercially available shroud or cowling with dust collection system. Several drilling equipment manufacturers sell dust extractors or dust collectors to minimize dust escaping into the work area. These systems include a vacuum with a filter cleaning mechanism and a filter with 99 percent or greater efficiency. Some examples include Bosch, DeWalt, Hilti, and Metabo (Document ID 3998, Attachment 10; 4073, Attachment 4a, Rows 15–18, 64–70, 111–119, 189–195, 289–301, 352–357). OSHA has determined that it is feasible for employers to obtain controls for handheld and stand-mounted drills that meet the specifications in Table 1.

Based on evidence in the record, OSHA finds that, for most tools, a commercial dust control system using an appropriate vacuum will provide the most reliable dust capture. Average respirable quartz levels varied among the different cowling/vacuum combinations. In one study, all commercial cowl/vacuum combinations tested resulted in personal breathing zone exposures of 28 μg/m³ or less during drilling (Document ID 1142, p. 42). Another study reported median silica exposures of 60 μg/m³ and 45 μg/m³, depending on drill bit size, in a room with limited air exchange (Document ID 1391, pp. 11–12, 15–19). These findings indicate that providing a means of exhaust when working indoors or in enclosed areas, as required under paragraph (c)(2)(i) of the standard for construction, in addition to using dust collection systems, will maintain exposures below 50 μg/m³. Based on these findings, OSHA is not requiring the use of respiratory protection when using handheld or stand-mounted drills, including overhead drilling, for any task duration.

The practice of dry sweeping or brushing debris from a hole, or using compressed air to clean holes, contributes to the exposure of employees using drills. Based on the evidence in the record, OSHA is requiring that holes be cleaned with a HEPA-filtered vacuum. Any method for cleaning holes can be used, including the use of compressed air, if a HEPA-filtered vacuum is used to capture the dust. If a HEPA-filtered vacuum is not used when cleaning holes, then the employer must assess and limit the exposure of that employee in accordance with paragraph (d) of the standard for construction.

While the paragraph on housekeeping (paragraph (f) of the standard for construction) also applies when employers are following paragraph (c) of the standard for construction, the employer must ensure that all of the engineering controls and work practices specified on Table 1 are implemented.

For example, paragraph (f)(2)(i) of the standard for construction permits the use of compressed air when used in conjunction with a ventilation system that effectively captures the dust cloud. However, to fully and properly implement the controls on Table 1, an employer using compressed air when cleaning holes during tasks using handheld or stand-mounted drills or dowel drilling rigs for concrete must use a HEPA-filtered vacuum to capture the dust, as specified in paragraphs (c)(1)(vii) and (viii) of the standard for construction, not just a ventilation system as specified in paragraph (f)(2)(i) of the standard for construction.

PCI noted that anchor holes must be blown clean to obtain adequate adhesion, and recommended that the use of compressed air and dry sweeping be allowed unless exposures will exceed 50 μg/m^3 (Document ID 2276, pp. 10–11). This recommendation assumes exposure assessment, however, the construction standard does not require such assessment where the task is included in Table 1 and the employer is following Table 1. Although OSHA is allowing the use of compressed air if used in conjunction with a HEPA-filtered vacuum to capture the dust, OSHA has determined that there are a number of feasible alternatives to using compressed air. At least one tool manufacturer offers an anchor system with ''no hole cleaning requirement whatsoever,'' due to the use of a drill with a ventilated drill bit (Document ID 4073, Attachment 4b, Slide 12). Another manufacturer offers a ''hole cleaning kit'' for large hammer hole drilling, which consists of a doughnut-shaped dust collection head that attaches directly to a vacuum cleaner hose. The head is placed against the surface to be drilled and captures dust generated as the hole is drilled (Document ID 4073, Attachment 4b, Slide 17). This hole cleaning kit also includes two sizes of hole cleaning tubes. Such a control could be used with existing as well as new drills (*e.g.*, Document ID 3998, Attachment 10, p. 42).

Data suggest that decreasing employees' reliance on blowing or dry sweeping drilling debris can reduce exposures by approximately 50 percent (*e.g.*, Document ID 1391, pp. 32–33). This 50 percent reduction would bring exposure levels to 50 μg/m^3 or below for all the drill operators who are currently exposed to silica at levels between 50 μg/m^3 and 100 μg/m^3. Thus, OSHA has determined that a HEPA-filtered vacuum must be used when cleaning holes in order to reduce silica exposure.

Dowel drilling rigs for concrete. Paragraph (c)(1)(viii) of the standard for construction covers dowel drills (*i.e.*, gang drills), which are drills with one or more drill heads used to drill holes in concrete for the placement of steel supports (*see* Section 5.9 of Chapter IV of the FEA). When operating dowel drills, Table 1 requires that the rig be equipped with a shroud around the drill bit and a dust collection system that has a filter with 99 percent or greater efficiency. In addition, Table 1 requires that dust collection equipment be equipped with a filter cleaning mechanism.

NIOSH found that employees using compressed air to clean the filter after dowel drilling resulted in some of the highest measured exposure to respirable dust during the task, and could cause damage to the filter (Document ID 4154, p. 26). NIOSH also pointed out that the reverse pulse feature on the dust collector should preclude the need to remove filters for cleaning (Document ID 4154, p. 26). OSHA agrees and has included the specification for a filter cleaning mechanism for dowel drills in Table 1. Finally, Table 1 requires that a HEPA-filtered vacuum is used when cleaning holes. OSHA recognizes that it may be necessary at times for employers to use compressed air to clean holes, and thus, as with handheld and stand-mounted drills, Table 1 does not preclude its use when cleaning the debris from holes caused by dowel drilling, so long as a HEPA-filtered vacuum is employed at the same time to effectively capture the dust.

In the proposed rule, OSHA included dowel drills within the entry titled ''Operating Vehicle-Mounted Drilling Rigs for Concrete.'' However, OSHA has determined that the exposures that result from dowel drilling rigs equipped with LEV systems are substantially higher than is the case for vehicle-mounted concrete drilling rigs. Therefore, respirator requirements are different for the two kinds of equipment (*see* Sections 5.4 and 5.9 of Chapter IV of the FEA).

Exposure information on concrete dowel drilling in the record is limited but shows that, even with LEV, exposures are likely to exceed 50 μg/m^3. Exposure studies by NIOSH on concrete dowel drills, manufactured by both EZ Drill and Minnich Manufacturing, that were equipped with close capture hoods and a dust collection system showed that workers were often still exposed to respirable silica dust levels well above 50 μg/m^3, with 8-hour TWA exposures to respirable quartz ranging from 24 to 420 μg/m^3 with a geometric mean of 130 μg/m^3 (Document ID 4154, p. 25). NIOSH found that using an air lance and compressed air to clean holes and to clean the filter and hoses of the dust collector contributed to these high exposures, and NIOSH recommended the use of a pneumatic vacuum to clean holes and components of the dust collector (Document ID 4154, p. 26). The record contains no information on exposures that result when vacuums are used to clean holes. As stated previously, exposures that result from dowel drilling rigs equipped with LEV systems are substantially higher than is the case for vehicle-mounted concrete drilling rigs. Based on this information, OSHA has modified the respirator requirement for dowel drilling, and is requiring the use of respiratory protection with a minimum APF of 10 regardless of task duration.

Comments on OSHA's proposed requirements for dowel drilling were limited. Holes Incorporated, Atlantic Concrete Cutting and CISC all stated that outdoor concrete dowel drilling should be included on Table 1 (Document ID 2338, p. 3; 2320, p. 14; 2367, p. 4). Atlantic Concrete Cutting further suggested that the appropriate control for dowel drilling is to limit this task to outdoors only and ''provide sufficient ventilation'' (Document ID 2367, p. 4). As suggested, OSHA has included a separate entry for concrete dowel drilling on Table 1, but with more detailed control requirements than suggested by Atlantic Concrete Cutting based on information contained in the record. OSHA agrees with Atlantic Concrete Cutting that the entry on Table 1 should be limited to outdoor operations since there is no information in the record as to the appropriate level of respiratory protection needed when operating dowel drills in enclosed areas, and has accordingly revised Table 1 of the final rule to so indicate.

PCI commented that anchor holes must be blown clean using compressed air to obtain adequate adhesion (Document ID 2276, p. 10). In its feasibility analysis, OSHA identified this task as a significant source of exposure to respirable crystalline silica. Therefore, for the reasons previously stated, Table 1 also includes a requirement to use a HEPA-filtered vacuum when cleaning holes, with or without the use of compressed air, in connection with this task.

Vehicle-mounted drilling rigs for rock and concrete. Paragraph (c)(1)(ix) of the standard for construction requires that vehicle-mounted rock and concrete drilling rigs be equipped with a dust collection system with a close capture hood or shroud around the drill bit with a low-flow water spray to wet the dust discharged from the dust collector, or be operated from within an enclosed cab in

conjunction with water applied at the drill bit for dust suppression (*see* Section 5.9 of Chapter IV of the FEA). The specifications of paragraph (c)(2)(iii) of the standard for construction apply to the cabs.

The proposed rule had separate entries for vehicle-mounted drilling rigs for rock and vehicle-mounted drilling rigs for concrete, both of which specified a combination of LEV and water use. OSHA has determined that, since the rigs and the approach to dust control are similar for both, they can be combined in Table 1 of the final standard for construction. OSHA has also determined that it is appropriate to allow employers the option of having the drill operator work within an enclosed cab meeting the requirements of paragraph (c)(2)(iii) of the standard for construction and to apply water at the drill bit to ensure that the operator and other employees assisting are protected when working near the drill bit.

Workers using vehicle-mounted drilling rigs position and operate the drill rigs from control panels mounted on the rigs. These workers may also perform intermittent tasks near the drilling point such as fine-tuning the bit position, moving debris away from the drill hole, and working directly or indirectly with compressed air to blow debris from deep within the holes. Workers using drilling rigs can be exposed to dust generated by the action of the drill bit and from dust raised by air movement or a compressed air nozzle. Although rig-based drilling is often a one-person job, some of the associated activities, such as fine-tuning the drill position and clearing debris from in or around the holes, can be performed by a second worker (Document ID 0908, p. 1; 1563, p. 3).

In the proposed rule, OSHA specified requirements for the dust collections systems regarding smooth ducts, transport velocities, clean-out points, pressure gauges, and activation of the LEV. These requirements came from a NIOSH evaluation of control technology for dowel-pin drilling (Document ID 1628). The final rule does not require these specific control parameters for vehicle-mounted drilling rigs for rock and concrete. OSHA has determined that dust controls for dowel drilling rigs are substantially different than vehicle-mounted rock and concrete drilling rigs; they are addressed separately in the previous section. Dust collection systems that use a hood or shroud around the drill bit have been proven effective in reducing exposures to respirable crystalline silica. NIOSH found that, when used properly, modern shroud designs now help achieve dust control objectives more consistently for rock drilling rigs than in the past (Document ID 0967, pp. 5–9). Based on information contained in the record, OSHA finds that dust collectors and shrouds are commercially available (Document ID 0669; 0813).

Although the LEV system will control dust emissions at the drill bit, there are still dust emissions at the dust collector discharge area, which can contribute to either the operator's or other employees' exposures. Organiscak and Page (1995) found that enclosing the dust collector discharge area with a shroud can reduce respirable dust levels by 80 percent (Document ID 3613, p. 11). However, evidence in the record shows that the combination of LEV at the drill bit and water application will be more effective in that water can be used to control dust emission points where drilled material is discharged. Organiscak and Page (1995) illustrated the effectiveness of combined wet methods and dust collectors in their U.S. Bureau of Mines study, which compared rock drilling using LEV with and without the addition of water for dust suppression. The addition of wet methods to the LEV system showed a 92 percent reduction in respirable dust and eliminated nearly all of the visible dust. Quartz results decreased from 143 $\mu g/m^3$ when the water was off (LEV alone) to 9 $\mu g/m^3$ when water was added. OSHA obtained sample results of 54 $\mu g/m^3$ and 35 $\mu g/m^3$ during an inspection for two workers drilling in granite that contained 30–40 percent crystalline silica (Document ID 0034, pp. 8, 23–26, 35–38). Both drillers were reportedly using water and LEV, although specific details about the configuration of the controls were not discussed (Document ID 0034, pp. 23, 89–93). A third sample that was below the limit of detection for crystalline silica was collected on the same site for a laborer who helped with positioning the drills (Document ID 0034, pp. 39–42).

OSHA received many comments related to the proposed requirements for rock and concrete drillers. CISC noted that it is more common to use wet methods when operating vehicle-mounted drilling rigs for rocks as opposed to using dust collection systems (Document ID 2319, pp. 108–109). A number of other commenters noted the prevalence of wet methods use in the industry (*e.g.*, Document ID 1983, pp. 1–2; 2116, Attachment 1, p. 33; 3496, p. 6). For instance, CSDA commented that nearly 100 percent of CSDA contractors use water on every job in order to prolong the life of the diamond blade (Document ID 3496, p. 6). The National Ground Water Association (NGWA) noted that it is industry practice when drilling water wells to use foam as a wet control method:

> Industry practice is to use the engineering control of soap injection where water is mixed with foam. The foam mixtures of water and foam products are effective in mitigating the hazard of dust when properly used as they can carry particles ranging from .03 mm to the size of a quarter. There are multiple manufacturers of the foam products and these products have been approved for use when drilling sanitary water wells. The foam agents are NSF approved and have also been approved for use in many states (Document ID 1983, pp. 1–2).

NGWA also explained that all rotary drilling machines have been equipped with some type of water injection system since the early 1970s (Document ID 1983, p. 2).

Historically, construction and mining investigators have reported dust control efficiencies of 96 to 98 percent through the routine use of wet dust suppression methods, depending on the methods used; however, the water flow necessary for dust control can create problems under certain working conditions (*e.g.*, moisture shortening the life of certain drill bits (such as tricone roller bits), high-pressure water causing spalling of the drill hole wall) (Document ID 0967, p. 6). Advances in recent decades have produced equipment that permits workers to use wet methods in a wider range of circumstances. New ''water separator sub'' designs extend bit life beyond the previous norm and reduce spalling in a variety of rock types (Document ID 0967, p. 6). Several commenters stated that wet methods are used frequently and are effective in controlling dust (Document ID 1983, pp. 1–2; 3580, Tr. 1435; 3496, p. 6).

OSHA's exposure profile contains five sample results for workers using wet methods with no other controls while drilling. These five samples have a mean of 24 $\mu g/m^3$ and a median of 17 $\mu g/m^3$, with a high exposure of 57 $\mu g/m^3$ and two results below the LOD (Document ID 0034; 0226). A review of studies by NIOSH (2008) evaluated the use of wet methods in different types of drilling, including roof bolting (rock bolting) and surface rock drilling (Document ID 0967). NIOSH found that for roof bolting, silica dust was best controlled at its source through dust collection or wet drilling, similar to the standard practice in metal mines of using pneumatic percussion drills with water in addition to compressed air to flush the drill cuttings from the hole. This drilling method was found to be the best method of dust control, with

dust reductions ranging from 86 percent to 97 percent (Document ID 0967, pp. 2, 4). The high dust reductions from wet drilling were confirmed in later studies that evaluated the use of water mists and foams injected through the drill steel and found that those controls reduced dust concentrations by 91 percent and 96 percent, respectively (Document ID 0967, p. 2). NIOSH also found that for surface drilling, wet drilling techniques provided the best dust control. Wet drilling provided dust control efficiencies of up to 97 percent at a water flow rate of 4.5 L/min (1.2 gallons per minute) (Document ID 0967, p. 6). OSHA thus finds that water directed at the material discharge point is an effective dust suppressant in vehicle-mounted rock and concrete drilling and specifies its use on Table 1 for this task.

OSHA also finds that the use of an enclosed cab can effectively reduce exposures for vehicle-mounted drill operators. Enclosed cabs, however, only benefit the operator when the operator remains in the cab, and they do not control employee exposure during positioning or hole-tending activities. Therefore additional controls are necessary to protect employees from exposure to silica dust when performing activities outside of the cab. As described above, OSHA has determined that the use of water for dust suppression on the drill bit will effectively reduce exposures in situations where employees must also perform activities outside the cab.

Based on the information discussed above, Table 1 of this standard provides the option for employees to operate a vehicle-mounted rock or concrete drill from within an enclosed cab in conjunction with water applied at the drill bit for dust suppression; wherever cabs are specified in Table 1, however, the cabs must meet the requirements of paragraph (c)(2)(iii) of the standard for construction, as discussed above. OSHA has determined that the enclosed cab will adequately protect the operator while the addition of water at the drill bit will reduce exposures for employees in the area. The alternative control option included in Table 1, a dust collection system and water sprays at the discharge point (where the system ultimately dumps extracted dust), has also been proven to reduce exposures for both the operator at the drill controls and those employees in the vicinity. When the specified dust control methods are fully and properly implemented, TWA exposure levels are expected to remain below 50 μg/m^3, and therefore, Table 1 does not require use of respiratory protection regardless of task duration for either control option. In the proposed rule, OSHA required the use of respiratory protection when the task lasted more than four hours. However, this was due to the inclusion of dowel drilling rigs within the entry for ''Operating Vehicle-Mounted Drilling Rigs for Concrete.'' As explained above, OSHA has determined that the exposures that result from dowel drilling rigs equipped with LEV systems, for which respirators are required regardless of task duration, are substantially higher than is the case for vehicle-mounted concrete drilling rigs.

IUOE commented that Table 1 would be clearer if it specified that employers who use open cabs during concrete drilling are not exempt from exposure assessment when employers implement the other controls listed for vehicle-mounted drilling rigs for concrete (Document ID 2262, Attachment 1, p. 48). OSHA considers the rule to be clear as written: If an employer chooses to operate vehicle-mounted drilling rigs for rock and concrete from within an enclosed cab, it must follow the requirements in paragraph (c)(2)(iii) of the standard for construction and apply water for dust suppression at the drill bit. Otherwise, the employer must follow the alternative shrouded dust-collection-system compliance method in Table 1 or the requirements in paragraph (d) of the standard for construction, which allow for alternate exposure control methods provided that employee exposures are assessed and exposures are kept at or below the PEL. Additionally, IUOE suggested that OSHA explicitly state on Table 1 that the employer does not have the option of respirator use as a means to control exposures during rock crushing or rock and concrete drilling if the employer chooses not to use enclosed cabs as an engineering control (Document ID 2262, Attachment 1, p. 48). OSHA notes that Table 1 of this final standard does not require that drilling rig operators work from enclosed cabs exclusively. Because employers can choose between the two control methods listed on Table 1, employees that use open cabs during drilling activities would not be required to conduct exposure assessments if they are using a dust collection system with a close capture hood or shroud around the drill bit and are ensuring that the material at the dust collector discharge point is being wetted. If that method is followed, OSHA, having found based on the exposure profile and record evidence that exposures will consistently be at or below the PEL, has not included a respirator requirement on Table 1; where respirators are not required to satisfy compliance obligations (as is the case here if Table 1 is fully and properly implemented), OSHA does not expect employers to require the use of respirators anyway. However employers that do not follow either control strategy specified in Table 1 must comply with paragraph (d) of the standard for construction, which could require respirator use if exposures are measured at or above the PEL when using feasible engineering and work practice controls.

IME stated that the final rule should allow for the use of equivalent, alternative control methods (Document 2213, Attachment 1, p. 2). Table 1 is intended to represent the most reliable control methods available for reducing exposures, based on the evidence contained in the record. Employers who wish to implement an alternative control method can do so, but those employers must comply with paragraph (d) of the standard for construction.

IUOE, among others, urged OSHA to explore additional options for exposure controls to protect operators working outside the cab when drilling. Both IUOE and Fann Contracting asserted that Table 1 does not address protection of operators who perform construction activities outside the cab with or without remote controls (Document ID 2262, Attachment 1, p. 45; 2116, Attachment 1, p. 5). In response, Table 1 of the final standard now includes a requirement to use water for dust suppression at the drill bit when the drill is being operated from an enclosed cab to minimize the exposure to other employees outside the cab.

OSHA's proposed Table 1 entry for rock drilling would have required that employees use respirators when working under the shroud. OSHA proposed this requirement based on a determination that employees' exposures would be high given their proximity to the point of dust generation. IME suggested that respirators should not be required at all times because there are circumstances where the time spent working under the shroud is extremely brief or infrequent and potential exposures will be minimal or negligible (Document ID 2213, p. 2). NUCA commented that this requirement creates hazards for employees working under the shroud (Document ID 2171, p. 10). In response to these comments and after reviewing the record, OSHA has not retained this respirator requirement in the final standard. The Agency finds that the record contains substantial evidence that when the dust controls required by Table 1 are fully and properly implemented, TWA exposures to silica are unlikely to exceed 50 μg/m^3

(*see* Section 5.9 of Chapter IV of the FEA). In reviewing dust controls historically for drilling operations, NIOSH found that, when used properly, modern shroud designs now help achieve dust-control objectives more consistently than in the past (Document ID 0967, pp. 5–9). Furthermore, the record indicates that work under a shroud is periodic or intermittent and contains no evidence suggesting that this work is likely to result in silica exposures exceeding 50 μg/m^3 as an 8-hour time-weighted average. Accordingly, Table 1, unlike in the proposed rule, does not include a respiratory protection requirement for rock and concrete drillers on open (or enclosed) vehicle-mounted rigs.

NSSGA recommended that OSHA clarify the requirement for wearing respirators while working under the shroud by replacing the term ''shroud'' with ''engineered fugitive dust control method, *e.g.,* a shroud, water spray, etc.'' (Document ID 2327, Attachment 1, p. 21). Since the Agency has eliminated the requirement for using respirators under the shroud, NSSGA's suggestion is moot.

Jackhammers and handheld powered chipping tools. Hand-operated breaking and chipping power tools and equipment, commonly known as jackhammers, pavement breakers, breaker hammers, percussion or chipping hammers, and needle guns, are used in construction for fracturing materials, which often include silica (*e.g.,* rock, concrete, asphalt, or masonry surfaces), by delivering rapid repetitive blows (*see* Section 5.5 of Chapter IV of the FEA). The hammers typically consist of a large compartment containing a motor, two attached handles to grip the tool, and a large socket out of which the drill or hammer-like metal breaking/chipping implement extends. A worker typically will aim the metal drill/hammer at a target surface while standing one to five feet away either directly overhead or at an angle, and press the point of contact into the surface to break, fracture, or chip away at it (Document ID 4073, Attachment 4a, Row 199).

In the proposed standard, this entry was titled ''Using Jackhammers and Other Impact Drillers.'' OSHA had a separate entry for ''Rotary Hammers or Drills.'' NIOSH commented on the potential for confusion with these titles, noting that a rotary hammer or drill is technically an impact driller (Document ID 2177, Attachment B, pp. 32–33). OSHA has revised the headings for the relevant Table 1 entries ((c)(1)(vii) and (x)). The revised heading for paragraph (c)(1)(x) removes the term ''other impact drillers'' and replaces it with ''handheld powered chipping tools.'' This change was made to clarify that this entry applies only to handheld tools that use an impact movement to chip or fracture the material being worked on. The heading for (c)(1)(vii) was revised from ''Using Rotary Hammers of Drills'' to ''Handheld and Stand-Mounted Drills (Including Impact and Rotary Hammer Drills)'' in order to clarify that all handheld drills, including impact drilling, are covered under that entry.

When using jackhammers and other handheld powered chipping tools at construction sites to fracture silica-containing material, paragraph (c)(1)(x) of the standard for construction requires the employer to operate the tools using either a water delivery system that supplies a continuous stream or spray of water at the point of impact, or a tool equipped with a commercially available shroud and dust collection system operated and maintained in accordance with manufacturer's instructions to minimize dust emissions. If the employer is operating a tool with the shroud and dust collection system, Table 1 requires that the dust collector (*i.e.,* LEV) must provide at least the air flow recommended by the tool manufacturer, and have a filter with 99 percent or greater efficiency and a filter cleaning mechanism. These specified controls are essentially the same as those that were proposed, but the final standard makes clear that if a shroud and dust collector are used, it must be commercially available equipment. Unlike the use of a shrouded dust collection system, a water delivery system is not required to be commercially available but can be assembled and installed by the employer.

OSHA revised the respirator use requirements from the proposed rule by distinguishing between indoor and outdoor environments. Table 1 of the final standard for construction does not require respiratory protection if tools are used outdoors for four hours or less per shift. OSHA based this revision on record evidence showing that exposures can be maintained at or below 50 μg/m^3 using either water sprays or LEV, provided work does not exceed the median task duration (231 minutes) reported by Flanagan *et al.* (Document ID 0677, p. 147; 0677, Attachment 2) (*see* Section 5.5 of Chapter IV of the FEA). If tools are used outdoors for more than four hours per shift, Table 1 requires the use of respiratory protection having a minimum APF of 10 to ensure that employees are protected from exposures above 50 μg/m^3. If the tools are used indoors or in an enclosed area, Table 1 requires the use of respiratory protection having a minimum APF of 10 to ensure that employees are protected from exposures above 50 μg/m^3, regardless of the amount of time the tools are operated during the work shift.

NUCA testified during the hearing that jackhammering is one of the construction activities most likely to expose employees to silica (Document ID 3583, Tr. 2255). OSHA's exposure profile for this task confirms this (Table IV.5.5–B in Section 5.5 of Chapter IV of the FEA); 73 of 98 TWA sample results (74 percent) were above 50 μg/m^3 for workers using jackhammers and handheld power chipping tools operated without controls. For tools operated with water, 12 of 16 TWA sample results (75 percent) exceeded 50 μg/m^3, but information on how the water was applied and whether it was sufficient was lacking. Various studies have demonstrated that properly used wet methods can substantially reduce respirable silica levels by 90 percent and higher (Document ID 0865, p. iv; 0867, p. 3; 0838, p. 1; 0914; 1267, pp. 493–494; 2177, Attachment D, p. 19). NIOSH studies that examined water spray devices designed to optimize dust suppression (directed mist or solid cone nozzle) have found that dust and/or silica exposures are reduced by 72 to 90 percent at a flow rate of approximately 350 milliliters per minute (ml/min) (Document ID 0865; 0867; 1267, pp. 493–494). Although not commercially available at this time, the record shows a number of examples of water suppression systems that have been developed and tested and are ready for commercial introduction or can be easily assembled from readily available hardware materials and instructions from the New Jersey Laborers' Health and Safety Fund (Document ID 0741; 0838; 0914; 2177, Attachment D, pp. 4–7; 3732, Attachment 3, p. 10).

The shroud and LEV control for jackhammers and handheld powered chipping tools was found to be less effective than water suppression but still reduced exposures up to 69 percent (Document ID 1267, pp. 493–494; 0865, p. iv; 0651, p. 1; 0667, pp. 1–3; 0862, pp.10–11, 14). Also, the respirable silica levels generated by these tools are dependent on whether they are being operated outdoors, indoors, or in an enclosed area. Several powered impact tool manufacturers currently offer LEV options (*e.g.,* Document ID 1288 p. 2; 1700, p. 1). Other companies specialize in manufacturing after-market shrouds or exhaust ventilation systems for various handheld tools such as jackhammers and chipping equipment

(Document ID 0566, p. 1; 1264, pp. 4–9; 1266, pp. 9–28; 1671; 1366; 1399; 3806, pp. 272–273, 276).

OSHA received a number of comments on the jackhammer and handheld powered chipping tool entries on Table 1. CISC commented that OSHA did not indicate in the proposed Table 1 that the dust collection system needed to be commercially available and did not set parameters for the functioning of the dust collection system (Document ID 2319, p. 107). Based on comments and testimony in the record, OSHA has clarified the entry in Table 1 for jackhammers and handheld powered chipping tools to read ''use tool equipped with commercially available shroud and dust collection system.'' OSHA has added to Table 1 the following requirements: Operate and maintain the tool in accordance with the manufacturer's instructions to minimize dust emissions; provide at least the air flow recommended by the tool manufacturer; and use a filter with a 99 percent or greater efficiency and a filter cleaning mechanism.

CISC also expressed concern that using wet methods may raise quality issues, for example by introducing water to the base when pouring new concrete (Document ID 2319, p. 107). The water delivery system required by Table 1 must deliver a continuous stream or spray of water at the point of impact. The water delivery system evaluated by NIOSH delivered between 250 and 300 ml of water per minute and the authors observed that water applied at these flow rates did not add a substantial amount of water to the work surface nor did it result in substantial accumulation of water (Document ID 0867, pp. 8, 15). Given that a substantial amount of water is not needed, OSHA finds that proper implementation of the water delivery system is unlikely to lead to quality control issues. Furthermore, other than the hypothetical situation raised by CISC, there is no evidence in the record showing that using wet methods with jackhammers and powered chipping tools results in quality issues. Furthermore, Table 1 of the final standard provides two options for dust control of jackhammers and handheld powered chipping tools. The employer can use a tool that is equipped with a commercially available shroud and dust collection system as an alternative to using water.

Some commenters discussed that water may introduce slip hazards; however, comments and hearing testimony described current contractor practices that countered these concerns (Document ID 2171 p. 4; 3589, Tr. 4295–4296). OSHA understands the concerns about possible slip hazards from the use of water; however, NIOSH investigators noted that the relatively low water flow rates (300 ml/min) used to suppress dust during jackhammering did not result in a substantial accumulation of water on work surfaces. OSHA expects that proper implementation of the water delivery system will include taking measures to contain any runoff to prevent the accumulation of water on walking and working surfaces.

The water delivery systems described in OSHA's feasibility assessment chapter on jackhammers, chipping hammers, and other powered handheld impact tools (*see* Section 5.5 of Chapter IV of the FEA), include portable water tank systems that can easily be brought to a construction site by a pickup truck or trailer, even in a remote area (Document ID 0867, p. 4; 0741 p. 1). These water delivery systems can be operated by one worker and would not require a second worker to supply the water at the point of impact (Document ID 0838, p. 2).

Handheld grinders for mortar removal (i.e., tuckpointing). Handheld grinders are tools fitted with rotating abrasive grinding blades, discs, or small drums. Tuckpointers are a subset of grinders who specialize in removing deteriorating mortar from between bricks and replacing it with fresh mortar (''tuckpointing'') (*see* Section 5.11 of Chapter IV of the FEA). Tuckpointing is most commonly performed for exterior wall maintenance and so generally occurs outdoors, but can occur indoors where there is interior masonry. The initial phase of tuckpointing involves using handheld grinders to grind old mortar from between bricks on a section of the wall. A grinder typically has two handles that can form various angles with each other and are connected to a rotating blade located between them. The worker typically holds one handle in each hand, forming an angle allowing the worker to press the rotating blade against the mortar between bricks to abrasively remove it (Document ID 4073, Attachment 4a, Row 226).

Paragraph (c)(1)(xi) of the standard for construction requires that this task be performed using a grinder equipped with a commercially available shroud and dust collection system and operated in accordance with manufacturer's instructions. Additionally, the dust collection system must be capable of providing at least 25 cfm of air flow per inch of wheel diameter and be equipped with a filter that has a 99 percent or greater efficiency and either a cyclonic pre-separator or a filter cleaning mechanism. The proposed requirement was similar but specified the air flow to be at least 80 cfm, rather than 25 cfm per inch of blade diameter, and also included a number of work practices. OSHA revised the controls for this task based on comments received in the record, as described below.

BCTD commented that ''Tuckpointing,'' as the entry was titled in proposed Table 1, is an operation that consists of a series of tasks (chipping or cutting out old mortar, preparing replacement mortar, cleaning the joints, applying fresh mortar, and applying a sealer), while the listed control was clearly directed at the task of using a ''hand-operated tuckpoint grinder'' (Document ID 2371, p. 25). To clarify its intent to address the grinding of old mortar, OSHA has re-named the entry for paragraph (c)(1)(xi) of the standard for construction to be ''Handheld grinders for mortar removal (*i.e.,* tuckpointing).''

Recent dust control efforts for tuckpointing have focused on using a dust collection hood (also called a shroud) that encloses most of the grinding blade and a vacuum cleaner system that is used to suction (exhaust) air from these hoods to collect dust and debris. These shroud and vacuum combinations generally capture substantial amounts of debris. In hearing testimony, Tom Ward, representing BAC, showed a video of local exhaust engineering controls for tuckpointing and described them as ''extremely effective'' (Document ID 3585, Tr. 3069). However, OSHA's exposure profile for tuckpointing shows that, even with these controls, silica exposures often exceed 100 μg/m^3 (25 percent of results exceed 250 μg/m^3 when workers use LEV for outdoor tuckpointing). An additional survey added to the rulemaking record reported results at two tuckpointing sites using vacuum and shroud systems. Air samples taken during 201 to 385 minutes of mortar grinding showed 8-hour TWA silica exposures ranging from 74 to 1,100 μg/m^3 (Document ID 4073, Attachment 9l, p. 4).

CISC questioned why employers can only use commercially available shrouds for hand-operated grinders, eliminating the use of specialty manufactured products (Document ID 2319, p. 110). OSHA is unsure of what CISC means by ''specialty manufactured products'' and CISC's written comments and testimony did not provide further detail. However, it is not OSHA's intent to eliminate the use of products that are custom made by aftermarket manufacturers (*i.e.,* made by someone other than the original tool manufacturer) which are intended to fit the make and model of the grinder and

designed to meet the particular needs and specifications of the employer purchasing the product. The ''commercially available'' limitation is meant only to eliminate do-it-yourself on-site improvisations by the employer. OSHA's technological feasibility analysis provides ample evidence that exposures to silica are substantially reduced when using commercially available dust controls (*see* Chapter IV of the FEA). To meet the requirements of Table 1, however, any specialty manufactured product has to satisfy all the requirements for this entry.

In proposed Table 1, OSHA specified that the dust collection system used must provide at least at 80 cfm airflow through the shroud. For the final standard, Table 1 requires that dust collectors have an air flow of at least 25 cfm per inch of wheel diameter. This change is due to OSHA's review of the evidence in the rulemaking record. Computational and laboratory studies by Heitbrink and Bennett (2006) and Collingwood and Heitbrink (2007) found that an air flow rate of 80 to 85 cfm (based on a 4- or 4.5-inch wheel) is the minimum needed to efficiently capture dust generated by angle grinders used for tuckpointing (Document ID 0728, p. 366; 0600, p. 877). ACGIH (2010) recommends 25 cfm to 60 cfm per inch of blade diameter (Document ID 3997, pp. VS–40–01—VS–40–03). For a typical 4-inch tuckpointing blade, 25 cfm/inch of diameter is equivalent to 100 cfm, higher than the 80 to 85 cfm used by Heitbrink and Bennett (2006) and Collingwood and Heitbrink (2007). Laboratory tests conducted by Heitbrink and Bennett indicate that a vacuum and shroud used by tuckpointers during grinding can reduce respirable dust emissions by a factor of more than 400 under ideal circumstances, but this reduction factor dropped to 10 when vacuum air flow was reduced to less than 80 cfm (Document ID 0728, p. 375). Furthermore, computational modeling showed that even a modest decrease in the air flow rate, from 85 cfm to 70 cfm, cuts the shroud's ability to capture dust by more than half. As a result, the estimated worker exposure level would be twice as high as it would have been if the air flow rate had remained constant at 85 cfm.

A NIOSH field trial on a vacuum that generated an air flow of 111 cfm for a grinder with a 4-inch blade showed that exposure levels for respirable dust were cut in half compared to using a 76 cfm flow rate (Document ID 0863, pp. 24–35). Based on the evidence contained in the record, OSHA has determined that the ACGIH (2010) recommendations are more protective given the variety of blade diameters, and is requiring a minimum 25 cfm of airflow per inch of grinding blade diameter instead of the 80 cfm minimum airflow (regardless of blade diameter) through the shroud.

To adequately capture debris during the grinding phase of tuckpointing, OSHA is requiring that vacuums be equipped with a cyclonic pre-separator to collect large debris before the air reaches the filters or be equipped with a filter cleaning mechanism. Cyclonic pre-separators minimize the accumulation of debris on filters in the vacuum, enhancing the ability of the vacuum to maintain the initial air flow rate. When testing a vacuum cleaner model equipped with a cyclonic pre-separator, Collingwood and Heitbrink found that the collected debris caused the average air flow rate to decrease only from 90 cfm to 77 cfm (Document ID 0600, p. 884). Heitbrink and Santalla-Elías evaluated two different brands of commercially available vacuum cleaners (Tiger-Vac and Dustcontrol) incorporating cyclonic pre-separation. Air flow rates for both of these vacuums were ''largely unaffected'' by debris accumulation up to 35 pounds. Debris accumulation also had very little effect on the flow rate measured before and after the filter was cleaned (Document ID 0731, pp. 377, 380). Similarly, during the Collingwood and Heitbrink field trials, the Dustcontrol vacuum with cyclonic pre-separator did not lose as much air flow as the vacuum designed with vacuum cleaner bags (bags are a more common pre-separation method but are subject to clogging) (Document ID 0600, pp. 883–884). OSHA concludes that cyclonic pre-separation is an effective technology for helping to maintain air flow and vacuum system effectiveness for the duration of tuckpointing tasks by preventing the static pressure increase caused by clogging that would otherwise lead to a dramatic decrease in air flow and loss of effective dust capture at the shroud.

The accumulation of material and debris on the filter (filter caking) during work causes pressure losses that eventually limit air flows in even the most powerful vacuums. As debris accumulates, the filter becomes caked with collected dust and air flow decreases. Unless the filter is properly cleaned following manufacturer's recommendations, the air flow declines rapidly. Cooper and Susi used a Dustcontrol 2900c vacuum with ICS Dust Director shroud and Bosch tuckpointing grinder to evaluate dust control in a field experiment. The authors reported that in four hours of continuous grinding up to 130 pounds of dust was collected, and that flow rates in the vacuum dropped from 90 cfm to 80 cfm in as little as 8 minutes. Thus, regular stops to conduct the proper reverse air pulse filter cleaning procedure were crucial to successful dust control (Document ID 4073, Attachment 9M, pp. 4–5, 7–9). Therefore OSHA is requiring the use of a filter-cleaning mechanism when a cyclonic pre-separator, which removes larger debris, is not in place. To assist employees in determining when it is time to run a filter cleaning cycle, vacuums equipped with a gauge indicating filter pressure or equivalent device (*e.g.,* timer to periodically pulse the filter) may be useful (Document ID 0731, p. 885).

PTI and OEHCS submitted comments emphasizing the importance of effective HEPA filtration in protecting employees from silica dust, and recommended that Table 1 require that dust collectors used with grinders be equipped with HEPA filters (Document ID 1953, pp. 3–4; 1973, p. 2–3). However, HEPA filters may rapidly clog during mortar grinding, leading to static pressure drop and loss of air flow needed to capture dust (*see* discussion about requirements for dust collection systems above). Instead, OSHA is requiring filters having at least 99 percent dust capture efficiency.

In proposed Table 1, OSHA included a specification that the grinder be operated flush against the work surface and that work be performed against the natural rotation of the blade (*i.e.,* mortar debris directed into the exhaust). A number of commenters discussed the difficulties of complying with this specification (Document ID 2183; 2319). Western Construction Group commented that it is not possible to always keep the grinder flush with the surface because the blade will be spinning at its full speed when cutting into the wall and when the blade is extracted from the surface, and explained that it would be difficult to keep the blade flush when removing vertical mortar joints (Document ID 2183, p. 2). OSHA acknowledges there are circumstances that do not always permit the tool to be operated in this manner, and has therefore removed this provision from Table 1. However, it is OSHA's position that full and proper implementation of Table 1 controls includes keeping the blade flush with the surface whenever possible, in order to optimize the effectiveness of local exhaust capture (*e.g.,* Document ID 0728, p. 376; 0600, p. 876).

Western Construction Group also commented that it is not always possible to operate the grinder against the natural rotation of the blade,

because a wall needs to be ''prepped'' in order to be in sufficient condition for mortar to be placed back into the wall (Document ID 2183, pp. 2–3). Western Construction Group explained that during final preparation, the blade needs to make short passes back and forth to clean the joint and prepare it, and that if workers only operated in one direction, they would place a significant burden on their shoulders and backs by having to make more passes on the wall to clean the joint (Document ID 2183, p. 3). Similarly, CISC commented that workers must move the grinder back and forth in short, deliberate motions when detailing the joint in order to provide the necessary quality finish (Document ID 2319, p. 106). OSHA recognizes that the requirement to operate against the direction of blade rotation may have an impact on job quality and may increase ergonomic stress. While OSHA has removed this specification from Table 1, it is OSHA's expectation that full and proper implementation of Table 1 controls includes operating against the direction of blade rotation, in accordance with the manufacturer's instructions, whenever practical.

CISC commented that a significant portion of tuckpointing takes place at elevated locations on scaffolds and expressed concern about the control measures listed introducing significant trip and fall hazards at elevated locations (Document ID 2319, p. 110). Grinding related to tuckpointing does take place on scaffolds, as evidenced by one building project evaluated by Cooper *et al.* where dust collectors were used on scaffolds to grind mortar from the exterior walls of a 12-story building (Document ID 4073, Attachment 9l, p. 1). When mortar grinding will take place on scaffolds, the employer's written exposure control plan should include procedures to ensure that the dust collector is operated in an effective and safe manner.

In the proposed standard, OSHA required personal air purifying respirators (PAPR) with an APF of 25 to be used while tuckpointing, regardless of task duration. The proposed requirement was based on high exposures results, including a TWA measurement of 6,196 μg/m^3 for an apprentice mortar grinding with LEV (Document ID 0229, p. 12). However, it is clear from this NIOSH report that the LEV system was not fully and properly implemented in that the grinder blade was operated in a back-and-forth manner with frequent insertions, and the hose from the tool to the dust collector would frequently kink and fall off. Based on data in the record, OSHA expects that a worker engaged in mortar grinding for four hours or less per shift can experience TWA exposures of less than 500 μg/m^3, while a worker performing this task more than four hours per shift could be exposed up to nearly 1,000 μg/m^3 TWA. Among tuckpointers using LEV outdoors, 40 percent of samples contained in the exposure profile measured exposures below 50 μg/m^3, with a mean exposure of 348 μg/m^3 (*see* Section 5.11 of Chapter IV of the FEA). Therefore, Table 1 of the final standard is requiring the use of respiratory protection with a minimum APF of 10 for work lasting four hours or less in a shift, which is reduced from the proposed APF of 25. Based on the evidence of continuing improvements in the effectiveness of LEV as reported in the literature, the exposure information, and the requirement in paragraph (c)(2)(i) to provide a means of exhaust as needed to minimize the accumulation of visible airborne dust indoors, OSHA concludes that the reduction to an APF of 10 is appropriate for tasks of four hours or less in duration. For work lasting more than four hours per shift, OSHA is maintaining the requirement to use respiratory protection with a minimum APF of 25.

Handheld grinders for uses other than mortar removal. Handheld grinders are tools fitted with rotating abrasive grinding blades, discs, or small drums used to smooth, roughen, or reshape concrete surfaces (including forming recesses or slots) (*see* Section 5.11 of Chapter IV of the FEA). Grinders may also be used to remove thin layers of concrete and surface coatings (*e.g.,* performing small-scale spot milling, scarifying, scabbling and needle-gunning). A grinder typically has two handles that can form various angles with each other and are connected to a rotating blade located between them. The worker typically holds one handle in each hand, forming an angle allowing the worker to press the rotating blade against the work surface and abrade the surface and remove the layer of target material (Document ID 4073, Attachment 4a, Row 91).

Paragraph (c)(1)(xii) of the standard for construction specifies two control options. The first control option, which applies only when grinders are used outdoors, is to use a grinder equipped with an integrated water delivery system that continuously feeds water to the grinding surface. When employers choose to use wet grinders indoors or in an enclosed area, they must comply with the requirements of paragraph (d) of the final rule. The second option is to use a dust collector equipped with a commercially available shroud and dust collection system. The dust collector must provide 25 cfm or greater of air flow per inch of wheel diameter and have a filter with a 99 percent or greater efficiency and a cyclonic pre-separator or filter-cleaning mechanism. OSHA is requiring that the control must be operated and maintained in accordance with manufacturer's instructions to minimize dust emissions. The second option is identical to the option required for handheld grinders used for mortar removal.

In the proposed standard, OSHA did not specify that the water delivery system be integrated with the grinder. However, OSHA has determined that systems that are designed and developed in conjunction with the tool are more likely to control dust emissions effectively by applying water at the appropriate rate and dust emission points based on tool configuration. Further, integrated systems will not interfere with other tool components or safety devices. These include free-flowing water systems designed for blade cooling as well as manufacturers' systems designed for dust suppression alone. OSHA is not specifying a minimum flow rate, but rather anticipates that the water flow rates specified by the manufacturer will optimize dust reduction. OSHA also recognizes that using makeshift water delivery systems can pose hazards. PTI commented that the use of a water feeding system not specified by the tool manufacturer could result in serious personal injury and electric shock for tools that are electrically operated (Document ID 1973, p. 1). Due to the potential hazards from using a water delivery system not specified by the manufacturer, and to ensure the effectiveness of the system in controlling dust, OSHA has modified Table 1 to require use of integrated water systems that are operated and maintained according to manufacturer's instructions to minimize dust emissions.

OSHA received a number of comments related to the use of wet methods as a control for handheld grinders. SMI and CISC commented on the difficulties of using an integrated water system while grinding, arguing that there is a lack of options with both safety guards and water supply, that grinders equipped with a water delivery system are designed to cool the blade rather than control the dust, and that the dust mitigation effects of the water are speculative (Document ID 2316, p. 2; 2320, p. 10). However, NIOSH reported that ''several manufacturers of smaller grinders do offer electric grinders with

integrated water supply capability'' and included the catalog of such suppliers (Document ID 4233, Attachment 1, pp. 7–8; 3998, Attachment 10). Studies by Linch *et al.* (2002), Akbar-Khanzadeh (2007, 2010), and Simcox *et al.* (1999) evaluated the use of wet methods during grinding (Document ID 0784; 0552; 3609; 1146). Although there were some differences in the effectiveness of systems tested by these investigators, all of them reduced dust levels substantially compared to dry grinding. Therefore the ability of water to control dust when grinding is not speculative and has been demonstrated in various studies throughout OSHA's technological feasibility analysis contained in Chapter IV of the FEA. In short, OSHA concludes that, based on the best available evidence, there are commercially available grinders with integrated water supply capability, and that wet methods can be an effective control for grinding in many circumstances (Document ID 0522, p. 778; 1146, pp. 578–579).

Francisco Trujillo of Miller and Long commented that wet methods often present significant slip and fall hazards and that attempting to apply wet methods to any non-horizontal surface has proven ineffective and often hazardous when using grinders (Document ID 2345, p. 2). Similarly, Stuart Sessions, an economist testifying on behalf of CISC, noted that it is difficult to use wet methods in winter in locations where the water may freeze (Document ID 3580, Tr. 1322). OSHA acknowledges that not every control option is practical in every situation, and in such situations, Table 1 of the final standard permits use of LEV systems to control dust. However, OSHA concludes that wet methods represent a feasible and effective option outdoors.

Those who do not implement the wet methods described above, or those grinding indoors, have the option to use a dust collector equipped with a commercially available shroud and dust collection system. Several rulemaking participants testified on the commercial availability of such equipment, including Gerry Scarano, Executive Vice President of BAC, Deven Johnson, director of training, health and safety for the Operative Plasterers and Cement Masons International Association, and Francisco Trujillo of Miller and Long (Document ID 3581, Tr. 1562, 1592–1593; 3585, Tr. 2962–2964). The record shows that Makita, DeWalt, Bosch, and Ostec all make grinding dust collection systems (*see* Chapter IV of the FEA).

The LEV-based exposure controls for surface grinding function similarly to the LEV-based controls for mortar removal described in paragraph (c)(1)(xi) of the standard for construction, as mortar removal (tuckpointing) is simply a specialized form of grinding that uses the same grinding tools. The factors that influence vacuum flow rate for mortar removal (tuckpointing) are equally important to LEV dust controls for all types of surface grinding, and for other hand-operated power tools as well. Collingwood and Heitbrink note that ''vacuum cleaners will probably continue to be an important control option for respirable dust exposures in construction for dust exposure sources such as mortar removal, concrete grinding, hole drilling, and brick cutting where water application is impractical'' (Document ID 0600, p. 884). Older studies of LEV effectiveness have found exposure reductions of 86–99 percent (Document ID 0611, p. 463; 0247, pp. 6, 8). A more recent study by Akbar-Khanzadeh *et al.* found silica dust exposure reduced by 98–99 percent, depending on the vacuum type used (Document ID 3609, p. 707). Akbar-Khanzadeh and Brillhart and Echt and Sieber both reported reduced silica exposures when workers used LEV shrouds with vacuum attachments during surface grinding, although the silica exposure results were variable and some exceeded 50 μg/m^3 even with use of the controls (Document ID 0521, pp. 344–345; 0632, pp. 459–460).

OSHA received a number of comments about the proposed entry on Table 1 for handheld (or hand-operated) grinders using LEV. The proposed entry specified use of a grinder with a commercially available shroud and dust control system. Several commenters questioned why shrouds needed to be commercially available and whether appropriate shrouds are, in fact, commercially available (*e.g.,* Document ID 2319, p. 105; 2316, p. 2; 2171, p. 9). Francisco Trujillo from Miller and Long stated ''dust collection systems used on hand grinders received very disappointing results. In fact, no hand grinder equipped with a dust collection system was capable of bringing exposure levels below the current [*i.e.,* the preceding] PEL'' (Document ID 3585, Tr. 2963). He further explained that this was due to the limited capabilities of the dust collection systems maintaining complete surface contact during the frequent grinding of columns and walls (Document ID 3585, Tr. 2963–2964). However, he found that a vacuum system designed for use with ceiling grinders ''greatly reduced the amount of dust expelled from the process but did not completely eliminate it. It was a very, very dusty activity, and now it's moderately so'' (Document ID 3585, Tr. 2962). He reported that although all sampling results were below the preceding PEL, three out of five samples were still above 50 μg/m^3. He also reported that none of the hand grinders with dust controls that Miller and Long evaluated were effective with columns and wall corners and that even with these LEV systems, the same number of workers were in Miller and Long's respiratory protection program (Document ID 3585, Tr. 2962–2964, 3012).

In Section 5.11 of Chapter IV of the FEA, OSHA's exposure profile shows that 60 percent of ceiling grinders who perform overhead grinding using LEV, and 50 percent of outdoor grinders using LEV or water have achieved exposures below 50 μg/m^3, while 25 percent of other grinders working indoors with LEV have achieved exposures below 50 μg/m^3. These results demonstrate that exposures of 50 μg/m^3 or below are achievable with technology available at the time of sampling. Much of the data in the exposure profile reflects samples collected over ten years ago, before many of the engineering studies described in the FEA were conducted. OSHA expects that capture technology will continue to improve in response to market demand.

In addition, Gerry Scarano, representing BAC, stated that since 2009, ''the availability and effectiveness of control options have improved, adding force to OSHA's conclusion that it is feasible to reduce the dust in most cases down to the proposed PEL'' (Document ID 3581, Tr. 1562). Thus, the effectiveness of controls available today is likely higher than those that were used when the exposure samples included in the exposure profile were obtained.

SMI commented that there are no commercially available dust shrouds that currently meet American National Standards Institute (ANSI) B7.1 (and OSHA) guard design requirements (Document ID 2316, p. 2). SMI stated that available dust shrouds are plastic and are used in place of the original equipment's steel guards but do not meet the requirements of ANSI B7.1, which is a safety design specification standard for grinding wheels (Document ID 2316, p. 2). However, NIOSH reported that several major tool manufacturers sell grinders with integrated dust shrouds designed to meet applicable safety standards, and the tools are labeled accordingly. For example, the Underwriter's Laboratory

(UL) mark carried by the products of several manufacturers signifies that their tools meet the requirements of ANSI/UL/CSA 60745–2–3, which incorporates ANSI B7.1 by reference (Document ID 4233, Attachment 1, p. 8). Catalogs of tool manufacturers submitted to the docket by NIOSH include grinders that meet this standard and other tools that bear the SA approval mark of the Canadian Standards Association, an OSHA Nationally Recognized Testing Lab (NRTL, described under 29 CFR 1910.7) (Document ID 3998, Attachment 10, pp. 7–9, 15, 45). OSHA anticipates that, once there is a market demand, additional tool manufacturers will offer shrouds meeting these machine guarding requirements. OSHA finds that compliant shrouds are already commercially available, and will not create a greater hazard.

In the proposed standard, OSHA specified that the dust collection system must have an air flow of at least 25 cfm per inch of wheel diameter. OSHA has maintained this requirement in the final standard. CISC commented that for larger blades, it may be difficult to design and operate a system that pulls air flow at 25 cfm per inch of blade diameter (Document ID 2319, p. 105). NAHB also expressed concern that a dust collector with a HEPA vacuum would need to be at least 112.5 cfm for a small, 4.5-inch grinder (Document ID 2296, Attachment 1, p. 29). PTI recommended revising the Table 1 entry for grinders to require use of vacuums equipped with a HEPA filter that operates at 80 cubic feet per minute or greater, noting that commercial dust collection systems are typically rated at approximately 130 cfm (Document ID 1973, pp. 2–3). BCTD, on the other hand, recommended that OSHA specify airflow rates for grinder LEV based on blade diameter (Document ID 2371, p. 32). As explained above in the discussion of grinders used for mortar removal, OSHA has determined that 25 cfm per inch of blade diameter is more protective and consistent with established engineering principles as reflected in the ACGIH Industrial Ventilation Manual, 28th Edition, which generally expresses minimum cfm requirements for a variety of (stationary) grinders in relation to the wheel diameter (Document ID 3883, pp. 13–147—13–152).

To adequately capture debris during the grinding, OSHA is requiring that dust collection systems used with grinders have a filter with 99-percent or greater efficiency, along with either a cyclonic pre-separator to collect large debris before the air reaches the filters or a filter-cleaning mechanism. Because the same factors that cause air flow to decline during tuckpointing affect air flow during other tasks such as surface grinding, the measures discussed in the section on grinders used for mortar removal also need to be used when surface grinding to minimize filter clogging.

Echt and Sieber reported respirable quartz concentrations ranging from 44 $\mu g/m^3$ to 260 $\mu g/m^3$ during two to three hour surface grinding tasks with LEV at a construction site. Each day, one or two 18-pound bags of debris were collected in a vacuum cleaner. The investigators measured actual air flow rates three times over the course of five sampling days, reporting an air flow range from 86 to 106 cfm (Document ID 0632, pp. 459–460). As noted in the discussion of LEV controls required for handheld grinders for mortar removal (tuckpointing), Heitbrink and Santalla-Elías also reported that air flow is affected by filter loading (Document ID 0731, p. 383). Using more extensive measurements (continuous data logging every 8 seconds), Collingwood and Heitbrink evaluated the same vacuum model used by Echt and Sieber and found that average initial air flow was 71 cfm, which declined to 48 cfm over the task-based work sessions, even with knocking the dust from filters using the manufacturer's recommended method as deemed necessary (Document ID 0600, p. 884). As previously discussed, the accumulation of material and debris on the filter (filter caking) during work causes pressure losses that eventually limit air flows in even the most powerful vacuums. As debris accumulates, the filter becomes caked with collected dust and air flow decreases. Unless the filter is properly cleaned according to the manufacturer's instructions, the air flows declines rapidly.

OSHA included three additional specifications in the proposed standard; two of these, preventing wet slurry from accumulating and drying, and ensuring that visible dust was not emitted from the process, were completely removed as described above. OSHA is retaining the third specification, which requires employers to minimize the accumulation of visible airborne dust when working indoors or in enclosed areas by providing sufficient ventilation when needed; this requirement is now located in paragraph (c)(2)(i) of the standard for construction.

In the proposed standard, OSHA required the use of a half-mask respirator with an APF of 10 during wet grinding for more than four hours. No respiratory protection was required when wet grinding for four hours or less. When using a grinder equipped with a commercially available dust collection system, OSHA required the use of a half-mask respirator with an APF of 10 regardless of task duration. In the final standard, OSHA has decided it is appropriate to distinguish between respiratory protection needed when grinding outdoors and grinding indoors or in enclosed areas. This division has allowed OSHA to more appropriately apply the use of respirators, limiting the number of tasks that requires their usage. Based on data in the record, OSHA concludes that most employees using hand-operated grinders without controls currently experience exposures above 50 $\mu g/m^3$ TWA. However, when grinders are operated with dust collection or wet systems outdoors, exposures will be reduced to or below 50 $\mu g/m^3$ most of the time. The exposure profile in Table IV.5.11–B in Section 5.11 of Chapter IV of the FEA shows that 50 percent of grinders working outdoors using water or LEV are exposed below 50 $\mu g/m^3$. These results demonstrate that silica exposures at or below 50 $\mu g/m^3$ have already been achieved for half of exposed workers with technology available at the time of sampling. Much of the data in the exposure profile reflects samples collected over ten years ago, before many of the engineering studies described in the FEA were conducted. OSHA expects that dust capture technology will continue to improve in response to market demand. When fully and properly implemented, OSHA expects that exposures to silica will be at or below 50 $\mu g/m^3$ most of the time when water-based dust suppression or LEV systems are used for outdoor grinding and that respiratory protection will not need to be relied on to protect employees.

The available data presented in Table IV.5.11–B in Section 5.11 of Chapter IV of the FEA suggest that the mean indoor grinding exposure level with dust collection systems is about twice that for grinding outdoors, with 50 percent of exposures between 100 and 250 $\mu g/m^3$. Exposures measured within a test chamber during grinding operations confirm that high exposures result from grinding concrete indoors, even with good dust collection equipment (Document ID 3609), with mean task-based sample results generally falling between 100 and 200 $\mu g/m^3$. Based on the available data for indoor grinding, OSHA concludes that, when grinding with a commercially available shroud and dust collection system for four hours or less per shift, resulting

exposures should generally be no higher than grinding outdoors for a full shift and thus should not necessitate the use of respiratory protection. However, for indoor grinding tasks performed more than four hours per shift, the Agency concludes that exposures will consistently exceed 50 μg/m³. Therefore, Table 1 requires respiratory protection with an APF of at least 10 when grinding with dust collection systems for more than four hours per shift indoors or in an enclosed area.

OSHA finds that there is inadequate evidence in the record to demonstrate that wet grinding indoors or in an enclosed area is as effective as using LEV. Accordingly, OSHA is permitting the use of water-based dust control for grinding tasks outdoors only and is not requiring the use of respiratory protection regardless of the duration of the task. OSHA notes from its exposure profile that the vast majority of exposure samples taken during indoor grinding where dust controls were used made use of LEV systems rather than water-based dust control systems (21 out of 23 samples) (*see* Section 5.11 of Chapter IV of the FEA). If an employer decides to use a wet method for indoor grinding, it will be operating outside of Table 1 and will have to comply with the paragraph (d) alternative method of compliance.

Walk-behind milling machines and floor grinders. Paragraph (c)(1)(xiii) of the standard for construction requires walk-behind milling machines and floor grinders used to grate or grind solid surfaces (such as concrete, asphalt, masonry walls and sidewalks, see Section 5.8 of Chapter IV of the FEA) to be equipped with an integrated water delivery system that continuously feeds water to the cutting surface, or with a dust collection system recommended by the manufacturer of the milling machine or floor grinder, a filter with 99 percent or greater efficiency, and a filter-cleaning mechanism. When using an LEV dust collector system indoors or in enclosed areas, Table 1 also requires that loose dust be cleaned with a HEPA-filtered vacuum in between passes of the milling machine or floor grinder. Both options require that the tool be operated in accordance with the manufacturer's instructions to minimize dust emissions. No respiratory protection is required by Table 1, regardless of task duration or work location.

Paragraph (c)(1)(xiii) of the standard for construction covers wheeled machines, equipped with a cutting tool, that are guided by hand with the worker positioned more than an arm's length away from the grinding action of the tool (*e.g.,* milling machines, scarifiers, floor grinders). Laborers or construction workers operate these machines during specialty tasks such as resurfacing floors, repairing pavement, or creating grooves for electrical cables (Document ID 0036, p. 15; 3958; 3959, p. 39). In the proposed standard, walk-behind milling machines were included under the entry for ''Milling'' as ''walk-behind milling tools.'' In response to commenters' recommendations, and recognizing that suitable dust control measures differ among different milling machines, OSHA has decided it is more appropriate to divide milling activities into three subgroups: Walk-behind machines and floor grinders, small drivable milling machines (less than half-lane), and large drivable milling machines (half-lane and larger) (Document ID 3583, Tr. 2171, 2212–2213; 2181, pp. 4, 7, 9).

Walk-behind milling machines and floor grinders are currently available with water systems (*e.g.,* Document ID 0524; 0642), and with dust collection systems (*e.g.,* Document ID 1276; 0636; 0642; 4073, Attachment 4a, Rows 131–133, 150–152). Additionally, some scarifiers, particularly those intended for indoor use, are available with both a vacuum port (for connecting to a portable industrial vacuum system) and a water mist system as standard equipment (Document ID 0642).

In specifying the option for a machine equipped with an integrated water delivery system that continuously feeds water to the cutting surface, OSHA is not specifying a minimum flow rate for water used with the integrated delivery system, but rather anticipates that the water flow rates specified by the manufacturer will optimize dust reduction. Evidence in the record demonstrates the effectiveness of wet methods to control exposures when using walk-behind milling machines and floor grinders. ERG (2000) measured exposure levels below the LOD (12 μg/m³) for workers using wet methods while milling a newly installed terrazzo floor indoors (Document ID 0200, p. 11). Echt *et al.* (2002) tested a custom-built water-fed system that provided a copious amount of water (15 gallons per minute) to the concrete work surface (not the cutting teeth) milled by a scabbler with an 8-inch cutting width. The investigators compared results from alternating 5-minute periods of milling with and without the water-feed activated. The water reduced average respirable dust levels by at least 80 percent. A separate NIOSH study on drivable milling machines reports that under common road milling conditions, water spray provided to the cutting drum area at 12 gallons per minute is capable of suppressing dust generated by a 7-foot wide (84 inches) drivable milling machine cutting drum (an application rate of just 0.14 gallons per minute per inch of cutting width) (Document ID 1251, pp. 7–9, 14). Based on this evidence, OSHA concludes that, with careful adjustment, water spray methods using a fraction of the water used in the Echt *et al.* (2002) scabbler study should prove at least as effective in reducing silica dust exposures generated by walk-behind milling machines and floor grinders.

Blute *et al.* (1999) evaluated silica exposures among workers using wet dust control methods for scabbling and large-scale grinding tasks at an underground construction site. In this case, rather than being walk-behind equipment, the scabblers and grinders were attached to the articulated arm of front-end loaders (Document ID 0562, p. 633). Although these workers used drivable machines (removing more material than the typical walk-behind milling machine), their work (scabbling and grinding excess concrete from tunnel walls) demonstrates the value of wet methods when these activities are performed in enclosed spaces. This is particularly relevant to walk-behind milling machines that are frequently used indoors to mill concrete surfaces. In the underground work environment, all three workers experienced task-based silica concentrations below the preceding PEL with only one of the results (79 μg/m³) exceeding 50 μg/m³ (Document ID 0562, p. 637). OSHA has determined that the information discussed above and in the FEA is the best available evidence and supports the use of wet methods to control silica dust while using walk-behind milling machines.

Alternatively, employers following Table 1 may use a machine equipped with a dust collection system recommended by the manufacturer. The similarity between vehicular and walk-behind milling machines supports the use of vacuum dust collection (exhaust suction) methods for the smaller, walk-behind form of milling equipment. A study by TNO Bouw (2002) found that when exhaust suction methods were applied to the milling drum area of drivable milling machines, exposure levels for operators obtained over a five-day period ranged from less than 4 μg/m³ to 28 μg/m³. The study also found similar exposure results for machine tenders, who walked next to the machines; results ranged from less than 3 μg/m³ to 29 μg/m³ (Document ID 1184, p. 25). OSHA inspection data from a construction site using a scarifier and

a floor grinder, both equipped with LEV, to mill a concrete floor found no silica exposure for either of the workers (Document ID 3958, Rows 209–211, 214–215). OSHA's exposure profile, contained in Section 5.8 of Chapter IV of the FEA, contains these and four other exposure results for workers using walk-behind equipment at two indoor construction sites using LEV, where only one detectable result exceeded 50 $\mu g/m^3$.

Based on the evidence in the record, OSHA has determined that employees' exposure when using walk-behind milling machines can be further reduced by cleaning up debris when work is performed indoors or in enclosed areas. During a study on exposures while operating a scabbler in a parking garage, researchers noted that the worker generated the most airborne dust when passing the machine over a previously milled area (Document ID 0633, pp. 812–813). OSHA's OIS data also contains a non-detectable silica exposure result for a helper who vacuumed behind the operator of a floor grinder and scarifier preparing an indoor concrete floor for painting where LEV was used as the dust control (Document ID 3958, Row 211). Under paragraph (c)(1)(xiii) of the standard for construction, when using a walk-behind milling machine or floor grinder indoors or in an enclosed area, milling debris in the form of loose dust must be removed with a HEPA-filtered vacuum prior to making a second pass over an area. This prevents the debris from interfering with the seal between machine and floor and minimizes the gap. Additionally, it prevents debris from being re-suspended and acting as another source of exposure. Accordingly, OSHA is requiring the use of a vacuum with a HEPA filter to clean up any loose dust prior to making additional passes over the area when work is conducted indoors or in enclosed spaces with LEV (Document ID 0633, pp. 812–813; 1391, pp. 28, 40).

In addition, the effectiveness of vacuum suction also depends on minimizing the gap between the bottom of the machine and the surface being milled, as discussed by Hallin (1983), who found that exposures to respirable dust increased when the housing around the base of the tool was removed (Document ID 1391, p. 25). To achieve acceptable dust control and ensure that the LEV system is fully and properly implemented, milling must proceed in a manner that limits the gap between the bottom of the walk-behind milling machine and the surface being milled.

Based on the data described above, OSHA concludes that most employees operating walk-behind milling machines will experience exposure levels of 50 $\mu g/m^3$ or below most of the time when employers implement the controls outlined in Table 1 under paragraph (c)(1)(xiii) of the standard for construction. OSHA finds that controls effective for driven milling machines are adaptable to the smaller walk-behind milling machines. Even in indoor environments, low exposures can be achieved for most walk-behind milling machine operators through the proper use of controls, including the use of HEPA-filtered vacuum systems intended to clear debris in between milling passes when dry grinding and the use of ventilation as required under paragraph (c)(2)(i) of the standard for construction. Therefore, OSHA concludes that exposure will remain below 50 $\mu g/m^3$ most of the time, even when working indoors for more than four hours, and is not requiring the use of respiratory protection, regardless of task duration or work location.

Small Drivable Milling Machines (less than half-lane). Employees engaged in this task use small drivable milling equipment to grate or grind solid surfaces, such as concrete floors, sidewalks, and asphalt roads. The smaller drivable machines mill a narrower strip of pavement than large milling machines (median of 20 inches compared to a minimum of 79 inches for large machines), and typically are capable of milling less depth (median 8 inches) than a large machine (median 13 inches) (Document ID 1229; 3958). Milling machinery, both large and small, often uses a rapidly rotating drum or a bit covered with nibs to abrade surfaces, although other mechanisms (including systems based on impact, shot-blast, or rotating abrasive cups) are common.

The proposed standard contained a single entry for ''Milling'' and treated all drivable milling machines alike, requiring them to use a water-fed system that continuously applied water at the cut point. In the final standard, OSHA has separated smaller milling machines (less than a half-lane wide) from larger ones based on comment and testimony in the record. In response to commenters, OSHA has decided it is more appropriate to divide drivable milling activities into separate entries for large milling machines (half-lane and larger) and small milling machines (less than half-lane) (Document ID, 3583, Tr. 2171, 2212–2213; 2181, pp. 4, 7, 9). IUOE and a road milling machine manufacturer categorized drivable milling machines as either small or large (half-lane or larger, with cutting drum about 79 inches or wider) (Document ID 3583, Tr. 2441; 1229). NAPA commented that large milling machines should be identified separately on Table 1 of the construction standard. Based on these comments and evidence showing that the dust control systems are different between the two classes of drivable milling machine (Document ID 3583, Tr. 2171, 2212–2213), Table 1 in the final standard treats them as two separate tasks.

Under paragraph (c)(1)(xiv) of the standard for construction, small drivable milling machines (less than a half-lane in width) must be used with supplemental water sprays designed to suppress dust. The water used must be combined with a surfactant. Manufacturers of smaller drivable milling machines currently make such systems (Document ID 1229; 4073, Attachment 4a). Unlike for larger milling machines, Table 1 does not specify as an option a water spray and exhaust ventilation combination system for small milling machines because it appears that such systems are not currently available.

Including a surfactant additive in the water is a practical way to reduce employee exposures to the lowest level achievable with this wet method (Document ID 1216, p. 3; 1217, Slides 4 and 8; 3583, Tr. 2187–2188). This is because it offers particle binding properties that are ideal for dust suppression (Document ID 1216, p. 3).

Small drivable milling machines generally produce less dust than large drivable machines, since small machines are used intermittently and have smaller cutting tools (Document ID 1229, pp. 1–3; 3583, Tr. 2213). As discussed in the technological feasibility section on millers using portable or mobile machines (*see* Section 5.8 of Chapter IV of the FEA), OSHA concluded that, rather than relying on the very limited (two) existing data points for workers using small drivable milling machines, the exposure profile for this group is better represented by a surrogate data set comprising the more comprehensive and wide ranging profile for the entire group of workers using drivable milling machines (including operators and tenders/helpers of both large and small drivable milling machines). Thus, the exposure profile for small drivable milling machines (n = 31) shows a median exposure of 21 $\mu g/m^3$ and a mean exposure of 48 $\mu g/m^3$, with overall exposures ranging from 5 $\mu g/m^3$ to 340 $\mu g/m^3$. Therefore, considering the ample evidence on the effectiveness of water-based dust control systems for large as well as small drivable milling machines, OSHA finds that this control is

applicable to small drivable milling machines.

Water applied to the cutting drum helps reduce respirable silica exposures among milling machine operators and helpers. In a study conducted in the Netherlands, a water spray dust emission suppression system using additives reduced the PBZ respirable quartz exposures of asphalt milling machine drivers to a mean of 20 μg/m³, with a range of 9 μg/m³ to 30 μg/m³ (Document ID 1216, p. 4). Milling machine tenders benefitted equally from the system, having a mean PBZ respirable quartz exposure of 8 μg/m³ with a range of 4 μg/m³ to 12 μg/m³. In his comments, Anthony Bodway, representing NAPA, stated his belief that employee exposures from asphalt road milling machines will be reduced to levels below 50 μg/m³ when milling machines are fitted with effectively designed water spray systems paired with surfactants and routine inspections to ensure the system components are working properly (Document ID 2181, p. 10). He noted that all six major road milling machine manufacturers have recently begun, or will soon be, offering dust control optimized water spray systems as standard equipment or retrofit kits (Document ID 2181, pp. 21–29). One water spray design for asphalt pavement milling evaluated by NIOSH showed more promise than others, reducing dust release by 38 to 46 percent (Document ID 4141, p. 26). Although his comment was related to large drivable milling machines, wet dust control technology is available for small drivable milling machines (Document ID 1229; 4073, Attachment 4a).

Based on information presented here and in the technological feasibility analysis (*see* Section 5.8 of Chapter IV of the FEA), OSHA concludes that employers using the controls required by paragraph (c)(1)(xiv) of the standard for construction can reduce exposure levels to 50 μg/m³ or below for most employees operating or helping with small drivable milling machines most of the time. The similarities to large drivable milling machines are sufficient to indicate that the wet dust suppression control technology is transferable to the smaller drivable machines. Even if these smaller machines do not achieve the extent of dust suppression demonstrated for larger machines because they perform specialty milling operations and not flat removal of asphalt typically performed by large drivable machines prior to laying of new asphalt, the intermittent nature of operations for which small drivable milling machines are used will help to maintain 8-hour TWA exposure levels substantially lower than they would be for continuous operation (Document ID 3583, Tr. 2213–2215). Therefore, OSHA is not requiring the use of respiratory protection regardless of task duration when using small drivable milling machines (less than half-lane) equipped with supplemental water sprays combined with a surfactant.

Large drivable milling machines (half-lane or larger). Paragraph (c)(1)(xv) of the standard for construction has three control options for employers operating large (one-half lane or wider) milling machines. When making cuts of four inches in depth or less on any substrate, the control options are either to use a machine equipped with exhaust ventilation on the drum enclosure and supplemental water sprays designed to suppress dust or a machine equipped with supplemental water spray designed to suppress dust combined with a surfactant. When milling only on asphalt, Table 1 allows cuts of any depth to be made when machines are equipped with exhaust ventilation on the drum enclosure and supplemental water sprays designed to suppress dust.

These controls are currently available (Document ID 2181, pp. 11, 21–29). All of the manufacturers of large milling machines currently provide dust-suppressing water spray systems on new equipment and as retrofit kits for older machines. In addition, as discussed in the Section 5.8.4 of Chapter IV of the FEA, new machines will be equipped with both dust-suppressing water spray systems and dust collection systems by 2017 at the latest, when industry members are committed under the Silica/Asphalt Milling Machine Partnership, which includes representatives from the road construction contractors industry and major road milling machine manufacturers, NAPA, AEM, IUOE, LHSFNA, and NIOSH, to equip new machines with both dust-suppressing water spray systems and LEV (Document ID 2181, pp. 11, 21–29).

The controls included on Table 1 for large drivable milling machines are based on research on dust control technologies conducted by the Silica/Asphalt Milling Machine Partnership, which has been studying dust controls for milling machines since 2003 (Document ID 2181, pp. 1–2; 3583, Tr. 2152, 2160; 4149) with the goal to develop innovative engineering controls ''that all but eliminate dust and potential silica exposure,'' and methods ''to retrofit existing milling machines to ensure a safe workplace'' (Document ID 3583, Tr. 2153). Much of the data contained in the record on the effectiveness of control strategies for large drivable milling machines come from the Partnerhip's efforts and are contained in NIOSH publications (*see* Table IV.5.8–B in Section 5.8 of Chapter IV of the FEA).

Based on the data in the record, exposures among large drivable milling machine operators can be reduced to 50 μg/m³ or less most of the time. The exposure profile in Section 5.8 of Chapter IV of the FEA shows that 79 percent of all large drivable milling machine operators already experience silica levels below 50 μg/m³ as a result of using water spray intended to cool the cutting drum. Similarly, exposure levels for 67 percent of tenders working alongside large milling machines are below 50 μg/m³. Based on the Agency's review of studies in the record, which show that low silica exposures can be achieved for both operators and tenders across varying water spray flow rates, OSHA concludes that improvements to cooling water spray systems can help to further reduce exposures of employees currently experiencing exposures above 50 μg/m³ (*see* Tables IV.5.8–D and IV.5.8–E in Section 5.8 of Chapter IV of the FEA). However, information is insufficient to confirm that the use of water alone in existing systems will reliably control all employees' exposures. Based on the Agency's review of evidence in the rulemaking record, OSHA has determined that supplementing water with a dust suppressant additive or with an exhaust ventilation on the drum enclosure (controls that were not included on proposed Table 1), will achieve levels below 50 μg/m³ for all or almost all operators and helpers most of the time when making cuts of four inches in depth or less on any substrate (*see* Table IV.5.8–E in Section 5.8 of Chapter IV of the FEA) (Document ID 1216, p. 4; 4147, pp. v, 13; 4149, pp. v, 13). Additionally, OSHA has determined that when milling asphalt only, the addition of exhaust ventilation on the drum enclosure will achieve levels below 50 μg/m³ for workers making cuts of any depth (Document ID 4149).

NIOSH recommended LEV plus water-spray dust suppression controls be included on Table 1 for drivable milling machines (Document ID 2177, Attachment B, p. 20). As discussed in Section 5.8.4 of Chapter IV of the FEA, a dust suppression system with a foam additive kept exposures below 30 μg/m³, and the use of water sprays combined with LEV systems kept exposures under 25 μg/m³ (Document ID 1184, pp. 5, 25; 1217, p. 4). These methods, combined with water spray

systems purposefully designed to control dust at the cutting drum, transfer points, and conveyors, will control silica exposures among vehicular milling machine operators and tenders to 50 μg/m³ or below during typical removal operations under the typical range of conditions. Manufacturers of large milling machines are committed under the Silica/Asphalt Milling Machine Partnership to equip new machines with both dust-suppressing water spray systems and LEV by 2017 (Document ID 2181, pp. 11, 21–29). Until such time that new machines equipped with LEV and water dust suppression systems are available, all six major road milling machine manufacturers have recently begun, or will soon be, offering dust control optimized water spray systems as standard equipment and/or retrofit kits, which are expected to meet the requirements for Table 1 for cuts of four inches in depth or less on any substrate (Document ID 2181, pp. 21–29).

Proposed Table 1 specified the use of a respirator (half-mask APF 10) for drivable milling machines with a water-fed system used more than four hours a day irrespective of the material milled. NAPA recommended removing the proposed requirements for use of respirators when milling asphalt (Document ID 2181, pp. 11–12, 16). Upon review of the evidence in the record, OSHA agrees that this is appropriate for all asphalt and concrete milling operations. As explained in Section 5.8 of Chapter IV of the FEA, the controls contained in Table 1 in the final standard will keep exposures below 50 μg/m³ for most operators and tenders of large drivable milling machines most of the time. Evidence submitted to the record by NAPA and NIOSH shows both water-based dust suppression systems and combination LEV/water-based systems during asphalt milling results in employee exposures lower than 50 μg/m³ (Document ID 2177 Attachment B, p. 20; 1184, pp. 5, 25; 1217, p. 4). Accordingly, respiratory protection is not required under Table 1 of the final standard for operating large drivable milling machines to mill asphalt. Although there is some qualitative evidence indicating that exposures when milling concrete for more than four hours may be somewhat higher, and could exceed 50 μg/m³ some of the time, there is no hard data permitting OSHA to treat asphalt and concrete milling differently with respect to imposing a respirator requirement or to conclude that most concrete milling for that duration will be above 50 μg/m³ most of the time. Therefore, OSHA is not including a respirator requirement in the final standard for either asphalt or concrete milling, regardless of task duration.

IUOE recommended separate treatment of operators and tenders of large milling machines since the exposures of operators are lower than the exposures of tenders. IUOE further stated that operators are located farther from the silica source than tenders, and appropriate protection varies depending upon the location of the worker from the silica source (Document ID 2262, p. 24). Evidence summarized above shows that most tenders and operators will not experience silica exposures in excess of 50 μg/m³ when either of the control options required by Table 1 is implemented. The exposure profile in Table IV.5.8–C in Section 5.8 of Chapter IV of the FEA shows that the mean of respirable crystalline silica exposures for operators of large milling machines is 39 μg/m³ (median 17 μg/m³) and the slightly higher mean for tenders is 57 μg/m³ (median 27 μg/m³). Sample results presented in the exposure profile indicate that 79 percent of all large drivable milling machine operators already experience silica levels below 50 μg/m³ as a result of using water spray intended to cool the cutting drum. Similarly, exposure levels for most tenders (67 percent) working alongside large milling machines are already below 50 μg/m³ (*see* Tables IV.5.8–D and IV.5.8–E in Section 5.8 of Chapter IV of the FEA). Therefore, OSHA concludes that separate control measures do not need to be specified for operators and tenders.

Proposed Table 1 contained dust control specifications for all drivable milling machines, including when milling concrete. OSHA received comments from IUOE, BCTD, and NAPA recommending that Table 1 be modified to separate asphalt milling and concrete milling and require appropriate controls based on the respective exposure levels (Document ID 2262, pp. 3, 17; 2371, Attachment 1, p. 26; 2181, p. 9). Concrete milling is performed less frequently than asphalt milling (Document ID 1231; 3583, Tr. 2213–2214), but silica exposures could be higher than when milling asphalt. This difference is likely due to the potential for the silica content to be higher in some concrete compared with some asphalts (Document ID 1699), and also the softness and ''stickiness'' of asphalt milled warm, which likely helps reduce separation of the pavement components and perhaps limits dust release in hot weather (Document ID 1251, p. 14; 1231). In addition, cutting drums for concrete have smaller teeth, which can produce more fine dust than is the case with asphalt (Document ID 1699). Anthony Bodway, representing NAPA, also noted that silica exposures are higher for concrete milling than for asphalt milling (Document ID 2181, p. 15). In the FEA, OSHA concludes that water dust suppression and LEV systems should be equally effective for concrete and asphalt in terms of percent reduction in dust emissions when making cuts of four inches in depth or less on any substrate (*see* Section 5.8 of Chapter IV of the FEA). However, to the extent that milling concrete is dustier (*i.e.,* a larger amount of respirable dust is liberated), exposures to silica during concrete milling may be somewhat higher than is the case for asphalt milling even with the use of dust controls. As previously explained, however, OSHA lacks quantitative data supporting these comments to allow it to impose more stringent requirements, specifically a requirement to use respirators, on concrete milling and not on asphalt milling or to conclude that exposures will be over the PEL for most operators most of the time doing either task.

The Silica/Asphalt Milling Machine Partnership conducted field trials for large road milling machine LEV systems making cuts up to 11 inches deep (Document ID 4147; 4149). NIOSH evaluated exposures among workers at four road construction sites (Document ID 4147, pp. v, 5–7, 13, Table 1; 4149, pp. v, 5–7, 13, Table 1). All the samples obtained during the studies for operators and tenders combined showed that exposure levels never exceeded 25 μg/m³ when workers used machines fitted with the LEV system, even when making cuts up to 11 inches deep in asphalt (Document ID 4147, pp. v, 6–7, 13, Table 1; 4149, pp. v, 5–7, 13, Table 1). In fact, the highest sample result (24 μg/m³ for a ''groundsman'' walking beside a milling machine removing 11 inches of pavement on each pass) was the only sample result to exceed 13 μg/m³ during the two sampling dates (Document ID 4147, pp. v, 5–7, 13, Table 1; 4149, pp. v, 5–7, 13, Table 1). Therefore OSHA is confident that when removing asphalt only, workers can make cuts of any depth without elevated exposures to silica.

However, other evidence contained in the record indicates that cutting depths of more than four inches, in one pass, reduces the effectiveness of controls (Document ID 3798, pp. 2, 14; 0555, p. 1). Therefore OSHA has determined that if an employer is using a large drivable milling machine to mill concrete, or road surface material that contains both concrete and asphalt, deeper than four

inches, it is not covered by Table 1 and the employer will be required to conduct exposure assessments and comply with the PEL in accordance with paragraph (d) of the standard for construction.

IUOE also recommended excluding road demolition and asphalt reclamation from asphalt milling in Table 1. Road demolition involves removal of the road substructure in addition to the road surface material and asphalt reclamation involves deeper cuts than typical ''mill and fill'' cuts of four inches in depth or less. IUOE asserted that this change should eliminate the need for respirator use by operators during typical asphalt ''mill and fill'' operations when engineering controls are properly implemented (Document ID 2262, p. 23).

Paragraph (c)(1)(xv) of the standard for construction excludes road demolition and asphalt reclamation operations by limiting milling activities on materials other than asphalt to cuts of four inches in depth or less. The NIOSH studies of LEV for drivable milling machines were conducted using large asphalt road milling machines (half-lane or wider) and provide strong evidence that exposure levels below 50 $\mu g/m^3$ (and even below 25 $\mu g/m^3$) can be achieved for employees operating this type of equipment during typical shallow ''mill and fill'' type road milling (*i.e.*, cuts of four inches in depth or less) (*see* Table IV.5.8–E in Section 5.8 of Chapter IV of the FEA). In one NIOSH study, the removal of excess pavement during milling machine demolition-type work (12 inches of pavement all at once), created a large gap between the road and the milling machine drum enclosure, allowing more dust to escape than during typical milling conditions (Document ID 0555, p. 1). Also, a NIOSH trial, using only drum cooling water and alternate spray nozzles, showed elevated silica exposure levels when the road milling machine intermittently ground through the asphalt layer into an aggregate and concrete underlayment (Document ID 3798, pp. 2, 14). Milling operators will rarely encounter these ''worst case'' conditions (Document ID 0555, p. 1).

As previously stated, when milling only on asphalt, OSHA is allowing cuts of any depth to be made when machines are equipped with exhaust ventilation on the drum enclosure and supplemental water sprays designed to suppress dust. When milling all other material to a depth of more than four inches Table 1 does not apply and employers will be required to conduct exposure assessments and comply with the PEL in accordance with paragraph (d) of the standard for construction. Additionally, road demolition, such as cutting the roadway into manageable size pieces or squares that involves equipment other than milling machines, such as saws, dowel drills, and various kinds of heavy equipment, is not covered under this entry on Table 1 (*see* Sections 5.3, 5.6, and 5.9 of Chapter IV of the FEA). In those instances employers will need to follow the appropriate entries on Table 1 for the equipment used or conduct exposure assessments and comply with the PEL in accordance with paragraph (d) of the standard for construction.

Crushing machines. Crushing machines are used to reduce large rocks, concrete, or construction rubble down to sizes suitable for various construction uses (*see* Section 5.10 of Chapter IV of the FEA). When using crushers, paragraph (c)(1)(xvi) of the standard for construction requires the use of equipment designed to deliver water spray or mist for dust suppression at crusher and other points where dust is generated (*e.g.*, at hoppers, conveyors, sieves/sizing or vibrating components, and discharge points), and a remote control station or ventilated booth that provides fresh, climate-controlled air to the operator. In the proposed standard, OSHA listed this entry as ''Rock Crushing.'' For the final standard OSHA has revised the title of this entry to clarify that it includes concrete crushing, which is often performed at demolition projects (Document ID 4073, Attachment 9a; 4073, Attachment 10a; 4073, Attachment 10b; 4234, Attachment 1, pp. 15–16). Proposed Table 1 would have required the use of wet methods or dust suppressants or LEV systems at feed hoppers and along conveyor belts. Information contained in the record indicates that LEV alone is not effective in reducing exposures to 50 $\mu g/m^3$ or below, and that it is necessary to require both a water spray system and either a remote control station or filtered control booth to protect the operator and employees engaged in crushing operations (*see* Section 5.10 of Chapter IV of the FEA).

Wet spray methods can greatly reduce the exposure levels of operators and laborers who work near crushers tending the equipment, removing jammed material from hoppers, picking debris out of the material stream, and performing other tasks (Document ID 0203, pp. 3–6, 9; 1152; 1360; 1431, pp. 3–93–3–94; 3472, pp. 61–76; 4073, Attachment 9a; 4073, Attachment 15g, p. 1). These systems are currently available and all crushers and associated machinery (conveyors, sizing screens, discharge points) can be retrofitted with water spray or foam systems (Document ID 1360; 0769; 0770; 0830; 0831; 0832). Spray systems can be installed for remote control activation (Document ID 0203, pp. 11, 12, 14; 0830). The design and application of water spray systems will vary depending on application. For airborne dust suppression, spray nozzles should be located far enough from the target area to provide coverage but not so far so as to be carried away by wind. In addition, nozzles should be positioned to maximize the time that water droplets interact with airborne dust. Droplet size should be between 10 and 150 µm (Document ID 1540, pp. 62–63). Alternatively, to prevent airborne dust from being generated, nozzles should be located upstream of dust generation points and positioned to thoroughly wet the material, and the volume and size of droplets increased to ensure that the material is sufficiently wetted (Document ID 1540, pp. 62–63). Information from IUOE, BCTD, and the U.K. Health and Safety Executive shows that water application can be expected to reduce exposure levels from 78 to 90 percent (Document ID 1330, p. 94; 4025, Attachment 2; 4073, Attachment 9a, pp. 1–4; 4073, Attachment 15g, p. 2).

The record did not contain information on exposures of tenders or other employees working near a crusher operation without dust controls. However, OSHA concludes that employees assisting with crusher operations can be exposed to elevated levels of respirable crystalline silica if water sprays are not used to control dust emissions. This conclusion is based on evidence gathered by OSHA's contractor, ERG, which visited a concrete crusher site. At the site, ERG observed a crusher operator who spent time outside of a control booth shoveling dried material from under a conveyor. The operator was exposed to 54 $\mu g/m^3$ TWA despite the time he spent in the booth where the silica concentration was non-detectable (Document ID 0203, p. 9). Thus, this operator's TWA exposure to silica can be entirely attributed to his work around the crusher, much as a tender would have been doing. Without the benefit of spending some time in the booth, and the fact that the material being crushed was wet from rain and a freeze the night before, the operator's exposure could have been even higher (Document ID 0203). This indicates that tenders assisting with crusher operations, who do not have the benefit of a booth for protection from exposure, can be exposed to excessive levels of crystalline silica-containing dust when

water is not applied to areas where dust emissions occur. The potential exposure of tenders and other employees who are in the vicinity of crusher operations underscores the importance of using water spray systems to reduce dust emissions. Such systems will reduce dust exposures generally, thereby reducing exposures for tenders and other employees in the vicinity of the crusher. Moreover, as discussed below, OSHA is not specifying the use of LEV systems for crushing operations on Table 1 of the final standard because LEV has not been proven to be an effective or widely available alternative.

CISC argued that OSHA's preliminary finding that it was feasible to achieve exposures of 50 μg/m^3 for tenders was unfounded and based on no data on exposures of crushing machine tenders (Document ID 2319, pp. 62–63). However, there are data in the record that inform the Agency with respect to exposure of crushing machine tenders and the effectiveness of dust controls in reducing their exposures to silica. As described above, a crusher operator performing tasks along the conveyor belt was exposed much as a tender would be. OSHA identified one exposure measurement from an enforcement case for a laborer working near a mobile crusher at an asphalt plant; the laborer's exposure was 43 μg/m^3 (8-hour TWA) based on a half-day of sampling (Document ID 0186, pp. 60–61). In addition to assisting with the crusher operation, he also mixed a blend of sand, crushed concrete, asphalt, and soil, which likely contributed to his exposure. He was working about 50 feet from the crusher hopper where it was evident from the inspection report that his exposure was much lower than that of the operator (Document ID 0186, p. 37). Bello and Woskie found exposures of demolition workers, including those near a crushing operation, were below 50 μg/m^3 when water was used as dust controls for the demolition project (Document ID 4073, Attachment 9a, pp. 3–4). OSHA thus rejects CISC's contention that the absence of direct evidence of exposures to tenders means that OSHA cannot regulate them or draw reasonable inferences about the technological feasibility of controlling their exposures (Document ID 2319, pp. 62–63).

Crushers are currently available with remote controls as standard equipment (Document ID 0770; 0769, p. 2). The remote operation permits the operator to stand back from the crusher or move upwind of dust emissions. IUOE provided exposure data from large highway reconstruction projects (Document ID 4025, Attachment 2, p. 9). Four samples were collected where the operator platform was next to the crushing operation and the operator was directly exposed to the crusher emissions, resulting in a mean respirable crystalline silica exposure of 410 μg/m^3 (Document ID 4025, Attachment 2, p. 9). Water use was observed but no details were provided on the extent of use or the systems in place. There was an approximately 66 percent reduction in exposure to respirable crystalline silica of the crusher operator working from a remote location (the remote location mean exposure was 140 μg/m^3) (Document ID 4025, Attachment 2, p. 9). IUOE addressed the utility of remote controls in its comments on the proposed standard, and requested that OSHA evaluate remote control technologies as an exposure control method and include this type of control in Table 1 (Document ID 2262, p. 45; 3583, Tr. 2341).

An isolated and ventilated operator control booth can significantly reduce the respirable silica exposures of employees associated with crushing. At a visit to a crusher facility, ERG found non-detectable levels of respirable crystalline silica inside the operator's control booth, compared to a concentration of 103 μg/m^3 outside, despite the booth having poor door seals, using recirculated rather than fresh air, and having foam filters (as opposed to the MERV–16 or better filters required by paragraph (c)(2)(iii)(E) of the standard for construction) (Document ID 0203, pp. 12–13).

Other studies of operator cabs also reported silica or dust exposure reductions ranging from 80 percent to greater than 90 percent (Document ID 0589, p. 3; 0590, p. 54; 1431, p. 3–95). In the PEA, OSHA recognized that control booths for crushers are commercially available, although they are not commonly used on construction sites (Document ID 1720, p. IV–494). However, Kyle Zimmer, director of health and safety for IUOE Local 478, stated during the hearing that ''contractors report that they are using portable crusher control booths with air conditioning to operate the plant remotely'' (Document ID 3583, Tr. 2341).

Evidence indicates that operators experience high exposure levels when they must operate the crusher from above the feed hopper where dust emissions are highest (Document ID 0030; 4073, Attachment 10a). In light of this evidence, OSHA concludes that removing or isolating the operator from this high-exposure location will be effective in lowering the exposure of the operator. It is not clear that a control booth alone will be sufficient to protect the operator from exposure to silica, since operators periodically leave the booth to perform work around the crusher, and the booth does not offer any protection for other employees outside the booth such as tenders. A study of crushers used in the South Australian extraction industry found operator exposures ranged from 20 to 400 μg/m^3 (with a median of 65 μg/m^3) while crushing dry material and using control booths or cabs (Document ID 0647). Four of the eight sample results were at or below 50 μg/m^3, and at least two of the sampled workers occasionally exited the cabins to free machinery blockages (Document ID 0647).

Because providing a filtered booth for the operator will not protect other employees assisting with the operation or working nearby, OSHA finds that a water-based dust suppression system is necessary to prevent excessive exposure to silica among tenders and other employees nearby. Therefore, OSHA has determined that the combination of water use and either a remote control station or a ventilated booth for the mobile crusher operator will be effective in minimizing exposure of the operators and tenders. Summary data submitted by IUOE show that, with water use, the addition of remote control stations further reduced operator exposures by a factor of 3 (Document ID 4025, Attachment 2, p. 9). At the crusher operation visited by ERG, the operator's TWA exposure was 54 μg/m^3 while working in a booth, and his exposure would have been lower had water been applied to dried material he was shoveling from under the conveyor.

In the proposed standard, OSHA required the use of a half-mask respirator with an APF of 10 for all employees outside of the cab, regardless of task duration or whether water sprays or LEV were implemented. No respiratory protection was required for those employees who operated the crusher from within the cab. OSHA proposed to require respirator use because the data available at the time suggested that neither water spray nor LEV systems would consistently reduce exposures to 50 μg/m^3 or less, and that high exposures (even in excess of the preceding PEL) could still occur. The crushing machine entry for Table 1 in the final standard does not require respiratory protection for tenders or mobile crusher operators because the evidence described above indicates that the use of water systems, combined with a remote control station or ventilated

booth, will reduce most employees' exposures to respirable silica to 50 μg/m³ or less most of the time.

Information from IUOE, BCTD and the U.K. Health and Safety Executive show that water application can be expected to reduce exposure levels by 78 to 90 percent (Document ID 1330; 4025, Attachment 2, pp. 7–23; 4073, Attachment 9a, pp. 1–4; 4073, Attachment 15g, p. 2). Using the mid-point of this exposure control range (84 percent) and applying it to the highest value in the exposure profile (300 μg/m³), would yield an exposure of slightly less than 50 μg/m³ TWA for an eight-hour work day. However, other evidence suggests that wet spray methods may not consistently achieve exposures below 50 μg/m³ (Document ID 0030; 4025, Attachment 2, pp. 7–23), although little detail was available on how water was applied. The evidence is clear that the highest exposures occur at the hopper where material is fed by front-end loaders or another conveyor, an area that is most likely to be tended by the operator (Document ID 0030; 4073, Attachment 10a; 0203). Therefore, OSHA finds that it is also necessary to use a remote control station or filtered booth to ensure the protection of crusher operators.

The use of LEV systems was discussed in the NPRM, but evidence in the record indicates that it has yet to be proven practicable for mobile construction crushing equipment and is not currently used extensively. William Turley of the Construction and Demolition Recycling Association stated, ''While there are crushing operations that have used baghouses on the crusher, none use . . . ventilation equipment for conveyors'' (Document ID 2220, p. 2). Phillip Rice of Fann Contracting contended that large crushing systems with multiple conveyor belts would make it very difficult to use LEV cost effectively (Document ID 2116, Attachment 1, p. 31). In contrast, Kyle Zimmer of IUOE testified that employers are using dust collectors with baghouses at some crushing operations (Document ID 3583, Tr. 2341). Nevertheless, the record does not contain substantial and convincing evidence that LEV alone can be applied when using mobile crushing machines to reduce exposure levels to the same extent as water-based dust suppression systems combined with the use of remote control stations or filtered control booths. Therefore, OSHA is not specifying the use of LEV systems for crushing operations on Table 1 of the final standard.

Heavy equipment and utility vehicles used to abrade or fracture silica containing materials (e.g., hoe-ramming, rock ripping) or used during demolition activities involving silica-containing materials. Employees engaged in this task operate a variety of wheeled or tracked vehicles ranging in size from large heavy construction equipment, such as bulldozers, scrapers, loaders, cranes and road graders, to smaller and medium sized utility vehicles, such as tractors, bobcats and backhoes, with attached tools that are used to move, fracture, or abrade rock, soil, and demolition debris (*see* Section 5.3 of Chapter IV of the FEA). For example, equipment operators typically perform activities such as the demolition of concrete or masonry structures, hoe-ramming, rock ripping, and the loading, dumping, and removal of demolition debris, which may include the loading and dumping of rock, and other demolition activities (*see* Table IV.5.3–A in Section 5.3 of Chapter IV of the FEA).

Paragraph (c)(1)(xvii) of the standard for construction requires the operator to be in an enclosed cab, regardless of whether other employees are in the area and the cab must meet the requirements of paragraph (c)(2)(iii) of the standard for construction. When other employees are engaged in the task, water, dust suppressants, or both combined must also be applied as necessary to minimize dust emissions. Paragraph (c)(2)(iii) of the standard for construction requires enclosed cabs to be kept as free as practicable from settled dust, to have door seals and closing mechanisms that work properly, to be under positive pressure maintained through continuous delivery of fresh air, to have gaskets and seals that are in good condition and work properly, to have intake air that is filtered through a filter that is 95 percent efficient in the 0.3–10.0 μm range, and to have heating and cooling capabilities.

In the proposed Table 1, OSHA included one entry for heavy equipment and required that an enclosed cab be used. Although OSHA analyzed all types of work with heavy equipment, including demolition, in its preliminary feasibility analysis for heavy equipment, the proposed Table 1 entry described the activity as ''use of heavy equipment during earthmoving activities.''

Several commenters requested clarification on what uses of heavy equipment OSHA intended to cover in the entry on proposed Table 1. IUOE requested that OSHA include a definition of the range of ''activities encompassed within earthmoving,'' and specifically acknowledge whether or not demolition activities are intended to be encompassed within this definition of earthmoving on Table 1 (Document ID 2262, p. 7). IUOE further explained that while earthmoving activities are ''dust-filled'' and likely to result in some exposure to respirable silica, it was inappropriate to combine earthmoving and demolition into one entry for heavy equipment operators on Table 1 because earthmoving ''does not fracture or abrade silica-containing materials, and thus, does not expose any heavy equipment operators to [a] high concentration of respirable silica.'' IUOE opined that treating the two tasks separately in the final rule would allow for better control of the hazards (Document ID 2262, pp. 3, 6, 9, 14). LHSFNA supported the IUOE position on demolition versus earthmoving and how it should be addressed in Table 1 (Document ID 4207, p. 3). BCTD requested that Table 1 specify that the Table 1 controls only apply when the listed task is performed on or with silica-containing materials, noting that some operations, such as earthmoving equipment, do not generate silica dust unless the material contains silica (Document ID 2371, p. 24).

OSHA agrees with these recommendations and has separated heavy equipment into two entries on Table 1: Paragraph (c)(1)(xvii) of the standard for construction covers heavy equipment and utility vehicles used to abrade or fracture silica-containing materials or during demolition activities; paragraph (c)(1)(xviii) of the standard for construction covers heavy equipment and utility vehicles used for tasks such as grading and excavating (but not including demolishing, abrading, or fracturing silica-containing materials). As explained below, only heavy equipment and utility vehicles used to abrade or fracture silica-containing materials or during demolition activities require an enclosed cab at all times, whereas the employer has a choice between an enclosed cab or applying water and/or dust suppressant when these vehicles are used for tasks such as grading and excavating, provided there are no other employees engaged in the task beside the heavy equipment operator.

In the proposed standard, the only control option for heavy equipment was to operate from within enclosed cabs. Several commenters noted that enclosed cabs do not protect other employees, such as laborers, who perform tasks in the area but remain outside the cab (*e.g.*, Document ID 2262, p. 24). Fann Contracting explained that not including laborers on Table 1 would ''render the table pointless because employers would have to conduct

frequent exposure assessments of those employees'' (Document ID 2116, Attachment 1, p. 3). Because of the reasonable concerns raised by these commenters, OSHA has included controls (water and/or dust suppressants) on Table 1 to protect employees, other than the operator, who are engaged in the tasks. The other employees included under this entry for Table 1 are typically laborers who work nearby supporting the heavy equipment operator (*i.e.*, applying dust suppressant, spotting, and clearing debris). When these materials contain crystalline silica, dust generated during these activities is a primary source of exposure for the equipment operators and the laborers.

NUCA expressed concern that operating from within a fully enclosed cab may reduce visibility of the work zone and impair verbal communication. and thereby pose potential safety risks (Document ID 2171, pp. 2, 4, 22). However, modern heavy equipment already come equipped with enclosed, filtered cabs that are designed with visibility in mind to allow the operator to perform the work required. Furthermore, radios or cell phones can be used for communication if necessary. Therefore, OSHA concludes that filtered, fully enclosed cabs have been and can continue to be used without compromising worker safety or the effectiveness of the cab.

The exposure profile in Table IV.5.3–B in Section 5.3 of Chapter IV of the FEA shows that approximately 8 percent (1 out of 13 samples) of heavy equipment operators performing demolition, abrading, or fracturing activities have exposures above 50 μg/m^3. OSHA also found a mean TWA exposure of 25 μg/m^3 for the six samples in the record for laborers who assisted heavy equipment operators by providing water for dust control during demolition projects. Table IV.5.3–C in Section 5.3 of Chapter IV of the FEA compares silica exposures among heavy equipment operators with the silica exposures of laborers engaged in the same task. These data are a subset of the exposure profile (Table IV.5.3–B in Section 5.3 of Chapter IV of the FEA) and provide evidence of the effectiveness of applying dust suppressants for dust control during demolition activities. The results for the six samples for laborers were less than 50 μg/m^3 and were lower than the heavy equipment operators not in an enclosed cab.

The information presented in OSHA's technological feasibility analysis for heavy equipment operators and ground crew laborers (Section 5.3 of Chapter IV of the FEA) and summarized above provides evidence that the use of enclosed cabs and water and/or dust suppressants will reduce exposures to 50 μg/m^3 or less for operators and laborers when these controls are fully and properly implemented. Therefore, OSHA is not requiring the use of respiratory protection for heavy equipment operators and laborers who assist heavy equipment operators during demolition activities involving silica-containing materials or activities where silica-containing materials are abraded or fractured, regardless of the duration of the task. Fann Contracting questioned whether operators who use enclosed cabs would be required to wear respiratory protection when exiting the equipment cab (Document ID 2116, Attachment 1, p. 23). Since the specified control method on Table 1 for this task requires the use of an enclosed cab, the task is not being performed once the operator exits the enclosed cab and the resulting exposure will have ceased, and no respiratory protection is required in that circumstance. However, if other abrading, fracturing, or demolition work is continuing while an operator is outside the cab, that operator is considered to be an employee ''engaged in the task'' and must be protected by the application of water and/or dust suppressants.

Heavy equipment and utility vehicles used for tasks such as grading and excavating but not including demolishing, abrading, or fracturing silica-containing materials. When operating heavy equipment and smaller sized utility vehicles for tasks such as grading and excavating that do not involve demolition or the fracturing or abrading of silica, paragraph (c)(1)(xviii) of the standard for construction requires that the employee who will be operating the equipment operate from within an enclosed cab or that the employer applies water and/or dust suppressants as necessary to minimize dust emissions. If other employees (*e.g.*, laborer) are engaged in the task, water and/or dust suppressants must be applied as necessary to minimize dust emissions even where the operator of the equipment is working inside an enclosed cab. However, the employer need not provide an enclosed, filtered cab for the operator of the equipment.

Employees engaged in this task operate a variety of wheeled or tracked vehicles ranging in size from large heavy construction equipment, such as bulldozers, scrapers, loaders, and road graders, to smaller and medium sized utility vehicles, such as tractors, bobcats and backhoes, with attached tools that are used to excavate and move soil, rock, and other silica-containing materials (see Section 5.3 of Chapter IV of the FEA). Typically tasks conducted with this equipment include earthmoving, grading, excavating, and other activities such as moving, loading, and dumping soil and rock (*see* Table IV.5.3–B in Section 5.3 of Chapter IV of the FEA). In addition, the railroad industry uses such heavy equipment to dump and grade silica-containing ballast in track work to support the ties and rails. Such track work is generally subject to OSHA's construction standards, and the use of heavy railroad equipment for this purpose is therefore covered under this task in Table 1 of the final standard.

As discussed under the explanation of (c)(1)(xvii) of the standard for construction, OSHA included one entry for heavy equipment operators performing earthmoving activities in the proposed standard, but has divided this entry to distinguish between the controls needed when using heavy equipment for abrading, fracturing, or demolishing silica-containing material, on the one hand, and for grading and excavating silica-containing materials, on the other hand.

OSHA's exposure profile for earthmoving (*i.e.*, excavation) operations shows that a large majority of exposures (87.5 percent) are below 25 μg/m^3 (*see* Section 5.3 of Chapter IV of the FEA). IUOE commented that earthmoving should not be the focus of the rule, stating that earthmoving activity ''does not fracture or abrade silica-containing materials, and thus, does not expose heavy equipment operators to high concentrations of respirable silica'' (Document ID 2262, p. 6). Martin Turek, assistant coordinator and safety administrator for IUOE Local 150, stated that ''it is unlikely that moving soil or clay will generate respirable silica in concentrations . . . above the [proposed] PEL'' (Document ID 3583, Tr. 2358).

Under both entries, however, the specified controls to protect laborers are the same. Thus, as when engaged in abrading, fracturing, or demolition tasks near or alongside heavy equipment or utility vehicles, OSHA has included a requirement that water and/or dust suppressants be applied as necessary to minimize dust emissions so that employees, including such laborers, who are engaged in such tasks as grading and excavating silica-containing materials in conjunction with operators of heavy equipment or utility vehicles are protected from excessive exposure to respirable crystalline silica.

Enclosed cabs are not mandated for this task. They may be used if the equipment operator is the only

employee engaged in the task, as an alternative to water and/or dust suppressants. However, where enclosed cabs are used, they must meet the requirements outlined in paragraph (c)(2)(iii) of the standard for construction. Those requirements specify that enclosed cabs must be kept as free as practicable from settled dust, must have door seals and closing mechanisms that work properly, must have gaskets and seals that are in good condition and work properly, must be under positive pressure maintained through continuous delivery of fresh air, must have intake air that is filtered through a filter that is 95 percent efficient in the 0.3–10.0 μm range, and must have heating and cooling capabilities. If employees other than the equipment operator are engaged in the task, Table 1 requires the application of water and/or dust suppressants as necessary to minimize dust emissions, which protects the operator as well as the laborers from silica exposures above the PEL. As demonstrated by OSHA's exposure profile and the other evidence in OSHA's technological feasibility for heavy equipment operators and ground crew laborers (Section 5.3 of Chapter IV of the FEA), wet dust suppression methods (*e.g.*, water or calcium chloride) are already a common and effective means for reducing exposures among heavy equipment operators and laborers to 50 μg/m^3 or below.

Other commenters were concerned about the availability of enclosed cabs on heavy equipment used for these types of earthmoving activities. NUCA, NAHB, and CISC expressed concern regarding the cab requirements; NUCA stated that the majority of earthmoving equipment is ''equipped with open canopies or unpressurized cabs'' (Document ID 2171, p. 3; 2296, p. 32; 2319, p. 114). OSHA understands that some equipment currently in use may not be equipped with enclosed, pressurized cabs as required by Table 1 when enclosed cabs are used. Where an employer chooses not to retrofit existing equipment for grading and excavating, it must apply water and/or dust suppressants as necessary to minimize dust emissions in order to comply with Table 1. Employers that neither choose to retrofit equipment nor suppress dust using water or other dust suppressants must comply with the requirements of paragraph (d) of the standard for construction.

Evidence in the record indicates that exposures of employees during common excavation and grading operations are likely to remain below 25 μg/m^3 most of the time. OSHA has therefore determined that respiratory protection is not needed when the employer fully and properly implements the controls on Table 1. Fann Contracting questioned whether operators who use enclosed cabs would be required to wear respiratory protection when exiting the equipment cab (Document ID 2116, Attachment 1, p. 23). As explained above, there is no requirement for respiratory protection when the employee is entering or exiting the cab since the task is not being performed at that time. However, if other grading or excavation work is continuing while an operator is outside the cab, that operator is considered to be an employee ''engaged in the task'' and must be protected by the application of water and/or dust suppressants.

Drywall finishers. Table 1 of the final rule does not specify controls for drywall finishing. In the proposed standard, ''drywall finishing (with silica-containing material)'' was an entry on Table 1. The control options on proposed Table 1 were to use a pole sander or hand sander equipped with a dust collection system or to use wet methods to smooth or sand the drywall seam. However, information in the rulemaking record indicates that drywall compound currently in use does not usually contain silica (Document ID 2296, pp. 32, 36). NAHB commented that much of the drywall joint compound currently used in residential construction has no or very low silica content and members can resolve any concerns regarding silica exposure by making sure to use low silica containing product (Document ID 2296, pp. 32, 36). While CISC agreed that contractors ''can utilize 'silica-free' joint compound and perform drywall installation in a manner that creates exposures below the proposed PEL,'' it expressed concern that ''silica-free'' joint compound may contain more than trace amounts of silica, which could result in exposures to silica (Document ID 2319, pp. 38, 43).

NIOSH tested bulk samples of a commercially available joint compound and found up to 6 percent quartz, although silica was not listed on the safety data sheet for the product (Document ID 0213, p. 5). However, in a more recent study, NIOSH determined that three of six drywall compounds purchased at a retail store contained only trace amounts of silica (less than 0.5 percent) (Document ID 1335, p. iii). The researchers concluded that for the most part the results of each sample analysis agreed with the composition stated in the manufacturers' material safety data sheets (Document ID 1335, pp. 3–4, 7, 10). OSHA finds that joint compound is more accurately labeled than it was in the past, and that manufacturers' labeling and SDSs are the best source for determining whether employees may be exposed to silica that could become respirable.

Additionally, the exposure profile includes 15 full-shift, personal breathing zone samples of respirable crystalline silica. The median exposure is 12 μg/m^3, the mean is 17 μg/m^3, and the range is 8 μg/m^3 (limit of detection (LOD)) to 72 μg/m^3, which was the only result above 50 μg/m^3. The 72 μg/m^3 sample was obtained for a worker performing overhead sanding directly above his breathing zone (Document ID 1335, p. 13). One other sample exceeded 25 μg/m^3 (Document ID 1335, p. 14). Therefore, because no additional controls are needed for most drywall finishers, OSHA has not included an entry for drywall finishers in Table 1 in the final standard.

In the event that the use of silica-free joint compound is not possible, or during renovation work where silica-containing joint compound might be present, OSHA has determined that there are engineering controls, as discussed in Section 5.2 of Chapter IV of the FEA, that reduce exposure to respirable crystalline silica to 50 μg/m^3 or below. In that situation employers will have to comply with paragraph (d) of the standard for construction. Johnston Construction Company commented that a requirement for air purifying respirators should be included in the rule for one of the dustiest tasks performed (Document ID 1951). OSHA agrees that sanding silica-free joint compound can potentially generate high levels of respirable nuisance dust that does not contain silica and for which respiratory protection may be needed in some situations. While high exposures to nuisance dusts may result from sanding joint compound, available evidence shows exposures to respirable crystalline silica will be low.

Abrasive blasting. Table 1 of the final standard does not specify controls for abrasive blasting; this is unchanged from the proposed rule.

The Society for Protective Coatings (SSPC) requested that abrasive blasting be included in Table 1 (Document ID 2120, p. 3). SSPC recommended the inclusion of an abrasive blasting entry which ''simplifies compliance and eliminates the need for measuring workers' exposure to silica, while still ensuring adequate protection for workers'' (Document ID 2120, p. 3). However, OSHA has determined that it is not appropriate to add abrasive blasting to Table 1.

There are a variety of options available to employers to control

exposure to respirable crystalline silica during blasting operations. As discussed in the technological feasibility analysis (Section 5.1 of Chapter IV of the FEA), these include (1) use of abrasive media other than silica sand to reduce crystalline silica dust emissions, (2) use of wet blasting techniques, (3) use of dust suppressors, (4) use of dust collection systems, and (5) use of hydro-blasting technologies that avoid having to use abrasive media.

OSHA has decided that employees will be best protected when employers, following the traditional approach set forth in paragraph (d) in the standard for construction, choose among these dust control strategies to select the controls that best fit the needs of each job. OSHA's conclusion is based on the following additional considerations: (1) Abrasive blasting operators must, separate from this rule, be provided with and wear the respiratory protection required by 29 CFR 1926.57(f), and (2) employees helping with the operation, or who otherwise must be in the vicinity of the operation, must also be adequately protected by a combination of engineering controls, work practices, and respirators. OSHA thus concluded that the Table 1 approach did not lend itself to specifying one or more controls that would be suitable for all such operations. Furthermore, based on its technological feasibility analysis for abrasive blasting (*see* Section 5.1 of Chapter IV of the FEA), respirators will be needed whatever engineering or work practice control the employer uses under the hierarchy of controls to lower silica exposure to the lowest level feasible. Accordingly, based on the reasons discussed above, the Agency is not mandating a particular dust control approach or approaches for abrasive blasting and has therefore not included it as an entry in Table 1 of the final standard.

Alternative Exposure Control Methods

Paragraph (d) of the standard for construction describes the requirements for the alternative exposure control methods approach, which applies for tasks not listed in Table 1 or where the employer chooses not to follow Table 1 or does not fully and properly implement the engineering controls, work practices, and respiratory protection described in Table 1. The alternative exposure control methods approach is similar to OSHA's traditional approach of demonstrating compliance with a permissible exposure limit (PEL) through required exposure assessments and controlling employee exposures through the use of feasible engineering controls and work practices (*i.e.*, the hierarchy of controls). With the exception of the option to comply with either paragraph (c) or paragraph (d), construction employers are required to comply with all other paragraphs of the standard for construction.

Paragraph (d)(1) specifies that construction employers who must or choose to follow paragraph (d) shall limit employee exposures to respirable crystalline silica at or below the PEL of 50 μg/m^3 as an 8-hour time weighted average. The PEL is fully discussed in the summary and explanation of *Permissible Exposure Limit*.

Paragraph (d)(2) specifies the requirements for exposure assessments, such as the types of assessments that are required under the standard (*i.e.*, performance or scheduled monitoring options), when or how often those assessments must be conducted, methods of sample analysis, employee notification of results, and the opportunity for employees or their representatives to observe monitoring. These requirements are fully discussed in the summary and explanation of *Exposure Assessment*.

Paragraph (d)(3) specifies the methods of compliance, which include a requirement to reduce exposure through feasible engineering and work practice controls before using respiratory protection, and cross-references standards for abrasive blasting. These requirements are fully discussed in the summary and explanation of *Methods of Compliance*.

Permissible Exposure Limit (PEL)

Paragraph (c) of the standard for general industry and maritime (paragraph (d)(1) in the construction standard) establishes an 8-hour time-weighted average (TWA) exposure limit of 50 micrograms of respirable crystalline silica per cubic meter of air (50 μg/m^3). This limit means that over the course of any 8-hour work shift, exposures can fluctuate but the average exposure to respirable crystalline silica cannot exceed 50 μg/m^3. The PEL is the same for both general industry/maritime and construction. The PEL of 50 μg/m^3 applies in the construction standard for tasks not listed on Table 1 or where the employer is not fully and properly implementing the specified exposure control methods in paragraph (c) of the standard. The PEL of 50 μg/m^3 does not apply directly to tasks listed on Table 1, but the ability to achieve that PEL was the metric by which OSHA decided on the specified exposure control(s) listed and whether supplementary respiratory protection is required in some or all circumstances for a particular task.

OSHA proposed a PEL of 50 μg/m^3 because the Agency preliminarily determined that occupational exposure to respirable crystalline silica at the previous PELs, which were approximately equivalent to 100 μg/m^3 for general industry and 250 μg/m^3 for construction and shipyards, resulted in a significant risk of material health impairment to exposed workers, and that compliance with the proposed PEL would substantially reduce that risk. OSHA also preliminarily found the level of risk remaining at the proposed PEL to be significant, but considered a PEL of 50 μg/m^3 to be the lowest level that was technologically feasible overall.

The PEL was a focus of comment in the rulemaking process, revealing sharply divided opinion on the justification for and attainability of a PEL of 50 μg/m^3. Many commenters representing labor unions, public health associations, academic institutions, occupational health professionals, and others expressed support for the proposed PEL (*e.g.*, Document ID 1785, p. 2; 1878, p. 1; 2080, p. 1; 2106, p. 3; 2145, p. 3; 2166, p. 1; 2173, p. 2; 2178, Attachment 1, p. 2; 2318, p. 10; 2339, p. 7; 2341, p. 2; 3399, p. 4; 3403, p. 2; 3478, p. 1; 3601, Attachment 2, p. 5; 3588, Tr. 3769; 4204, p. 50; 4207, p. 1). Other commenters representing a wide range of industries, including construction, foundries, concrete, brick and tile manufacturing, mineral excavation, utility providers, and others, did not believe the proposed PEL was appropriate. Stakeholders also offered opinions on the proposed alternative PELs of 25 μg/m^3 and 100 μg/m^3.

Some commenters contended that OSHA's proposed PEL was too low, arguing that the proposed limit was infeasible or not justified by the health and risk evidence (*e.g.*, Document ID 1964; 1992, pp. 1, 8–10; 2024, pp. 1–2; 2067, p. 3; 2075, pp. 1–2; 2104, p. 1; 2119, Attachment 1; 2143, pp. 1–2; 2171, p. 1; 2185, pp. 2–4; 2191, p. 3; 2210, Attachment 1, p. 6; 2268; 2269, pp. 2–3; 2279, pp. 2, 9; 2284, p. 2; 2289, p. 3; 2296; p. 39; 2301, Attachment 1, pp. 7–9; 2305, pp. 4–5, 15; 2312, p. 2; 2348, Attachment 1, pp. 32–33; 2349, p. 3; 2350, pp. 10–11; 2384, pp. 2, 9; 2182, pp. 3–4; 2102, pp. 1, 3; 2211, pp. 3–4; 2283, p. 2; 2250, p. 2; 2288, p. 8; 2300, p. 2; 2338, p. 2; 2356, p. 2; 2376; 2379, Appendix 1, p. 53; 3275, pp. 1–2). Many of these commenters supported the adoption of the proposed alternative PEL of 100 μg/m^3.

Other commenters, including the United Automobile, Aerospace, and Agricultural Implement Workers of America and the American Public Health Association, contended that the

remaining risk at 50 μg/m³ is excessive and argued that OSHA should adopt a PEL of 25 μg/m³ or even lower (*e.g.*, Document ID 2163, Attachment 1, pp. 3, 13; 2176, pp. 1–2; 3577, Tr. 851–852; 3582, Tr. 1853–1854; 3589, Tr. 4165; 4236, pp. 5–6). The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) urged OSHA to fully evaluate the evidence and set a lower PEL if deemed to be feasible (Document ID 3578, Tr. 923–924).

After considering the evidence in the rulemaking record, OSHA is establishing a PEL of 50 μg/m³. OSHA's examination of health effects evidence, discussed in Section V, Health Effects, and Section VI, Final Quantitative Risk Assessment and Significance of Risk, confirms the Agency's preliminary conclusion that exposure to respirable crystalline silica at the previous PELs results in a significant risk of material health impairment to exposed workers, and that compliance with the revised PEL will substantially reduce that risk. OSHA's Quantitative Risk Assessment indicates that a 45-year exposure to respirable crystalline silica at the preceding general industry PEL would lead to between 11 and 54 excess deaths from lung cancer, 11 deaths from silicosis, 85 deaths from all forms of non-malignant respiratory disease (including silicosis as well as other diseases such as chronic bronchitis and emphysema), and 39 deaths from renal disease per 1000 workers. Exposures at the preceding construction and shipyard PEL would result in even higher levels of risk. As discussed in Section VII of this preamble, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis, these results clearly represent a risk of material impairment of health that is significant within the context of the ''*Benzene*'' decision (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607 (1980)). OSHA has determined that lowering the PEL to 50 μg/m³ will reduce the lifetime excess risk of death per 1000 workers to between 5 and 23 deaths from lung cancer, 7 deaths from silicosis, 44 deaths from non-malignant respiratory disease, and 32 deaths from renal disease.

The Agency considers the level of risk remaining at the revised PEL to be significant. However, based on the evidence evaluated during the rulemaking process, OSHA has determined a PEL of 50 μg/m³ is appropriate because it is the lowest level feasible. As discussed in Chapters IV and VI of Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA) and summarized in Section VII of this preamble, the PEL is technologically and economically feasible for all industry sectors, although it will be a technological challenge for several affected sectors and will require the use of respirators for certain job categories and tasks. As guided by the 1988 ''*Asbestos*'' decision (*Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (D.C. Cir. 1988)), OSHA is including additional requirements in the rule to further reduce the remaining risk. OSHA anticipates that the ancillary provisions in the rule will further reduce the risk beyond the reduction that will be achieved by the PEL alone.

OSHA has also determined that the proposed alternative PELs, 100 μg/m³ and 25 μg/m³, are inappropriate. As noted above, significant risk to employees' health exists at the previous PELs, and at and below the PEL of 50 μg/m³. Because OSHA has determined that a PEL of 50 μg/m³ is technologically and economically feasible, the Agency concludes that setting the PEL at 100 μg/m³—a level the Agency knows would continue to expose workers to significant risk of material impairment to their health greater than is the case at 50 μg/m³—would be contrary to the mandate in the OSH Act, which requires the Secretary to promulgate a standard

> . . . which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life (29 U.S.C. 655(b)).

Thus, the Agency has rejected the proposed alternative PEL of 100 μg/m³.

Even though OSHA's risk assessment indicates that a significant risk also exists at the revised action level of 25 μg/m³, the Agency is not adopting the alternative PEL of 25 μg/m³ because a PEL of 50 μg/m³ is the lowest exposure limit that can be found to be technologically feasible for many of the industries covered by the rule. Specifically, OSHA has determined that the information in the rulemaking record either demonstrates that the proposed alternative PEL of 25 μg/m³ would not be achievable for most of the affected industry sectors and application groups or the information is insufficient to conclude that engineering and work practice controls can consistently reduce exposures to or below 25 μg/m³. Therefore, OSHA cannot find that the proposed alternative PEL of 25 μg/m³ is achievable for most operations in the affected industries (*see* Section VII of this preamble and Chapter IV of the FEA). Moreover, OSHA also concludes that it would hugely complicate both compliance with and enforcement of the rule if it were to set a PEL of 25 μg/m³ for a minority of industries or operations where it would be technologically feasible and a PEL of 50 μg/m³ for the remaining industries and operations where technological feasibility at the lower PEL is demonstrably unattainable, doubtful or unknown.

Instead, OSHA has concluded that a PEL of 50 μg/m³ is economically and technologically feasible for all of the affected industries and has decided to exercise its discretion to issue this uniform PEL to avoid the enormous compliance and enforcement complications that would ensue if it were to bifurcate the PEL (*see* Section II, Pertinent Legal Authority, discussing the chromium (VI) decision). Other issues related to OSHA's adoption of a PEL of 50 μg/m³ are discussed below. The discussion is organized around the following topics: Coverage of quartz, cristobalite, and tridymite; the PEL as a gravimetric measurement of respirable dust; industry-specific PELs; enhanced enforcement; environmental sources of crystalline silica exposure; collection efficiency; coal dust; and CFR entries.

Coverage of quartz, cristobalite, and tridymite. As discussed in the summary and explanation of *Definitions,* the PEL applies to the three forms of crystalline silica (*i.e.*, quartz, cristobalite, and tridymite) covered under previous OSHA PELs. Specifically, paragraph (b) of the rule defines the term ''respirable crystalline silica'' to mean

> . . . quartz, cristobalite, and tridymite contained in airborne particles whose measurement is determined by a sampling device designed to meet the characteristics for particle-size-selective samplers specified in International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

The proposed definition of respirable crystalline silica also would have established a single PEL that would have encompassed the three forms of silica covered under the previous OSHA silica PELs. While commenters generally supported a single PEL for respirable crystalline silica, they did not all agree on whether a single PEL should include quartz, cristobalite, and tridymite (*e.g.*, Document ID 1731, p. 2; 2315, p. 9). Some commenters argued that the PEL should include all three forms; some suggested that the single PEL should be for only quartz and cristobalite (*e.g.*, Document ID 2177, Attachment B, p. 10; 2196, Attachment

1, p. 5; 3403, p. 4; 4212, p. 3) or only quartz (*e.g.*, Document ID 2185, p. 6). NIOSH noted that ''tridymite is extremely rare in workplaces, so a separate PEL probably cannot be supported by epidemiologic evidence and may not be warranted for this material (Document ID 2177, Attachment B, p. 10). Southern Company argued that

> . . . the inclusion of tridymite and cristobalite are not supported by the data and, due to their rare nature, serve to unnecessarily create upward bias of the exposure evaluations due to the laboratory detection limitations (Document ID 2185, p. 2).

Halliburton Energy Services said that, given that OSHA has acknowledged that the risk to workers exposed to a given level of respirable crystalline silica may not be equivalent in different work environments, OSHA's ''one size fits all'' silica PEL for different forms of crystalline silica with varied physicochemical properties was unwarranted (Document ID 2302, p. 5).

As discussed in Section V, Health Effects, OSHA has concluded, based on the available scientific evidence, that quartz, cristobalite, and tridymite have similar toxicity and carcinogenic potency. The Agency therefore concludes that a single PEL is appropriate for quartz, cristobalite, and tridymite.

The PEL as a gravimetric measurement of respirable dust. The revised PEL, like OSHA's proposed PEL, is expressed as a gravimetric measurement of respirable crystalline silica. The preceding PELs were formulas that were inconsistent between industries and forms of crystalline silica. For general industry (*see* 29 CFR 1910.1000, Table Z–3), the PEL for crystalline silica in the form of respirable quartz was based on two alternative formulas: (1) A particle-count formula (PEL_{mppcf} = 250/(% quartz + 5) as respirable dust); and (2) a mass formula proposed by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1968 (PEL = (10 mg/m^3)/(% quartz + 2) as respirable dust). The general industry PELs for crystalline silica in the form of cristobalite and tridymite were one-half of the value calculated from either of the above two formulas for quartz. For construction (29 CFR 1926.55, Appendix A) and shipyards (29 CFR 1915.1000, Table Z), the formula for the PEL for crystalline silica in the form of quartz (PEL_{mppcf} = 250/(% quartz + 5) as respirable dust), which requires particle counting, was derived from the 1970 ACGIH threshold limit value (TLV). Based on the formulas, the PELs for quartz, expressed as time-weighted averages (TWAs), were approximately equivalent to 100 µg/m^3 for general industry and 250 µg/m^3 for construction and shipyards. As detailed in the discussion of sampling and analysis in Chapter IV of the FEA, OSHA finds that the formula based on particle-counting technology used in the preceding general industry, construction, and shipyard PELs has been rendered obsolete by respirable mass (gravimetric) sampling.

A number of commenters supported the proposed switch from these formulas to a PEL expressed as a gravimetric measurement of respirable crystalline silica. For example, several stakeholders, including the American Foundry Society (AFS), the American Petroleum Institute, the Fertilizer Institute, and the North American Insulation Manufacturers Association, agreed that OSHA should revise the previous formulaic PELs into straightforward concentration/gravimetric-based thresholds (*e.g.*, Document ID 2101, p. 4; 2145, p. 3; 2278, p. 2; 2301, Attachment 1, p. 4; 4213, p. 8; 4229, p. 27). Others suggested the previous formulaic PELs are confusing, complicated (*e.g.*, Document ID 2175, p. 5; 2185, p. 2), and outdated (*e.g.*, Document ID 2163, Attachment 1, p. 2; 2204; 3588, Tr. 3769). Ameren Corporation also expressed support for the elimination of the PELs calculated based on the percent silica in the sample (Document ID 2315, p. 8).

After considering the record on this issue, OSHA has decided to adopt a PEL which is expressed as a gravimetric measurement of respirable crystalline silica. OSHA expects that the revised PEL will improve compliance because the PEL is simple and relatively easy to understand, and is consistent with modern sampling and analytical methods. In addition, OSHA finds that a uniform PEL will provide consistent levels of protection for workers in all sectors covered by the rule.

Industry-specific PELs. Some commenters urged OSHA to take an industry-specific approach to regulating respirable crystalline silica exposures. Southern Company urged OSHA to consider a vertical standard that addresses industries with known negative health impacts from silica-containing materials (Document ID 2185, p. 2). Battery Council International asked OSHA to set the PEL based on relevant particle size and the size distribution data and recommended that OSHA adjust the PEL for different industry segments consistent with these data (Document ID 2361, pp. 1–2). Other commenters suggested that the PEL should be lower for certain industries, such as hydraulic fracturing and dental equipment manufacturing (Document ID 2282, Attachment 3, p. 12; 2374, Attachment 1, p. 5).

OSHA considers the level of risk remaining at the new PEL of 50 µg/m^3 to be significant. Although OSHA expects the ancillary provisions of the standard to reduce this risk below what engineering and work practice controls alone can achieve, the Agency realizes that lower PELs might be achievable in some industries and operations, which would reduce this risk even further. However, as explained below, OSHA concludes that the significant costs, including opportunity costs, of devoting the resources necessary to attempting to establish and apply multiple PELs for the diverse group of industries and operations covered by the standard would undermine the value of this reduction (*see Building & Constr. Trades Dep't* v. *U.S. Dep't of Labor*, 838 F.2d 1258, 1273 (D.C. Cir. 1988) (administrative difficulties, if appropriately spelled out, could justify a decision to select a uniform PEL)).

Requiring OSHA to set multiple PELs—taking into account the feasibility considerations unique to each industry or operation or group of them—would impose an enormous evidentiary burden on OSHA to ascertain and establish the specific situations, if any, in which a lower PEL could be reached. Such an onerous obligation would inevitably delay, if not preclude, the adoption of important health standards. In addition, the demanding burden of setting multiple PELs would be complicated by the difficulties inherent in precisely defining and clearly distinguishing between affected industries and operations where the classification determines legal obligations. The definitional and line-drawing problem is far less significant when OSHA merely uses a unit of industries and operations for analytical purposes, and when it sets a PEL in the aggregate, *i.e.*, when its analysis is limited to determining whether a particular PEL is the lowest feasible level for affected industries as a whole. If OSHA had to set multiple PELs, and assign industries or operations to those PELs, the problem would become much more pronounced as the consequences of imprecise classifications would become much more significant.

OSHA also finds that a uniform PEL will ultimately make the standard more effective by making it easier for affected employers to understand and comply with the standard's requirements. Moreover, a uniform PEL makes it

possible for OSHA to provide clearer guidance to the regulated community and to identify non-compliant conditions. For these reasons, OSHA has always interpreted Section 6(b)(5) of the Act to accord the Agency substantial discretion to set the PEL at the lowest level that is feasible for industries and operations as a whole. In adopting the arsenic standard, for example, OSHA expressly declined to set different PELs, finding that ''[s]uch an approach would be extremely difficult to implement'' (43 FR 19584, 19601 (5/5/1978)). In that instance, OSHA explained:

> The approach OSHA believes appropriate and has chosen for this and other standards is the lowest level achievable through engineering controls and work practices in the majority of locations. This approach is intended to provide maximum protection without excessively heavy respirator use. Id.
>
> OSHA has also rejected such an approach in rulemakings on benzene and chromium (VI).
>
> (*see* 43 FR 5918, 5947 (2/10/1978); 71 FR 10100, 10337–10338 (2/28/2006)).

In the case of cotton dust, where OSHA did set different PELs for certain discrete groups, the groups involved exposures to different kinds of cotton dust and different degrees of risk. Even so, OSHA did not adopt a unique PEL for every single affected sector (*see* 43 FR 27350, 37360–37361 (6/23/1978)); OSHA set one PEL for textile industries and a separate PEL for non-textile industries, but expressly rejected the option of adopting different exposure limits for each non-textile industry). OSHA recognizes that the exception from the scope of this rule for exposures that result from the processing of sorptive clays results in a different PEL being enforced in that sector. However, the processing of sorptive clays is a very small industry sector, and OSHA finds that this sector can be readily segregated from other industry sectors covered by the rule.

Enhanced enforcement. Several commenters suggested retaining the preceding PELs and focusing OSHA efforts on enhanced enforcement rather than on a new rule (*e.g.*, Document ID 1741, Attachment 1; 2067, p. 4; 2183, p. 4; 2185, p. 2; 2210, Attachment 1, pp. 3, 7; 2261, pp. 2–3; 2283, p. 2; 2292, p. 2; 2344, p. 2; 2349, p. 3; 2363, p. 10; 3486, p. 1; 3496, p. 3). Some of these commenters, such as the Small Business Administration's Office of Advocacy, indicated that OSHA data show widespread noncompliance with the previous PELs and suggested that silica-related illnesses could be linked to noncompliance (*e.g.*, Document ID 2349, p. 3). Others, such as Arch Masonry, urged OSHA to consider information and testimony about noncompliant work environments as evidence of an enforcement problem rather than evidence to support a new rule (*e.g.*, Document ID 3587, Tr. 3651–3652). The Mercatus Center asked OSHA to explain how improved enforcement of the existing rule is not superior to a more stringent PEL (Document ID 1819, p. 9).

As discussed in Section V, Health Effects, OSHA does not find these arguments persuasive. First, many of the commenters used OSHA's enforcement data to make this point. These data were obtained during inspections where non-compliance was suspected and thus were skewed in the direction of exceeding the preceding PELs. As the Building and Construction Trades Department, AFL–CIO (BCTD) explained, OSHA data showing noncompliance with the preceding PEL is not representative of typical exposure levels, since sampling for compliance purposes targets worst-case exposure scenarios (Document ID 3581, Tr. 1634–1636).

Moreover, not all commenters agreed that overexposures were ''widespread.'' A few other commenters (*e.g.*, AFS) thought that OSHA substantially overstated the number of workers occupationally exposed above 100 $\mu g/m^3$ in its PEA (Document ID 2379, Attachment B, p. 25). In either case, OSHA's analysis evaluated risks at various exposure levels, as is required by the OSH Act. As noted above, the available data indicate that exposure to respirable crystalline silica at the preceding PELs results in a significant risk of material health impairment among exposed employees. Simply enforcing the preceding PELs will not substantially reduce or eliminate this significant risk.

Exposure Variability. Commenters, including the Asphalt Roofing Manufacturers Association (ARMA), argued that because OSHA PELs are never-to-be-exceeded limits, employers must maintain average exposures well below the PEL to have confidence that exposures are rigorously maintained at or below the PEL every day, for every worker (*e.g.*, Document ID 2291, pp. 5–7). The Construction Industry Safety Coalition (CISC) made a similar argument regarding the need to control exposure levels to well below the PEL due to the variability of silica exposures on construction worksites in order to assure compliance (Document ID 4217, p. 12).

OSHA recognizes that differences in exposure can occur due to workplace variables such as fluctuations in environmental conditions or air movement. However, many of the major sources of day-to-day variability can be moderated by the consistent use of engineering controls and appropriate work practices (Document ID 3578, Tr. 971; 3589, Tr. 4251–4252; 4234, Attachment 2, pp. 31–38).

OSHA has acknowledged and discussed exposure variability in past rulemakings where the same issue was raised (*e.g.*, benzene, 52 FR 34534; asbestos, 53 FR 35609; lead in construction, 58 FR 26590; formaldehyde, 57 FR 22290; cadmium, 57 FR 42102; and chromium (VI), 71 FR 10099). In its asbestos rulemaking, for example, OSHA found that industry's argument about uncontrollable fluctuations was exaggerated because such fluctuations could be minimized through proper inspection and maintenance of engineering controls and through proper training and supervision of employees whose work practices affected exposure levels (59 FR 40964, 40967 (8/10/94)). The Agency also noted that its enforcement policy gives employers the opportunity to show that a compliance officer's measurement over the PEL is unrepresentatively high and does not justify a citation, thus alleviating the concern employers might have that they will be cited on the basis of a single measurement that results from uncontrollable fluctuations (59 FR at 40967).

Reviewing courts have held that OSHA's obligation to show that a PEL can be achieved in most operations most of the time has been met despite the presence of random exposure variability. These courts have noted, in particular, OSHA's flexible enforcement policies, which allow the Agency to take such exposure variability into account before issuing a citation (*e.g., Building & Constr. Trades Dept.* v. *Brock,* 838 F.2d 1258 (D.C. Cir. 1988) (''*Asbestos II*'')). In the *Asbestos II* case, the D.C. Circuit cited with approval OSHA's policy of allowing for a possible re-inspection if OSHA measured an asbestos exposure above the PEL during an inspection. If the employer appeared to be using, to the extent feasible, appropriate work practices and engineering controls, OSHA could agree not to issue a citation at that time based on that inspection and to re-inspect at a later time. Such a re-inspection would help determine if that over-exposure was typical or simply a random, uncontrollable fluctuation; OSHA could then determine whether or not to issue a citation accordingly (*Asbestos II* at 1268; 51 FR 22653 (6/20/1986)). Thus OSHA has, in the past, adopted fair and flexible enforcement policies to deal with the issue of exposure variability

and will do the same for enforcement of the new silica standards.

Such an enforcement policy recognizes the possibility that OSHA may measure silica exposures on a day when exposures are above the PEL due to unforeseeable, random exposure variations. In such a case, when the employer has previously monitored the work area, OSHA inspectors would review the employer's long-term body of data demonstrating the exposure pattern for tasks/operations that are representative of those under OSHA's evaluation. After comparing the employer's exposure data with OSHA's sampling results, OSHA's determination whether to resample would be governed by the inspector's judgment of whether the OSHA sampling results are representative.

Where an employer can show, based on a series of measurements made pursuant to the sampling and analytical protocols set out in these standards or other relevant data, that the OSHA one-day measurement may be unrepresentatively high, OSHA may re-inspect the workplace and measure exposures again. If, after such a reinspection, OSHA has reason to believe that there are circumstances that account for the high exposure measurement, OSHA may decide not to issue a citation.

For OSHA to consider a reinspection rather than citation, an employer must demonstrate that the inspector's one-day sample is unrepresentative of normal exposure levels. In most cases, this demonstration would consist of a series of full shift measurements representative of the exposure of the employee under consideration. These measurements should consist of all valid measurements related to the employee under consideration taken within the last year and should show that only on rare occasions could random fluctuations result in TWA concentrations above the PEL.

Environmental sources of crystalline silica exposure. Some stakeholders raised concerns about the extent to which crystalline silica dust from naturally-occurring environmental sources (*e.g.*, in southwestern regions of the United States) might contribute to employee exposures to respirable crystalline silica and artificially inflate sampling measurements (*e.g.*, Document ID 1785, p. 4; 2116, Attachment 1, pp. 19–20; 3230, p. 1; 3533, p. 22). SMI cited an EPA study published in 1996 (Document ID 3637), and indicated that mean concentrations of ambient atmospheric respirable crystalline silica across 22 cities in the United States range from 0.9 to 8 $\mu g/m^3$ (Document ID 3533, p. 20). OSHA recognizes that there can be occasions when environmental sources of silica may affect occupational sampling results. However, OSHA notes that the data utilized in the 1996 study were originally published in an earlier (1984) journal article by Davis *et al.* (Document ID 3852), and the EPA report included important caveats about the environmental data that were available at the time (Document ID 3637, pp. 3–29, 3–31—3–34). For example, the section of the EPA report on ''Limitations of Current Data'' states:

> The lack of current, direct measures of ambient quartz concentrations is a major limitation of the data available for use in estimating U.S. ambient silica concentrations (Document ID 3637, pp. 3–31).

The report also indicated that ''. . . another limitation of the available data is the fact that neither current nor dated quartz measurements were taken using PM_{10} samplers'' (Document ID 3637, pp. 3–33).

In addition, OSHA notes that the sampling methodology used in the Davis study does not measure respirable crystalline silica, as defined in OSHA's silica rule. Rather, the Davis study presents data from dichotomous samplers that are equipped with particle size selection inlets. These samplers allow for measurement of two particle size fractions: A fine fraction with particle sizes having aerodynamic diameter less than 2.5 microns ($PM_{2.5}$) and a coarse fraction designed to eliminate particles greater than about 15 microns in aerodynamic diameter (PM_{15}). By contrast, OSHA's definition for respirable crystalline silica is tied to an International Organization for Standardization (ISO) sampling methodology that has different size-specific mass collection efficiencies. Of particular importance, the dichotomous samplers from the Davis study collect particles with aerodynamic diameters between 10 and 15 microns that are generally excluded from the ISO sampling methodology; and the dichotomous samplers likely collect a considerably higher portion of particles with aerodynamic diameters between 5 and 10 microns.

OSHA concludes that the sampling results presented in the Davis study are not comparable to respirable crystalline silica measurements, as defined in OSHA's rule. It is clear that the sampling methodology considered in the Davis study would overstate respirable crystalline silica levels measured using the ISO sampling methodology. Moreover, OSHA has demonstrated that compliance with the PEL is technologically feasible. OSHA's evaluation of the technological feasibility of the PEL involved evaluation of thousands of respirable crystalline silica samples collected in a variety of occupational settings that include contributions from environmental sources in different geographic areas. Because the exposure data considered by OSHA in its evaluation of the technological feasibility of the PEL includes contributions from environmental sources, these contributions are already taken into account in determining the feasibility of the PEL. Therefore, OSHA finds that environmental sources of respirable crystalline silica exposure, to the extent they contribute to workplace exposures, are already considered in the Agency's conclusion that the revised PEL is feasible.

Collection efficiency. In the rule, OSHA is adopting the ISO/CEN particle size-selective criteria for respirable dust samplers used to measure exposures to respirable crystalline silica. Several commenters, including U.S. Aggregates, the National Industrial Sand Association, and the U.S. Chamber of Commerce, argued that moving from the current criteria to the ISO/CEN convention effectively decreases the PEL and action level below the levels intended, since more dust would be collected by samplers that conform to the ISO/CEN convention than by those that conform to the current criteria (Document ID 2174; 2195, p. 30; 2285, pp. 3–4; 2317, p. 2; 3456, p. 10; 4194, pp. 15–16). However, as discussed in Chapter IV of the FEA, the Dorr-Oliver 10-mm cyclone used by OSHA for enforcement of respirable dust standards conforms to the ISO/CEN specification with acceptable bias and accuracy when operated in accordance with OSHA's existing method (*i.e.*, measurements taken using the Dorr-Oliver 10-mm cyclone following OSHA's existing method provide results that are consistent with the ISO/CEN convention, and therefore are acceptable for measuring respirable crystalline silica exposures under the rule). The change from the previous criteria to the ISO/CEN convention is therefore effectively a continuation of current practice.

Coal dust. Southern Company, the American Iron and Steel Institute, and Ameren Corporation indicated that revising the respirable crystalline silica PEL creates uncertainty with regard to the PEL for coal dust, which continues to use the previous criteria for calculation of respirable crystalline silica (Document ID 2185, p. 2; 2261, pp. 2, 5; 2315, p. 8). They urged the Agency to address how the existing coal

dust PEL will interact with the new PEL and calculation for exposure to respirable crystalline silica. For example, Southern Company stated:

> . . . it is unclear to us what the expectation would be in evaluating and managing exposures to either of these substances when the effective source of these exposures is the same. If both PELs apply, this would mean duplicate or dual sampling (Document ID 2185, p. 2).

Ameren also questioned whether employers would be required to sample for both respirable crystalline silica and respirable coal dust on workers who are potentially exposed to both substances. Ameren suggested that OSHA should consider changing the PELs for amorphous silica and coal dust so that they are consistent with the revised PEL for respirable crystalline silica (Document ID 2315, pp. 2, 8).

OSHA clarifies that the respirable crystalline silica rule does not change the existing PEL for coal dust. However, as indicated previously, the Dorr-Oliver 10-mm cyclone used by OSHA for enforcement of respirable dust standards exhibits acceptable bias against the ISO/CEN specification when operated in accordance with OSHA's existing method. Employers can continue to use the Dorr-Oliver cyclone to evaluate compliance with the new respirable crystalline silica PEL, as well as with the PEL for coal dust; duplicate sampling is not necessary. Employers can also use other ISO/CEN-compliant samplers to evaluate compliance with either or both PELs.

CFR entries. The rule revises entries for crystalline silica in 29 CFR 1910.1000 Table Z–1 to cross-reference the new standard, 1910.1053. A comparable revision to 29 CFR 1915.1000 Table Z cross-references 1915.1053, which in turn cross-references 1910.1053. The entries for crystalline silica in 29 CFR 1926.55 Appendix A are revised to cross-reference 1926.1153. General industry standards are located in Part 1910; maritime standards are located in Part 1915; and construction standards are located in Part 1926.

The preceding PELs for respirable crystalline silica are retained in 29 CFR 1910.1000 Table Z–3, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A. Footnotes are added to make clear that these PELs apply to any sectors or operations where the new PEL of 50 $\mu g/m^3$ is not in effect, such as the processing of sorptive clays. These PELs are also applicable during the time between publication of the silica rule and the dates established for compliance with the rule, as well as in the event of regulatory delay, a stay, or partial or full invalidation by the Court.

While the preceding PELs for respirable crystalline silica in 29 CFR 1910.1000 Table Z–3 are being retained, the PELs for total crystalline silica dust are being deleted. OSHA proposed to delete the previous general industry PELs for exposure to total crystalline silica dust because development of crystalline silica-related disease is related to the respirable fraction of, rather than total, dust exposure (*see* Section V, Health Effects). This view is consistent with that of ACGIH, which no longer has a Threshold Limit Value for total crystalline silica dust. NIOSH does not have a Recommended Exposure Level for total crystalline silica exposure, and neither the National Toxicology Program nor the International Agency for Research on Cancer has linked exposure to total crystalline silica dust exposure to cancer, as they have with respirable crystalline silica exposure.

Exposure Assessment

Paragraph (d) of the standard for general industry and maritime (paragraph (d)(2) of the standard for construction) sets forth requirements for assessing employee exposures to respirable crystalline silica. The requirements are issued pursuant to section 6(b)(7) of the OSH Act, which mandates that any standard promulgated under section 6(b) shall, where appropriate, ''provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees'' (29 U.S.C. 655(b)(7)).

Assessing employee exposure to toxic substances is a well-recognized and accepted risk management tool. The purposes of requiring an assessment of employee exposures to respirable crystalline silica include: Determination of the extent and degree of exposure at the worksite; identification and prevention of employee overexposure; identification of the sources of exposure; collection of exposure data so that the employer can select the proper control methods to be used; and evaluation of the effectiveness of those selected methods. Assessment enables employers to meet their legal obligation to ensure that their employees are not exposed in excess of the permissible exposure limit (PEL) and to ensure employees have access to accurate information about their exposure levels, as required by section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)). In addition, exposure data enable the physicians or other licensed health care professionals (PLHCP) performing medical examinations to be informed of the extent of occupational exposures.

In the proposed standard for general industry and maritime, OSHA included a requirement for employers to assess the exposure of employees who are reasonably expected to be exposed to respirable crystalline silica at or above the action level of 25 $\mu g/m^3$. This obligation consisted of: An initial exposure assessment, unless monitoring had been performed in the previous 12 months, or the employer had objective data to demonstrate that exposures would be below the action level under any expected conditions; periodic exposure assessments, following either a scheduled monitoring option (with the frequency of monitoring determined by the results of the initial and subsequent monitoring) or a performance option (*i.e.,* use of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures); and additional exposure assessments when changes in the workplace resulted in new or additional exposures to respirable crystalline silica at or above the action level. The proposed standard also included provisions for the method of sample analysis, employee notification of assessment results, and observation of monitoring.

The proposed standard for construction included the same requirements for exposure assessment as the proposed standard for general industry and maritime; however, employers were not required to assess the exposure of employees performing tasks on Table 1 where the employer fully implemented the engineering controls, work practices, and respiratory protection specified in Table 1. This exception to the general requirement for exposure assessment was intended to relieve the construction employer of the burden of performing an exposure assessment in these situations, because appropriate control measures are already identified.

Commenters, such as the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), the American Society of Safety Engineers (ASSE), the National Industrial Sand Association (NISA), and the International Diatomite Producers Association, supported the inclusion of an exposure assessment provision in the general industry standard (*e.g.,* Document ID 4204, pp. 52–54; 2339, p. 4; 2195, pp. 5–6, 9–10, 33; 2196, Attachment 1, p. 4), while other commenters, including the American Public Health Association (APHA), the National Consumers League (NCL) and

Dr. James Cone, more generally concurred with OSHA's proposed exposure assessment requirements (*e.g.,* Document ID 2178, Attachment 1, p. 2; 2373, p. 2; 2157, p. 7). However, commenters from the construction industry, including the National Utility Contractors Association, the American Subcontractors Association (ASA), the Leading Builders of America (LBA), the Associated Builders and Contractors (ABC), the Associated General Contractors of America, Fann Contracting, Inc., the National Association of Home Builders (NAHB), and the Construction Industry Safety Coalition (CISC), as well as the American Fuel and Petrochemical Manufacturers (AFPM), whose members regularly perform construction tasks, contended that the proposed exposure assessment requirements were unworkable, impractical, or exceedingly expensive due to the dynamic construction environment where frequent changes in environmental conditions, materials, tasks and the amount of time tasks are performed, locations, and personnel would require constant assessment and monitoring (*e.g.,* Document ID 2171, p. 2; 2187, p. 5; 2269, p. 6; 2289, p. 6; 2323, p. 1; 2116, Attachment 1, pp. 13–14; 2296, pp. 24–25; 2350, p. 10; 3521, p. 7; 4217, pp. 12–13). More specifically, commenters, including the Distribution Contractors Association and the Sheet Metal and Air Conditioning Contractors National Association (SMACNA), expressed concerns about the initial or periodic assessment requirements (*e.g.,* Document ID 2309, p. 3; 2226, p. 2). Fann Contracting, ASA, and the Edison Electric Institute (EEI) argued that initial and periodic exposure assessments do not make sense for construction projects where conditions, tasks, and potential exposures are constantly changing (Document ID 2116, Attachment 1, pp. 5, 16; 2187, p. 5; 2357, p. 13).

Other commenters from both construction and general industry, including Ameren Corporation (Ameren), the Concrete Company, the Glass Association of North America, the Washington Aggregates and Concrete Association, the North American Insulation Manufacturers Association (NAIMA), EEI, the National Stone, Sand, and Gravel Association (NSSGA), the National Association of Manufacturers (NAM), Lafarge North America (Lafarge), the Asphalt Roofing Manufacturers Association (ARMA), and NAHB, argued that employers should not be required to conduct air monitoring for employees on each shift, for each job classification, and in each work area unless differences exist between shifts (*e.g.,* Document ID 2315, p. 3; 2317, p. 2; 2215, p. 9; 2312, p. 2; 2348, Attachment 1, p. 39; 2357, p. 23; 2327, Attachment 1, p. 18; 2380, Attachment 2, pp. 26–28; 2179, p. 3; 2291, pp. 20–21). The American Foundry Society (AFS) argued that repetitious full shift sampling is also ''burdensome and unnecessarily dangerous to employees who must wear heavy and awkward equipment during the sampling session'' (Document ID 2379, Attachment B, p. 28). Commenters from the construction industry, including ABC, LBA, the Hunt Construction Group, and CISC argued that conducting air monitoring for employees on each shift, for each job classification, and in each work area or representative sampling of employees was not possible in constantly changing construction environments (*e.g.,* Document ID 2289, p. 6; 2269, p. 6; 3442, pp. 2–3; 2319, pp. 83–84).

In response to these comments, OSHA restructured the exposure assessment requirements in order to provide employers with greater flexibility to meet their exposure assessment obligations using either the performance option or the scheduled monitoring option. This restructuring emphasizes the performance option in order to provide additional flexibility for employers who are able to characterize employee exposures through alternative methods. Commenters, including Arch Masonry, Inc., the Building and Construction Trades Department, AFL–CIO (BCTD), and the Precast/Prestressed Concrete Institute (PCI), strongly supported this approach (*e.g.,* Document ID 2292, p. 3; 3587, Tr. 3655; 2371, Attachment 1, p. 10; 4223, p. 68; 2276, p. 10). However, some commenters from the construction industry, including CISC, Holes Incorporated, and ABC, considered a performance option to be unworkable in the construction industry due to variability in exposures (*e.g.,* Document ID 2319, p. 85; 3580, Tr. 1448–1450; 4216, pp. 2–3; 2226, p. 2). SMACNA also suggested that using historical air monitoring data or objective data is not a legitimate option for small employers who do not have this type of information (Document ID 2226, p. 2).

While some small businesses and construction employers, like Holes Incorporated, noted the difficulties with utilizing this option, there were other similarly situated commenters, like Arch Masonry, that felt the performance option was necessary to fulfill their exposure assessment obligations (*e.g.,* Document ID 3580, Tr. 1448–1450; 2292, p. 3). OSHA understands that the performance option may not be the preferred choice of every employer, but it expects it will provide many employers with substantial flexibility to meet their exposure assessment obligations. Thus, the Agency has included the performance option in the rule to complement the scheduled monitoring option.

In addition, the restructured standard for construction provides added flexibility to construction employers in another significant way. As described in the summary and explanation of *Specified Exposure Control Methods,* where the employer fully and properly implements the engineering controls, work practices, and respiratory protection specified on Table 1 for a task, the employer is not required to assess the exposure of employees engaged in that task or take additional measures to ensure that the exposures of those employees do not exceed the revised PEL (*see* paragraph (c)(1) of the standard for construction). These revisions will relieve construction employers of the burden of performing exposure assessment in many situations and will provide them with greater flexibility to meet the requirements of the standard, while still providing construction workers with the same level of protection as that provided to other workers.

The rule also includes the scheduled monitoring option in order to provide employers with a clearly defined, structured approach to assessing employee exposures. Some commenters, such as CISC and ASSE, urged OSHA to reconsider the inclusion of the scheduled monitoring option, finding it to be impractical, infeasible, and burdensome (*e.g.,* Document ID 2319, p. 86; 3578, Tr. 1052). On the other hand, NISA and the Shipbuilders Council of America (SCA) supported the inclusion of both a performance option and a scheduled monitoring option for exposure assessment (Document ID 2195, p. 36; 2255, p. 3). AFL–CIO supported periodic exposure assessments when exposures are above the action level, with more frequent assessments required if exposures exceed the PEL, as required under the scheduled monitoring option. It also noted that similar requirements for periodic exposure assessments are included in all other health standards that include exposure monitoring and argued that they should also be included in the rule (Document ID 4204, pp. 53–54). As discussed below, the Agency finds that this option may be useful for certain employers and has retained it in order to maximize flexibility in the rule.

General requirement for exposure assessment. Paragraph (d)(1) of the standard for general industry and maritime (paragraph (d)(2)(i) of the standard for construction) contains the general requirement for exposure assessment. This provision, which remains the same as proposed except for minor editorial changes, requires employers to assess the exposure of each employee who is or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level of 25 μg/m³ in accordance with either the performance option or the scheduled monitoring option. All employers covered by the standard for general industry and maritime must abide by this provision. However, as discussed in the summary and explanation of *Specified Exposure Control Methods,* employers following the standard for construction need only follow this provision, and the remainder of paragraph (d)(2), for tasks not listed in Table 1 or where the employer does not fully and properly implement the engineering controls, work practices, and respiratory protection described in Table 1 (*see* paragraph (d) of the standard for construction).

OSHA received a number of comments on this general provision. For example, the Center for Progressive Reform (CPR) recommended that OSHA require employers to conduct exposure assessments for each employee who is or may ''foreseeably'' be exposed at or above the action level, rather than only for those employees ''reasonably expected'' to be exposed at or above the action level. They argued that ''expected'' exposures might be lower than ''foreseeable'' exposures, and cited equipment malfunctions and problems with respiratory protection programs as situations that are ''foreseeable'' but may not be ''expected'' (Document ID 4005, pp. 2–4). OSHA is not persuaded by this argument. The Agency has decided that employers should not be required to conduct assessments when employee exposures are only likely to exceed the action level during a foreseeable, but unexpected event. Therefore, an employer who reasonably expects the exposure of an employee to remain below the action level does not have to assess the exposure of that employee. However, if equipment malfunctions or other unexpected events that could affect employee exposures occur, then the employer may not be able to reasonably expect employee exposure to remain below the action level and would be required to conduct an assessment. As to CPR's comment that anticipated problems with respiratory protection programs might be foreseeable, but unexpected, OSHA reminds employers that this rule defines ''employee exposure'' to mean exposure that would occur without the use of a respirator, so inadequacies in an employer's respiratory protection program do not affect the requirement for exposure assessment.

OSHA also received a number of comments on whether triggering exposure monitoring at an action level of 25 μg/m³ is appropriate. Some commenters, including the Center for Effective Government (CEG), APHA, NCL, and the Association of Occupational and Environmental Clinics (AOEC) agreed that the proposed action level trigger of 25 μg/m³ for exposure assessment was needed (*e.g.,* Document ID 2341, pp. 2–3; 2178, Attachment 1, p. 2; 2373, p. 2; 3399, p. 5). CEG argued that an action level trigger of 25 μg/m³ is needed to ensure that exposures are reduced below the PEL (Document ID 2341, p. 3). AOEC commented that this trigger is needed to help protect employees from crystalline silica isomorphs that are particularly toxic (Document ID 3399, p. 5). Dr. Franklin Mirer, Professor of Environmental and Occupational Health at CUNY School of Public Health, representing AFL–CIO, and the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), supported an action level trigger, but stated that an action level below 25 μg/m³ might be necessary in order to ensure that exposures are continuously below the PEL (Document ID 2256, Attachment 3, p. 1; 2282, Attachment 3, pp. 1, 14).

Other commenters, including NISA, the Industrial Minerals Association—North America, the Institute of Makers of Explosives (IME), and the American Petroleum Institute (API), agreed that assessing exposures at an action level was necessary, but believed the action level should be 50 μg/m³ (with a PEL of 100 μg/m³) (*e.g.,* Document ID 2195, pp. 5–6; 2200, pp. 2–3; 2213, p. 3; 2301, Attachment 1, p. 4). NISA, for example, disagreed with OSHA's characterization of significant risk at the proposed PEL and action level, but argued that an action level trigger is needed in order to maintain individual employees' exposures below the PEL (Document ID 2195, p. 6). Francisco Trujillo, safety director for Miller and Long, proposed that exposure assessment should be triggered at an action level of 75 μg/m³ (with a PEL of 100 μg/m³) for the construction industry (Document ID 2345, p. 2). The American Exploration and Production Council (AXPC) encouraged OSHA to trigger all ancillary provisions in this rule (presumably including exposure assessment) only when exposures are at or above an action level of 50 μg/m³ after ''discount[ing] exposure levels to reflect the demonstrated effectiveness of respiratory protection . . .'' (Document ID 2375, Attachment 1, p. 3). The National Institute for Occupational Safety and Health and CPR agreed that the action level should be the trigger, but did not specify where the action level should be set (Document ID 3579, Tr. 138–139; 2351, p. 10).

On the other hand, commenters including the Fertilizer Institute, NSSGA, and Acme Brick Company and others in the brick industry did not believe that an action level trigger for exposure assessment was necessary and that the PEL should be the trigger for exposure assessment (*e.g.,* Document ID 2101, p. 10; 3583, Tr. 2303–2305; 2023, p. 6). NSSGA argued that triggering sampling at the action level is not sufficient to ensure compliance and instead, the individual employer should determine when and how much sampling should be done in order to ensure compliance with the PEL (Document ID 3583, Tr. 2303–2305). In addition, several commenters, such as Lafarge, ASA, NSSGA, AFPM, the Tile Council of North America (TCNA), the American Iron and Steel Institute, and CISC discussed the challenges of measuring exposures at an action level of 25 μg/m³ (*e.g.,* Document ID 2179, pp. 2–3; 2187, p. 5; 2327, Attachment 1, p. 16; 2350, p. 9; 2363, p. 4; 3492, p. 3; 2319, pp. 85–86).

OSHA concludes that an action level trigger for exposure assessment is appropriate and agrees with commenters that an action level trigger is needed in order to maintain exposures below the PEL. An action level trigger, typically set at half the PEL, is consistent with other OSHA health standards, such as the standards for 1,3-butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026). It provides employees and employers with some assurance that variations in exposure levels will be accurately tracked and exposures above the PEL will be identified and corrective actions will be taken to protect employees. Assessment at the action level is also necessary to determine eligibility for medical surveillance in the standard for general industry and maritime. Where it is possible for employers to reduce exposures below the action level, the trigger encourages employers to do so in order to minimize their exposure assessment obligations while maximizing the protection of

employees' health. As discussed in Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA), OSHA has also concluded that it is technologically feasible to reliably measure employee exposures at an action level of 25 μg/m³.

OSHA disagrees with AXPC's suggestion to consider the effect of respiratory protection when setting the exposure assessment trigger or when triggering other provisions in this rule. Although there may be some circumstances where a breathing zone sample does not reflect the actual exposure of an employee who is being protected by a respirator, this argument overlooks the fact that exposure monitoring is not a single purpose activity. It is necessary to know employee exposure levels without the use of respiratory protection to evaluate the effectiveness of the required engineering and work practice controls and to determine whether additional controls must be instituted. In addition, monitoring is necessary to determine which respirator, if any, must be used by the employee, and it is also necessary for compliance purposes.

In addition, as discussed in the summary and explanation of *Methods of Compliance*, respirators will not protect employees if they are not fitted and maintained correctly and replaced as necessary or if employees do not use them consistently and properly. If any one of these conditions is not met, the protection a respirator provides to an employee can be reduced or eliminated. Thus, discounting exposure levels based on respirator use would be inappropriate. Moreover, the requirement to use respiratory protection under paragraph (f)(1) of the standard for general industry and maritime (paragraph (d)(3)(i) of the standard for construction) is triggered by employee exposures that exceed the PEL. It is unclear how AXPC believes the original exposure assessment level (to which the discount would be applied) could be derived without conducting an exposure assessment. Therefore, OSHA declines to adopt this suggestion.

EEI urged OSHA to consider exempting intermittent and short-duration work in the electric utility industry from the exposure assessment requirement where employees exposed at or above the action level wear appropriate personal protective equipment required under either 29 CFR part 1910, subpart I or 29 CFR part 1926, subpart E (Document ID 2357, pp. 13–14). While OSHA understands that conducting exposure monitoring in these situations may present challenges, it is important that employees who perform intermittent and short-duration work in the electric utility industry have their exposures assessed; the need for accurate information on exposures is no less for these employees than for other employees exposed to respirable crystalline silica at or above the action level. Where exposure assessments are required for intermittent and short-duration work, the performance option provides considerable flexibility for meeting these obligations. However, other provisions of the rule may relieve employers from conducting exposure assessments in some of these situations. For general industry and maritime, in situations where employers have objective data demonstrating that employee exposure will remain below 25 μg/m³ as an 8-hour TWA under any foreseeable conditions, including during intermittent and short-duration work, paragraph (a)(2) exempts the employer from the scope of the rule. For construction, in situations where employee exposure will remain below 25 μg/m³ as an 8-hour TWA under any foreseeable conditions, including during intermittent and short-duration work, paragraph (a) exempts the employer from the scope of the rule. In addition, as discussed in the summary and explanation of Scope, where tasks performed in a general industry or maritime setting are indistinguishable from construction tasks listed on Table 1, OSHA permits employers to comply with either all of the provisions of the standard for general industry and maritime or all of the provisions of the standard for construction. When this occurs and the employer fully complies with the standard for construction, the employer will not be required to conduct exposure assessments for employees engaged in those tasks. Therefore, OSHA has concluded that a specific exemption from exposure assessment requirements for intermittent and short-duration work in the electric utility industry is neither needed nor sufficiently protective.

As discussed above, paragraph (d)(1) of the standard for general industry and maritime (paragraph (d)(2)(i) of the standard for construction), unlike the general exposure assessment requirement in the proposal, provides two options for exposure assessment—a performance option and a scheduled monitoring option. The scheduled monitoring option provides a framework that is familiar to many employers, and has been successfully applied in the past. The performance option provides flexibility for employers who are able to characterize employee exposures through alternative methods. In either case, employers must assess the exposure of each employee who is or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level.

The performance option. Paragraph (d)(2) of the standard for general industry and maritime (paragraph (d)(2)(ii) of the standard for construction) describes the performance option. This option provides employers flexibility to assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica. OSHA recognizes that exposure monitoring may present challenges in certain instances, particularly when tasks are of short duration or performed under varying environmental conditions. The performance option is intended to allow employers flexibility in assessing the respirable crystalline silica exposures of their employees.

Where the employer elects this option, the employer must conduct the exposure assessment prior to the time the work commences, and must demonstrate that employee exposures have been accurately characterized. To accurately characterize employee exposures under the performance option, the assessment must reflect the exposures of employees on each shift, for each job classification, in each work area. However, under this option, the employer has flexibility to determine how to achieve this. For example, under this option an employer could determine that there are no differences between the exposure of an employee in a certain job classification who performs a task in a particular work area on one shift and the exposure of another employee in the same job classification who performs the same task in the same work area on another shift. In that case, the employer could characterize the exposure of the second employee based on the characterization of the first employee's exposure.

Accurately characterizing employee exposures under the performance option is also an ongoing duty. In order for exposures to continue to be accurately characterized, the employer is required to reassess exposures whenever a change in production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred (*see* discussion below of paragraph (d)(4) of

the standard for general industry and maritime and paragraph (d)(2)(iv) of the standard for construction).

When using the performance option, the burden is on the employer to demonstrate that the data accurately characterize employee exposure. However, the employer can characterize employee exposure within a range, in order to account for variability in exposures. For example, a general industry or maritime employer could use the performance option and determine that an employee's exposure is between the action level and the PEL. Based on this exposure assessment, the employer would be required under paragraph (i)(1)(i) to provide medical surveillance if the employee is exposed for more than 30 days per year. Where an employer uses the performance option and finds exposures to be above the PEL after implementing all feasible controls, the employer would be required to provide the appropriate level of respiratory protection. For example, an employer who has implemented all feasible controls could use the performance option to determine that exposures exceed the PEL, but do not exceed 10 times the PEL. The employer would be required under paragraph (g) of the standard for general industry and maritime (paragraph (e) of the standard for construction) to provide respiratory protection with an assigned protection factor of at least 10, as well as medical surveillance for employees exposed for more than 30 days per year.

Several commenters requested that OSHA provide more guidance as to how employers should implement the performance option. Commenters, including AFL–CIO, the International Union of Bricklayers and Allied Craftworkers (BAC), the United Steelworkers, BCTD, and the International Union of Operating Engineers (IUOE), felt that clarification and guidance on the kind of data that may or may not be relied upon was needed in order to ensure that the data adequately reflected employee exposures (Document ID 2256, Attachment 2, p. 10; 2329, p. 4; 2336, p. 6; 2371, Attachment 1, pp. 11–13; 3581, Tr. 1693–1694; 3583, Tr. 2341; 4204, p. 54; 4223, p. 70). The American College of Occupational and Environmental Medicine recommended that OSHA more precisely specify the type and periodicity of collection of industrial hygiene data that would be required to assure representative exposure measurements (Document ID 2080, p. 4). The American Industrial Hygiene Association (AIHA) argued that a sufficient number of samples and a sampling strategy that is representative of the employees and tasks being sampled is needed to ensure that exposure assessments using the performance option accurately characterize employee exposure (Document ID 3578, Tr. 1049–1050). To do this, AIHA suggested that OSHA,

> . . . point to American Industrial Hygiene Association language on what an acceptable judgment of exposure can be based upon: number of samples for statistical validity, an acceptable tolerance for an error in that statistical judgment, and the connection of the sample set to a set of conditions occurring during the worker exposure measurement (Document ID 2169, p. 3).

CISC also indicated that the construction industry needed additional guidance, such as how often and when monitoring should be conducted under the performance option in order to determine whether it would be effective and viable (Document ID 2319, p. 86). Charles Gordon, a retired occupational safety and health attorney, suggested the performance option was too flexible and needed to be omitted until real-time monitoring could be incorporated into it (Document ID 2163, Attachment 1, p. 17).

OSHA has not included specific criteria for implementing the performance option in the rule. Since the goal of the performance option is to give employers flexibility to accurately characterize employee exposures using whatever combination of air monitoring data or objective data is most appropriate for their circumstances, OSHA concludes it would be inconsistent to specify in the standard exactly how and when data should be collected. Where employers want a more structured approach for meeting their exposure assessment obligations, OSHA also provides the scheduled monitoring option.

OSHA does, however, offer two clarifying points. First, the Agency clarifies that when using the term ''air monitoring data'' in this paragraph, OSHA refers to any monitoring conducted by the employer to comply with the requirements of this standard, including the prescribed accuracy and confidence requirements. Second, the term does not include historic air monitoring data, which are ''objective data.'' Additional discussion of the types of data and exposure assessment strategies that may be used by employers as ''objective data'' to accurately characterize employee exposures to respirable crystalline silica can be found in the summary and explanation of *Definitions*.

For example, trade associations and other organizations could develop objective data based on industry-wide surveys that members could use to characterize employee exposures to respirable crystalline silica. For example, the National Automobile Dealers Association (NADA) conducted air monitoring for employees performing a variety of tasks in automobile body shops (Document ID 4197; 4198). NADA worked to ensure that the results of the study were representative of typical operations. The sampling procedures and techniques for controlling dust were documented. These data may allow body shops that perform tasks in a manner consistent with that described in the NADA survey to rely on this objective data to characterize employee exposures to respirable crystalline silica.

Employers could also use portable, direct-reading instruments to accurately characterize employee exposures to respirable crystalline silica. These devices measure all respirable dusts, not only crystalline silica. But where the employer is aware of the proportion of crystalline silica in the dust, direct-reading instruments have the advantage of providing real-time monitoring results. For example, in a facility using pure crystalline silica, the employer could assume that the respirable crystalline silica concentration in the air is equivalent to the respirable dust measurement provided by the direct reading instrument. Where exposures involve dusts that are not pure crystalline silica, the employer could determine the concentration of crystalline silica by analysis of bulk samples (*e.g.,* geotechnical profiling) or information on safety data sheets, and calculate the air concentration accordingly. In such situations, the analysis of bulk samples or safety data sheets would be part of the objective data relied on by the employer. In addition, employers could use a wide variety of other types of objective data to assess exposures, including data developed using area sampling or area exposure profile mapping approaches. Where new methods become available in the future that accurately characterize employee exposure to respirable crystalline silica, data generated using those methods could also be considered objective data and could be used by employers to assess employee exposures.

Where employers rely on objective data generated by others as an alternative to developing their own air monitoring data, they will be responsible for ensuring that the data relied upon from other sources are accurate measures of their employees' exposures. Thus, the burden is on the

employer to show that the exposure assessment is sufficient to accurately characterize employee exposures to respirable crystalline silica.

CPR suggested that OSHA require an independent audit of employers' objective data calculations to ensure that they provide the same degree of assurance of accurate exposure characterization as air monitoring data (Document ID 2351, pp. 12–13). As explained above, employers using the performance option must ensure that the exposure assessment is sufficient to accurately characterize employee exposure to respirable crystalline silica. Because employers already bear the burden of ensuring accurate characterization of employee exposures, OSHA does not find that an independent audit of employers' objective data is necessary to assure proper compliance.

The Laborers' Health and Safety Fund of North America urged OSHA to collect and post all objective data that meet the definition on its Web site, so that it could be used by anyone performing the same task under the same conditions (Document ID 2253, p. 4). Other commenters, including BAC, BCTD, and IUOE, agreed that developing a means for collecting and sharing objective data was important (Document ID 2329, p. 4; 2371, Attachment 1, p. 13; 3583, Tr. 2394–2395). OSHA recognizes that the collection and sharing of objective data can be a useful tool for employers characterizing exposures using the performance option. OSHA anticipates that there could be a substantial volume of objective data that would require significant resources to collect, organize, present, and maintain in a way that is accessible, understandable, and valuable to employers. The Agency does not have the resources to do this; however, employers, professional and trade associations, unions, and others that generate objective data are encouraged to aggregate and disseminate this type of information.

As with the standard for chromium (VI), 29 CFR 1910.1026, OSHA does not limit when objective data can be used to characterize exposure. OSHA permits employers to rely on objective data for meeting their exposure assessment obligations, even where exposures may exceed the action level or PEL. OSHA's intent is to allow employers flexibility to assess employee exposures to respirable crystalline silica, but to ensure that the data used are accurate in characterizing employee exposures. For example, where an employer has a substantial body of data (from previous monitoring, industry-wide surveys, or other sources) indicating that employee exposures in a given task exceed the PEL, the employer may choose to rely on those data to determine his or her compliance obligations (*e.g.,* implementation of feasible engineering and work practice controls, respiratory protection, medical surveillance).

OSHA has also not established time limitations for air monitoring results used to characterize employee exposures under the performance option. Although the proposed standard would have limited employers using air monitoring data for initial exposure assessment purposes to data collected no more than twelve months prior to the rule's effective date, there were no such time restrictions on monitoring data used to conduct periodic exposure assessments under the performance option. Nevertheless, many commenters, including Ameren, TCNA, NAM, NAIMA, Associated General Contractors of New York State, ARMA, EEI, the National Rural Electric Cooperative Association, the Glass Packaging Institute, Verallia North America, and Holes Incorporated, found the 12-month limit on the use of monitoring results for initial exposure assessments using existing data to be too restrictive (*e.g.,* Document ID 2315, p. 3; 2363, p. 6; 2380, Attachment 2, pp. 28–29; 3544, pp. 12–13; 2145, p. 3; 2291, pp. 2, 21–23; 2348, pp. 37–39; 2357, pp. 22–23; 2365, pp. 10–11, 23; 2290, p. 4; 3493, p. 6; 3584, Tr. 2848; 3580, Tr. 1492). For example, Southern Company noted that:

> We have been collecting data on silica for several years as well as sharing within our industry group. This provision seems to be arbitrary and provides only a short window of time for data collection while eliminating the value and importance of past [efforts] we have placed on this issue (Document ID 2185, p. 7).

OSHA has been persuaded by these commenters not to establish time limitations for monitoring results used to assess exposures under the performance option, as long as the employer can demonstrate the data accurately characterize current employee exposures to respirable crystalline silica. The general principle that the burden is on the employer to show that the data accurately characterize employee exposure to respirable crystalline silica applies to the age of the data as well as to the source of the data. For example, monitoring results obtained 18 months prior to the effective date of the standard could be used to determine employee exposures, but only if the employer could show that the data were obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Regardless of when they were collected, the data must accurately reflect current conditions.

Any air monitoring data relied upon by employers must be maintained and made available in accordance with the recordkeeping requirements in paragraph (k)(1) of the standard for general industry and maritime (paragraph (j)(1) of the standard for construction). Any objective data relied upon must be maintained and made available in accordance with the recordkeeping requirements in paragraph (k)(2) of the standard for general industry and maritime (paragraph (j)(2) of the standard for construction).

NISA commented that a performance option needs to be consistently interpreted by compliance officers in order for such an approach to be truly useful to employers (Document ID 2195, p. 36). OSHA agrees. OSHA regularly establishes policies and directives to guide compliance officers in a uniform, consistent manner when enforcing standards. These policies ensure that all the provisions of OSHA standards, including performance options, are consistently applied in the field.

The scheduled monitoring option. Paragraph (d)(3) of the standard for general industry and maritime (paragraph (d)(2)(iii) of the standard for construction) describes the scheduled monitoring option. This option provides employers with a clearly defined, structured approach to assessing employee exposures. Under paragraph (d)(3)(i) of the standard for general industry and maritime (paragraph (d)(2)(iii)(A) of the standard for construction), employers who select the scheduled monitoring option must conduct initial monitoring to determine employee exposure to respirable crystalline silica. Monitoring to determine employee exposures must represent the employee's time-weighted average exposure to respirable crystalline silica over an eight-hour workday. Samples must be taken within the employee's breathing zone (*i.e.,* ''personal breathing zone samples'' or ''personal samples''), and must represent the employee's exposure without regard to the use of respiratory protection. OSHA intends for employers using the scheduled monitoring option to conduct initial monitoring as soon as work begins. Employers must be aware of the level of exposure when work is performed to identify situations where control measures are needed.

Under the scheduled monitoring option, just as under the performance option, employers must accurately characterize the exposure of each employee to respirable crystalline silica. In some cases, this will entail monitoring all exposed employees. In other cases, monitoring of ''representative'' employees is sufficient. Representative exposure sampling is permitted when several employees perform essentially the same job on the same shift and under the same conditions. For such situations, it may be sufficient to monitor a subset of these employees in order to obtain data that are ''representative'' of the remaining employees. Representative personal sampling for employees engaged in similar work, with respirable crystalline silica exposure of similar duration and magnitude, is achieved by monitoring the employee(s) reasonably expected to have the highest respirable crystalline silica exposures. For example, this could involve monitoring the respirable crystalline silica exposure of the employee closest to an exposure source. The exposure result may then be attributed to other employees in the group who perform the same tasks on the same shift and in the same work area.

Exposure monitoring should include, at a minimum, one full-shift sample taken for each job function in each job classification, in each work area, for each shift. These samples must consist of at least one sample characteristic of the entire shift or consecutive representative samples taken over the length of the shift. Where employees are not performing the same job under the same conditions, representative sampling will not adequately characterize actual exposures, and individual monitoring is necessary.

Stakeholders offered numerous comments and suggestions about the proposed provisions that would have required employers to assess employee exposure on the basis of personal breathing zone air samples that reflect the exposure of employees on each shift, for each job classification, and in each work area. Many of these comments and suggestions involved specific concerns with the practicality and necessity of assessing employee exposure on each shift, for each job classification, and in each work area (*e.g.,* Document ID 2315, p. 3; 2317, p. 2; 2215, p. 9; 2312, p. 2; 2348, Attachment 1, p. 39; 2357, p. 23; 2327, Attachment 1, p. 18; 2380, Attachment 2, pp. 26–28; 2179, p. 3; 2291, pp. 20–21). As discussed previously, OSHA responded to these comments by restructuring the exposure assessment requirements to allow employers to use the performance option for all exposure assessments required by this rule. Although employers utilizing the performance option must still accurately characterize the exposures of each of their employees, these employers have latitude to broadly consider the best way this can be accomplished.

NAIMA suggested that OSHA should make adjustments to exposure monitoring requirements for extended work shifts (*e.g.,* 12-hour shifts). They proposed that

> . . . exposure assessment should follow the standard practice of measuring any continuous 8-hour period in the shift that is representative, or allow using multiple samples to sample the entire extended shift and selecting the 8 hours which represent the highest potential exposure (Document ID 3544, p. 14).

OSHA agrees that this is an appropriate way to conduct sampling for extended work shifts. This practice is already reflected in the OSHA Technical Manual, which describes the two approaches advanced by NAIMA, including sampling the worst (highest exposure) eight hours of a shift or collecting multiple samples over the entire work shift and using the highest samples to calculate an 8-hour TWA (OSHA Technical Manual, Section II, Chapter 1, 2014, *https://www.osha.gov/dts/osta/otm/otm_ii/otm_ii_1.html#extended_workshifts*).

CISC argued that the ASTM Standard E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, takes what CISC considered to be a more reasonable approach to representative air monitoring in the construction industry. The ASTM standard states that measurements ''need to be representative of the worker's customary activity and be representative of work shift exposure'' (Document ID 1504). CISC argued that this approach is,

> . . . more reasonable because it inherently recognizes that an employee's exposure would vary on any given day due to a multitude of factors and that an employer should attempt to understand the exposure levels when performing his/her customary activity (Document ID 2319, pp. 83–84).

OSHA acknowledges that variability in exposures is a concern in the construction industry. The construction standard does not require exposure assessment for employees engaged in a task identified on Table 1 where the employer fully and properly implements the specified exposure control methods presented on Table 1 (*see* paragraph (c) of the standard for construction). As noted above, the performance option, in paragraph (d)(2) of the standard for general industry and maritime (paragraph (d)(2)(ii) of the standard for construction), also provides flexibility to characterize employee exposures in a manner that accounts for variability, in that it allows exposures to be assessed using any combination of air monitoring data and objective data. But OSHA does not consider that it is appropriate to allow exposure assessment to include only an employee's ''customary activity,'' because such an approach would ignore activities that may involve higher exposures to respirable crystalline silica, and the higher levels of risk associated with those exposures.

Under the scheduled monitoring option, requirements for periodic monitoring depend on the results of initial monitoring and, thereafter, any required subsequent monitoring. Paragraphs (d)(3)(ii)–(iv) of the standard for general industry and maritime (paragraphs (d)(2)(iii)(B)–(D) of the standard for construction) describe the employers' duties depending on the initial (and, after that, the most recent) monitoring results. If the initial monitoring indicates that employee exposures are below the action level, no further monitoring is required. If the most recent exposure monitoring reveals employee exposures to be at or above the action level but at or below the PEL, the employer must repeat monitoring within six months of the most recent monitoring. If the most recent exposure monitoring reveals employee exposures to be above the PEL, the employer must repeat monitoring within three months of the most recent monitoring.

Paragraph (d)(3)(v) of the standard for general industry and maritime (paragraph (d)(2)(iii)(E) of the standard for construction) provides that if the most recent (non-initial) exposure monitoring indicates that employee exposures are below the action level, and those results are confirmed within six months of the most recent monitoring by a second measurement taken consecutively at least seven days afterwards, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. As discussed below, reassessment is always required whenever a change in the workplace may be reasonably expected to result in new or additional exposures at or above the action level or the employer has any reason to believe that new or additional exposures at or above the action level have occurred, regardless of whether the employer has ceased monitoring because exposures are below the action level under

paragraph (d)(3)(ii) or (d)(3)(v) of the standard for general industry and maritime (paragraph (d)(2)(iii)(B) or (d)(2)(iii)(E) of the standard for construction) (*see* paragraph (d)(4) of the standard for general industry and maritime (paragraph (d)(2)(iv) of the standard for construction)).

OSHA made a number of minor changes to the requirements for periodic monitoring under the scheduled monitoring option from the proposal based on stakeholder comments. For example, paragraph (d)(3)(i)(B) of the proposed regulatory text provided that ''[w]here initial or subsequent exposure monitoring reveals that employee exposures are above the PEL, the employer shall repeat such monitoring at least every three months.'' Subparagraph (C) then stated: ''the employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level, at which time the employer may discontinue monitoring . . .''

ARMA argued that these provisions were confusing and ''might be interpreted to require employers to continue monitoring quarterly, even if two consecutive measurements are at or above the action level but at or below the PEL''—a reading that ARMA believed conflicted with the language of paragraph (d)(3)(i)(A), which provided that ''[w]here initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring at least every six months'' (Document ID 2291, p. 23). ARMA added that it anticipated that OSHA intended these provisions to impose the same periodic monitoring requirements that appear routinely in other OSHA health standards. It explained: ''[u]nder that approach, even if periodic monitoring must be conducted quarterly because the initial (or subsequent) assessment shows exposures in excess of the PEL, the frequency can be reduced to quarterly once two consecutive measurements more than seven days apart fall below the PEL but above the action level'' (Document ID 2291, p. 23).

OSHA agrees with ARMA's comment and has revised the periodic monitoring provisions under the scheduled monitoring option to better reflect OSHA's intent—as a general rule, the most recent exposure monitoring sample determines how often an employer must monitor. OSHA has also revised proposed paragraph (d)(3)(i)(C) to clarify the circumstances under which employers who choose the scheduled monitoring option may discontinue periodic monitoring.

Stakeholders also commented on how often employers should be required to conduct exposure monitoring. Several commenters, including the National Tile Contractors Association (NTCA), Dal-Tile, Grede Holdings, ORCHSE Strategies (ORCHSE), Benton Foundry, PCI, TCNA, and NISA, disagreed with the proposed frequency of monitoring and suggested other frequencies (every 6 months, 12 months, 18 months, or as determined by a competent person) (*e.g.,* Document ID 2267, p. 7; 2147, p. 3; 2298, p. 4; 2277, p. 3; 1972, p. 2; 2276, p. 6; 3584, Tr. 2744; 2363, p. 7; 2195, p. 36). IUOE and EEI, among others, suggested that the three or six-month intervals for follow-up exposure assessment will do nothing to protect employees on jobs of short duration (*e.g.,* Document ID 2262, p. 11; 2357, p. 31). AFS suggested that a scheduled monitoring option ''that includes quarterly and semi-annual monitoring does not gather useful information and is punitive in intent'' (Document ID 2379, Appendix 1, p. 55). EEI urged OSHA to revise the scheduled monitoring option to either:

> . . . (a) permit employers to conduct subsequent exposure assessments without an arbitrary timetable of three or six months; (b) permit employers to conduct subsequent exposure assessments in longer, more reasonable intervals, such as annually or biennially; or (c) create an exception to periodic exposure assessment requirement when no changes in the workplace, control equipment, or work practices have occurred (Document ID 2357, p. 21).

Francisco Trujillo, representing Miller and Long, proposed that where exposures were between the action level and the PEL, exposure assessment be required at least every six months unless employers implement the same controls used to control exposures above the PEL (Document ID 2345, p. 3). OSHA recognizes that exposures in the workplace may fluctuate. Periodic monitoring, however, is intended to provide the employer with reasonable assurance the employees are not experiencing exposures that are higher than the PEL and require the use of additional control measures. If the employer installs or upgrades controls, periodic monitoring will demonstrate whether or not controls are working properly or if additional controls are needed. In addition, periodic monitoring reminds employees and employers of the continued need to protect against the hazards associated with exposure to respirable crystalline silica. Because of the fluctuation in exposures, OSHA finds that when initial monitoring results equal or exceed the action level, but are at or below the PEL, employers must continue to monitor employees to ensure that exposures remain at or below the PEL. Likewise, when initial monitoring results exceed the PEL, periodic monitoring allows the employer to maintain an accurate profile of employee exposures. Selection of appropriate respiratory protection also depends on adequate knowledge of employee exposures.

In general, the more frequently periodic monitoring is performed, the more accurate the employee exposure profile. Selecting an appropriate interval between measurements is a matter of judgment. OSHA concludes that the frequencies of six months for subsequent periodic monitoring for exposures in between the action level and the PEL, and three months for exposures above the PEL, provide intervals that are both practical for employers and protective for employees. This finding is supported by OSHA's experience with comparable monitoring intervals in other standards, including those for chromium (VI) (1910.1026), cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), methylene chloride (29 CFR 1910.1052), and formaldehyde (29 CFR 1910.1048). Where employers find that a different frequency of monitoring is sufficient to accurately characterize employee exposure to respirable crystalline silica, they can use that air monitoring data to meet their exposure assessment obligations under the performance option.

Commenters, including National Electrical Carbon Products, Lapp Insulators, the Indiana Manufacturers Association, ORCHSE, Murray Energy Corporation, the Motor and Equipment Manufacturers Association, IME, PCI, and NAM, urged OSHA to permit employers to cease monitoring or monitor on a reduced schedule when it has been determined it is infeasible to reduce exposures below the PEL using engineering and work practice controls (*e.g.,* Document ID 1785, p. 5; 2130, p. 2; 2151, p. 2; 2277, p. 3; 2102, p. 2; 2326, pp. 2–3; 2213, p. 4; 2276, p. 6; 2380, Attachment 2, pp. 29–30). OSHA concludes, however, that periodic air monitoring serves as a useful tool for evaluating the continuing effectiveness of engineering and work practice controls, and can assist employers in ensuring that they have met their obligation to use all feasible controls to limit employee exposures to the PEL. Nevertheless, an employer may decide that continued monitoring does not serve to better characterize employee exposure. In these cases, as long as the

air monitoring data continue to accurately characterize employee exposure, employers can use the existing data to meet their exposure assessment obligations under the performance option without conducting additional monitoring.

Reassessment of exposures. Paragraph (d)(4) of the standard for general industry and maritime (paragraph (d)(2)(iv) of the standard for construction) requires employers assessing exposures using either the performance option or the scheduled monitoring option to reassess employee exposures whenever there has been a change in the production, process, control equipment, personnel, or work practices that may reasonably be expected to result in new or additional exposures to respirable crystalline silica at or above the action level, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred. For example, if an employer has conducted monitoring while a task is performed using local exhaust ventilation and the flow rate of the ventilation system is decreased, additional monitoring would be necessary to assess employee exposures under the modified conditions. In addition, there may be other situations that can result in new or additional exposures to respirable crystalline silica that are unique to an employee's work situation. OSHA inserted the phrase ''or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred'' in the rule to make clear that reassessment of exposures is required whenever there is reason to believe that a change in circumstances could result in new or additional exposures at or above the action level. For instance, an employee may move from an open, outdoor location to an enclosed or confined space. Even though the task performed and the materials used may remain constant, the changed environment could reasonably be expected to result in higher exposures to respirable crystalline silica. In order to account for these situations, the rule requires employers to reassess employee exposures whenever a change may result in new or additional exposures at or above the action level. OSHA considers this reevaluation necessary to ensure that the exposure assessment accurately represents existing exposure conditions. The exposure information gained from such assessments will enable the employer to take appropriate action to protect exposed employees, such as instituting additional engineering controls or providing appropriate respiratory protection.

Some commenters, including Southern Company, EEI, API, and AFPM, raised concerns about the requirement to conduct additional exposure assessments (*e.g.,* Document ID 2185, p. 7; 2357, pp. 21–22; 2301, Attachment 1, p. 80; 2350, p. 10). Southern Company commented that employers should not have to reassess exposures for every personnel change, but rather only those changes that result in significant changes in employee exposure (Document ID 2185, p. 7). EEI urged OSHA to clarify what kind of change could trigger additional assessments (Document ID 2357, pp. 21–22). API presented concerns that this requirement could be interpreted to require additional assessments at unworkably frequent intervals (Document ID 2301, Attachment 1, p. 80). AFPM argued that the provision would require its members to conduct continuous monitoring given the requirement to reassess every time there is an environmental shift that would result in a new respirable crystalline silica level (Document ID 2350, p. 10).

As described above, the requirement to reassess exposures only applies where there are changes in the workplace that may reasonably be expected to result in new or additional exposures at or above the action level or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred. OSHA does not intend for employers to conduct additional monitoring simply because a change has occurred, so long as the change is not reasonably expected to result in new or additional exposures to respirable crystalline silica at or above the action level. Thus, in some of the situations highlighted by the commenters, employers may not need to reassess exposures. For example, where a personnel change does not have an expected impact on the magnitude of employee exposure to respirable crystalline silica, the employer would not have to reassess exposures. When the environmental conditions on a construction site change in ways that would not result in new or additional exposures at or above the action level, such as a change from dry, dusty conditions to wet, rainy conditions, the employer would not have to reassess exposures. Other changes that would be reasonably expected to lower exposures to respirable crystalline silica, rather than result in new or additional exposures at or above the action level, such as moving from an indoor to an outdoor location or using a product with a lower silica content than that previously used in the same process, would not require the employer to reassess exposures.

Methods of sample analysis. Paragraph (d)(5) of the standard for general industry and maritime (paragraph (d)(2)(v) of the standard for construction) requires employers to ensure that all samples taken to satisfy the monitoring requirements are evaluated in accordance with Appendix A, which contains specifications for the methods to be used for analysis of respirable crystalline silica samples. The proposed provision would also have required employers to ensure that all samples taken to satisfy the air monitoring requirements in the exposure assessment paragraph were evaluated using the procedures specified in certain analytical methods. However, in the proposal, the analytical methods were laid out in paragraph (d), rather than in a separate Appendix.

Several commenters, including the Korte Company, AFS, TCNA, and NAM expressed concerns that the proposal placed responsibility for laboratory performance on the employers, who are not in a position to ensure that laboratories are complying with specific analytical requirements (*e.g.,* Document ID 3230, p. 1; 2379, Appendix 1, p. 56; 2363, p. 7; 2380, Attachment 2, p. 31). OSHA does not expect employers to oversee laboratory practices. An employer who engages an independent laboratory to analyze respirable crystalline silica samples can rely on a statement from that laboratory confirming that the specifications in Appendix A were met.

One stakeholder, Southern Company, recommended that OSHA require use of accredited laboratories and move all other laboratory requirements to an appendix as a guide for laboratories that analyze silica samples (Document ID 2185, p. 7). OSHA agrees with this suggestion and has decided to retain the substance of the proposed provisions addressing analysis of samples, but has moved these provisions to a new appendix. The Agency concludes that segregating these requirements in an appendix to each standard provides greater clarity for both employers and the laboratories that analyze samples. The specifications contained in Appendix A are discussed in the summary and explanation of *Appendix A* in this section.

Commenters, including NSSGA, SCA, OSCO Industries, ORCHSE, Associated General Contractors of Michigan (AGCM), and PCI expressed concern about the availability of a sufficient number of qualified laboratories capable

of analyzing the increased number of air samples expected given the standard's exposure assessment requirements (*e.g.*, Document ID 1992, p. 12; 2255, p. 1; 2265, Attachment 1, p. 2; 2277, p. 3; 2327, Attachment 1, pp. 4–6; 3589, Tr. 4357). There are approximately 40 laboratories that are accredited by AIHA Laboratory Accreditation Programs for the analysis of crystalline silica; these laboratories are already capable of analyzing samples in accordance with the laboratory requirements of this rule (Document ID 3586, Tr. 3284). While the number of accredited laboratories for the analysis of crystalline silica has declined over the last 10 or 20 years, William Walsh, the Vice Chair of the Analytical Accreditation Board of the AIHA Laboratory Accreditation Programs, testified that there is still sufficient capacity available to analyze crystalline silica samples and, in fact, ''each lab's capacity has gone up'' due to increased efficiency in the sample analysis process (Document ID 3586, Tr. 3311).

OSHA expects that the additional demand for respirable crystalline silica exposure monitoring and associated laboratory analysis with the rule will be modest. Most construction employers are expected to implement the specified exposure control measures in paragraph (c) of the standard for construction, and will therefore not be required to conduct exposure monitoring. The performance option for exposure assessment provided in both the standard for general industry and maritime at paragraph (d)(2) and the standard for construction at paragraph (d)(2)(ii) also serves to lessen the future volume of exposure monitoring and associated laboratory analysis for crystalline silica. As discussed in the summary and explanation of *Dates*, the time allowed for compliance with the standard for general industry and maritime also serves to diminish concerns about laboratory capacity by providing additional time for laboratory capacity to increase and distributing demand for sample analysis over an extended period of time.

Employee notification of assessment results. Paragraph (d)(6) of the standard for general industry and maritime (paragraph (d)(2)(vi) of the standard for construction) contains the requirements for employee notification of assessment results and corrective actions. Under paragraph (d)(6)(i) of the standard for general industry and maritime, employers must notify each affected employee of the results of the exposure assessment within 15 working days of completing the assessment. Paragraph (d)(2)(vi)(A) of the standard for construction requires this notification not more than five working days after the exposure assessment has been completed. Notification is required under both standards whenever an exposure assessment has been conducted, regardless of whether or not employee exposure exceeds the action level or PEL. Employers must either notify each individual employee in writing or post the assessment results in an appropriate location accessible to all affected employees. The term ''affected'' as used here means all employees for which an exposure assessment has been conducted, either individually or as part of a representative monitoring strategy. It includes employees whose exposure was assessed based on other employees who were sampled, and employees whose exposures have been assessed on the basis of objective data. As discussed with regard to the performance option, exposures can be characterized as a range, *e.g.*, below the action level or between the action level and the PEL. The employer is notifying employees of employee exposures, *i.e.*, exposures that would occur if the employee were not using a respirator. Any engineering and work practice controls used would be reflected in the assessment results.

The provisions in the rule are identical to the proposed provisions for both general industry and maritime and construction. A number of commenters offered opinions on these provisions. For example, some commenters, including Southern Company and EEI, objected to the differences between the general industry and construction notification requirements. These stakeholders argued that establishing different reporting requirements for general industry and construction (*i.e.*, requiring notification within 5 working days in construction and 15 working days in general industry), would create confusion and make compliance difficult to achieve, especially for employers with blended general industry/construction operations, such as electric utilities (Document ID 2185, p. 4; 2357, p. 23). EEI urged OSHA to harmonize the requirements or clarify which section applies to the situation with blended general industry/construction operations (Document ID 2357, p. 23).

This issue is not unique to this rulemaking. In October 2002, OSHA published the second phase of its Standard Improvement Project (SIPS), which proposed to revise a number of health provisions in its standards for general industry, shipyard employment, and construction. The proposal was part of OSHA's effort to continue to remove and revise provisions of its standards that are outdated, duplicative, unnecessary, or inconsistent. One of the issues OSHA examined in Phase II of SIPS was the ''variety of different time limits between receipt of employees' exposure monitoring results and notification of employees'' in OSHA's substance specific standards. After a thorough review of the record, OSHA adopted a 15-day notification period for general industry and a 5-day period in construction. The Agency explained that its decision to set two different time frames was due, in part, to the general differences in the industries, *i.e.*, general industry on average has ''a more stable workforce,'' while ''[e]mployment at a particular location is often brief in construction . . .'' (70 FR 1112, 1126 (1/5/05)).

Some stakeholders from the construction industry, including CISC and ASA, were concerned that they could not comply with the proposed five-day notification requirement due to the often short duration of tasks and employment in this sector. They argued that employers and employees will frequently have moved to a different job before the results are available, making it difficult or impossible to reach affected employees and rendering the data irrelevant to the new project with varying conditions and circumstances (*e.g.*, Document ID 2319, p. 87; 2187, p. 5). These comments suggest that a 5-working-day notification period would be too long for many employers in the construction industry. Thus, OSHA concludes that it would make little sense to lengthen the notification period in the construction standard to correspond to the time period proposed in general industry and maritime.

OSHA also concludes that shortening the proposed provision in general industry to mirror that in construction would likewise make little sense, especially insofar as most of OSHA's health standards for general industry already utilize a 15-working-day period. As OSHA explained in Phase II of SIPS, ''a uniform time limit for notifying employees in general industry has substantial benefits[,]'' including reduced employer paperwork burdens because of simpler, uniform compliance programs and probable improvement in employee protection due to improved compliance. Therefore, OSHA finds that the reasons discussed in the SIPS rulemaking apply equally here. Consequently, OSHA has chosen to adopt the proposed 5 and 15-working-day assessment results notification periods in the rule.

OSHA has also considered commenters' concerns that the nature of construction work will make it

logistically difficult to notify employees of assessment results because they may have moved on to different jobsites or employers. Employers have options available for notifying employees in such circumstances; for example, notifications could be made individually in writing by including the assessment results in the employees' final paycheck.

OSHA considers notification of assessment results to be important, even if the work conditions and circumstances have changed by the time the assessment results are available. Notification is not simply for purposes of identifying appropriate controls at the time the work is performed. The assessment results are still relevant after the exposure has occurred, to inform employees of their exposure, to provide context for future work that may be performed under similar conditions and circumstances, and to inform PLHCPs who provide medical surveillance for the employee.

NAM urged OSHA to provide flexibility as to when an assessment is deemed complete rather than obligating the employer to notify employees within five days of receiving a laboratory result (Document ID 2380, Attachment 2, p. 32). NAM argued that employers need time to perform and get the results of comprehensive surveys, perform appropriate quality assurance of those results, and meet with employees as appropriate to discuss the results. OSHA recognizes the value of these measures, but also considers the necessity of assessing exposures and notifying employees in a timely manner so that appropriate protective measures are taken. The Agency is convinced that the required notification can be made within the required 15 or 5 day time period, which are standard in OSHA health standards. Additional information that is developed from the collection of data in comprehensive surveys, any revisions to initial results as a result of quality assurance activities, or meetings to discuss the assessment results can take place at a later date.

Where the employer follows the performance option provided in paragraph (d)(2) of the standard for general industry and maritime (paragraph (d)(2)(ii) of the standard for construction), the 15 (or 5) day period commences when the employer completes an assessment of employee exposure levels (*i.e.*, normally prior to the time the work operation commences, and whenever exposures are re-evaluated). OSHA expects that many construction employers will follow the performance option, where they are not using the specified exposure control methods approach. Therefore, OSHA expects that it will not be difficult to reach affected employees as the assessment would take place prior to the time the work operation begins and the assessment results could then be posted in a location accessible to employees at the beginning of the job. Where the employer follows the scheduled monitoring option provided in paragraph (d)(3) of the standard for general industry and maritime (paragraph (d)(2)(iii) of the standard for construction), the 15 (or 5) day period for notification commences when monitoring results are received by the employer.

In addition, as discussed in the summary and explanation of *Scope*, where tasks performed in a general industry setting may be essentially indistinguishable from construction tasks listed on Table 1, OSHA permits employers to comply with either all of the provisions of the standard for general industry and maritime or all of the provisions of the standard for construction. When choosing to follow the construction standard, the employer must notify employees within five working days after completing an exposure assessment.

The notification provisions in the rule, like those in the proposal, require employers to notify ''affected'' employees. As noted above, the term ''affected'' as used here means all employees for which an exposure assessment has been conducted, either individually or as part of a representative monitoring strategy. It includes employees whose exposure was assessed based on other employees who were sampled, and employees whose exposures have been assessed on the basis of objective data. Several commenters, including Ameren and EEI, suggested that notification should only be required where air monitoring has been performed, should not be applicable to employers who choose the performance option for meeting the exposure assessment requirement, and should already be captured by training or a written safety program (*e.g.*, Document ID 2315, p. 3; 2357, p. 23). Newmont Mining Corporation commented that notification for every exposure assessment would be excessive and should only be required when the results change (*e.g.*, exposures above the PEL drop below PEL) (Document ID 1963, p. 4).

OSHA disagrees. Notifying employees of their exposures provides them with knowledge that can permit and encourage them to be more proactive in working to control their own exposures through better and safer work practices and more active participation in safety programs. As OSHA noted with respect to its Hazard Communication Standard: ''Employees provided with information and training on chemical hazards are able to fully participate in the protective measures instituted in their workplaces'' (77 FR 17574, 17579 (3/26/12)). Exposures to respirable crystalline silica below the PEL may still be hazardous, and making employees aware of such exposures may encourage them to take whatever steps they can, as individuals, to reduce their exposures as much as possible. The results of exposure assessment are not specifically required to be communicated to employees under the hazard communication and employee information and training requirements in paragraph (j) of the standard for general industry and maritime (paragraph (i) of the standard for construction) nor as a part of the written exposure control plan required in paragraph (f)(2) of the standard for general industry and maritime (paragraph (g) of the standard for construction). Exposure assessments are likely to be conducted more frequently than training and, given the differences in timing, OSHA concludes that it would not make sense to incorporate them into a written exposure control plan. Thus, it is important to separate the notification of exposure assessment results from other information and training employees are required to receive under the rule.

NAM offered its opinion on what information the notification should provide to employees and urged OSHA to provide flexibility in this area:

> Many employers require that air sampling results be accompanied by statements concerning the relationship of the results to existing standards, practices and procedures required as a result of the exposure levels, and a discussion of any steps the employer is taking in addition to further control exposures. OSHA acknowledges that employees benefit from having information about the exposures and potential control measures, including the use of PPE, to reduce their risk. OSHA should recognize that an assessment may include more than simple analytical results from a laboratory. Therefore, OSHA should propose language to make clear that the employers have this flexibility in communicating the results to employees (Document ID 2380, Attachment 2, p. 32).

The notification requirement specifies what information must be included; however, this does not limit employers from including the types of information described by NAM in the written notification to employees.

The standard also requires employers to either notify each affected employee in writing or post the assessment results in an appropriate location accessible to all affected employees. CPR urged OSHA to strengthen the notification requirements by requiring: Personal notification to workers in writing; notification in a language the employee can understand; and inclusion of information about the silica standard, silica-related disease from an individual or community perspective, and available health care benefits (Document ID 2351, p. 12). The Agency has determined that the notification requirements and the training requirements in the rule adequately address these suggestions. As discussed, the rule requires employers to notify employees, either in writing or by posting in an appropriate location. The training requirements in paragraph (j)(3) of the standard for general industry and maritime (paragraph (i)(2) of the standard for construction) require the employer to ensure that each covered employee can demonstrate knowledge and understanding of the silica standard, tasks that could result in exposure to respirable crystalline silica, the health hazards associated with exposure, specific procedures the employer has implemented to protect employees from exposure, and the medical surveillance provided under the rule. OSHA intends that these requirements will ensure that employees comprehend their exposure to respirable crystalline silica, the potential adverse effects of that exposure, and protective measures that are available. This would include employee understanding of any corrective action the employer is taking to reduce exposures below the PEL that is described in the written notification. The notification requirement, however, does not require that employers provide notification in a language that the employee can understand; as with other information provided to employees (*e.g.*, labels and safety data sheets), training ensures that the information is understood.

In addition, paragraph (d)(6)(ii) of the standard for general industry and maritime (paragraph (d)(2)(vi)(B) of the standard for construction) requires that whenever the PEL has been exceeded, the written notification must contain a description of the corrective action(s) being taken by the employer to reduce employee exposures to or below the PEL. Several commenters raised issues with the requirement to notify employees about corrective actions being taken where exposures are above the PEL. ASA and CISC suggested that in the construction environment, five days is not sufficient time to determine what caused the exposure, to research alternative solutions to limit future exposure, and to decide on the appropriate corrective action (Document ID 2187, p. 5; 2319, p. 87; 3442, pp. 3–4).

Similarly, in the general industry context, Newmont Mining Corporation argued that ''[d]etermination of controls to reduce exposures when exposure assessments exceed the PEL may take more than 15 days'' and suggested that OSHA revise the proposed language to allow employers 60 to 90 days to develop a corrective action plan and explain it to employees (Document ID 1963, p. 4). NAM also noted that the requirement to notify employees of the corrective actions being taken to reduce employee exposures below the PEL does not make sense for situations where it is infeasible to bring the exposure level down to the PEL (Document ID 2380, Attachment 2, p. 32).

OSHA disagrees. In OSHA's view, the requirement to inform employees of the corrective actions the employer is taking to reduce the exposure level to or below the PEL is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required under section 8(c)(3) of the OSH Act (29 U.S.C. 657(c)(3)). OSHA understands that it may take more than 15 days to determine what engineering controls may be appropriate in a particular situation. However, the corrective action described in the written notification is not limited to engineering controls; when the exposure assessment indicates that exposures exceed the PEL, and the employer needs more than 15 days (or, in the case of the standard for construction, 5 days) to identify the engineering controls that will be necessary to limit exposures to the PEL, the employer is required to provide exposed employees with appropriate respiratory protection. In such a situation, respiratory protection is the corrective action that would be described in the written notification. Similarly, respiratory protection is the corrective action that would be described in the written notification in situations where it is infeasible to limit exposures to the PEL.

CEG and Upstate Medical University suggested that exposure assessment results should not only be reported to employees, but also should be reported to OSHA (Document ID 3586, Tr. 3321; 2244, p. 4). OSHA has not included such a requirement in the rule as such information would not be of practical use to the Agency. OSHA does not possess the resources to review and consider all of the material that will be generated by employers assessing employee exposures under the rule. OSHA would not have sufficient context to consider that material even if sufficient resources were available, given that only limited information is included in such assessments. Where such information would be of practical value to OSHA, such as when compliance staff conduct workplace inspections, the Agency is able to review exposure records in accordance with the standard addressing access to exposure and medical records (29 CFR 1910.1020).

Observation of monitoring. Paragraph (d)(7) of the standard for general industry and maritime (paragraph (d)(2)(vii) of the standard for construction) requires the employer to provide affected employees or their designated representatives an opportunity to observe any air monitoring of employee exposure to respirable crystalline silica, whether the employer uses the performance option or the scheduled monitoring option. When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required for any workplace hazard, the employer must provide the observer with that protective clothing or equipment at no cost, and assure that the observer uses such clothing or equipment.

The requirement for employers to provide employees or their representatives the opportunity to observe monitoring is consistent with the OSH Act. Section 8(c)(3) of the OSH Act mandates that regulations developed under section 6 of the Act provide employees or their representatives with the opportunity to observe monitoring or measurements (29 U.S.C. 657(c)(3)). Also, section 6(b)(7) of the OSH Act states that, where appropriate, OSHA standards are to prescribe suitable protective equipment to be used in dealing with hazards (29 U.S.C. 655(b)(7)). The provision for observation of monitoring and protection of the observers is also consistent with OSHA's other substance-specific health standards such as those for cadmium (29 CFR 1910.1027) and methylene chloride (29 CFR 1910.1052).

In his testimony, Shawn Ragle of UAW Local 974, in responding to Rebecca Reindel of AFL–CIO, described the importance of allowing the observation of monitoring:

MS. REINDEL: . . . Mr. Ragle, you mentioned that there's limited air monitoring in your plant. I was wondering, as a safety rep, have you ever been allowed to observe the air monitoring that has been done?

MR. RAGLE: . . . Actually, I've requested to be an observer for air monitoring, and the company has denied me that access. They've chosen to go with the employee that they put the monitor on.

Really, if you're doing your job, how are you going to monitor your monitor to make sure everything is going correctly? I really think that we need to have a little more voice, or at least some validation that the monitoring is being done correctly.

We shouldn't put that on the employee wearing the monitor (Document ID 3582, Tr. 1895–1896).

Similarly, James Schultz, a former foundry employee from the Wisconsin Coalition for Occupational Safety and Health, testified that he was,

. . . heartened to see that the proposal mandates that the employer provide protective clothing and equipment at no cost to the observers that are doing the observation and the monitoring of the hazards in the workplace (Document ID 3586, Tr. 3200).

Opposing this requirement, CISC and Hunt Construction Group argued that the provision was unnecessary given that the observer will not be close enough to the silica-generated tasks to pose a risk (Document ID 2319, pp. 87–88; 3442, pp. 4–5). ASA expressed concern about the unnecessary cost of providing protective clothing to an observer (Document ID 2187, p. 5). Similarly, AGCM argued that requiring the employer to provide personal protective equipment and training is an unnecessary additional cost and requirement (Document ID 2265, Attachment 1, p. 2).

Commenters, including the Korte Company and ASA, were also concerned that this requirement burdened the employer with providing the employee's representative with protective clothing or equipment whether or not the representative is trained or qualified to be wearing the required PPE (*e.g.*, medical evaluation or fit test to wear a respirator) (*e.g.*, Document ID 3230, p. 1; 2187, p. 5). Commenters, including NTCA and TCNA, asked OSHA to state that it is the responsibility of the employer of the employee's representative to provide the necessary respirator and ensure that the employee's representative is medically cleared, appropriately trained, and fit tested if a respirator is needed to observe the monitoring (*e.g.*, Document ID 2267, p. 5; 2363, p. 5). NAHB argued that this provision is ''neither reasonable nor prudent'' as it ''needlessly impos[es] liability on covered employers by requiring them to assume responsibility for an 'observer' who may come onto a jobsite where silica may be present'' (Document ID 2296, p. 25). AGCM argued that the observer's employer is already required to provide the necessary personal protective equipment and training, not the employer being observed (Document ID 2265, Attachment 1, p. 2).

Section 8(c)(3) of the OSH Act states that occupational safety and health standards which require employers to monitor or measure employee exposure to potentially toxic materials ''shall provide employees or their representatives with an opportunity to observe such monitoring or measuring.'' Provisions requiring employers to provide affected employees or their designated representatives an opportunity to observe any monitoring, as well as protective clothing or equipment where it is required, appear in 15 substance-specific health standards. Two substance-specific health standards (1,3-butadiene and methylene chloride) require employers to ''provide the observer with protective clothing or equipment at no cost'' (§ 1910.1051(d)(8)(ii) and § 1910.1052(d)(6)(ii)), as does this rule for respirable crystalline silica.

OSHA's policy conclusion is that employers conducting monitoring must bear the cost of complying with the standard's provisions for observer protections, even if the observer is not an employee of the employer. First, the Agency concludes that it would be an extremely rare occurrence for an observer to be unfamiliar with the use of the types of protective clothing or equipment that would be necessary for observation. In OSHA's experience, observers, whether they are another employee or a designated representative, typically have knowledge and experience such that they would already be medically cleared to use appropriate respiratory protection and may even have access to an appropriate respirator. Thus, OSHA expects the employer conducting the monitoring in these situations to communicate with the observer about what hazards are present in the workplace and what protective clothing and equipment, including medical clearances, are needed to observe the monitoring at their establishment. OSHA also expects the employer to assess whether the observer already has the necessary equipment and training to observe the monitoring. In situations where the necessary equipment is not already available to the observer, OSHA considers it to be the employer's responsibility to provide the protective clothing and equipment, as well as other training, clearance, or evaluation needed to ensure that the observer uses such clothing and equipment.

Second, OSHA recognizes that, in some situations, observers may not need to enter an area requiring the use of protective clothing or equipment in order to effectively observe monitoring. In those cases, no protective clothing or equipment is needed by the observer and OSHA would not expect or require the employer to provide such observer with any protective clothing or equipment. Some possible options to avoid exposing the observer to hazards that require the use of protective clothing or equipment include conducting the set-up for the monitoring outside of hazardous areas and ensuring that the observer can view the monitoring while remaining outside of the hazardous areas or, where exposure to respirable crystalline silica is the only hazard requiring the use of protective clothing or equipment, conducting the set-up for monitoring before the exposure-generating task is performed and ensuring that the observer can view the monitoring while remaining outside of the area of exposure.

Third, OSHA finds that employers conducting monitoring are in the best position to understand the hazards present at the workplace, including the protective clothing and equipment needed to protect against those hazards and the training, clearance, or evaluation needed to ensure that the observer is protected from those hazards. OSHA concludes that employers' familiarity with the worksite, the work, and their employees puts them in the best position to conduct exposure monitoring in a timely, effective, and safe manner. Therefore, OSHA appropriately requires the employer to bear the responsibility for ensuring that any observer in his or her establishment is adequately protected.

OSHA thus decided that employers conducting monitoring are responsible for the full costs of protecting observers, by providing the necessary equipment as well as any training, clearance, or evaluation needed to properly use the equipment, regardless of whether the observers are employees or designated representatives.

The requirements for exposure assessment in the rule are consistent with ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for

Construction and Demolition Activities, the national consensus standards for controlling occupational exposure to respirable crystalline silica in general industry and in construction, respectively. Each of these voluntary standards has explicit requirements for exposure assessment. For general industry, the ASTM standard includes requirements for: Initial sampling; periodic sampling; sampling and analytical methods; observation of monitoring; and notification of assessment results. Similarly, for construction, the ASTM standard includes requirements for: Initial sampling; reassessment of exposures when changes have the potential to result in new or additional exposures; sampling and analytical methods; and notification of assessment results. It also notes the challenges of monitoring in a dynamic construction environment and suggests that employers may also use a combination of historical data, objective data, or site-specific employee exposure monitoring to assess exposures.

While OSHA's standard for respirable crystalline silica includes these elements, it includes a performance-oriented approach to exposure assessment that best reflects the realities of assessing exposures to respirable crystalline silica. The standard also includes a scheduled approach, which provides specific requirements for initial and periodic monitoring, for industries and tasks that can utilize such an option. Including both of these options maximizes the flexibility for employers to meet their exposure assessment obligations, and in doing so, better effectuates the purposes of the OSH Act and protects employees from exposures to respirable crystalline silica. OSHA thus concludes that the exposure assessment provision in the rule achieves the important purpose of assessing employee exposure, while providing sufficient flexibility for employers.

Regulated Areas

Paragraph (e) of the standard for general industry and maritime sets forth the requirements for regulated areas. In paragraph (e)(1), employers are required to establish regulated areas wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the permissible exposure limit (PEL). In paragraph (e)(2) and (e)(3), employers must demarcate regulated areas, and limit access to regulated areas to persons authorized by the employer and required by work duties to be present in the regulated area, persons observing exposure monitoring, or any person authorized by the Occupational Safety and Health (OSH) Act or regulations issued under it to be in a regulated area. Finally, paragraph (e)(4) requires employers to provide each employee and the employee's designated representative entering a regulated area with an appropriate respirator and require its use while in the regulated area.

The requirements for regulated areas serve several important purposes. First, requiring employers to establish and demarcate regulated areas ensures that the employer makes employees aware of the presence of respirable crystalline silica at levels above the PEL. Second, the demarcation of regulated areas must include warning signs describing the dangers of respirable crystalline silica exposure in accordance with paragraph (j) of the standard for general industry and maritime, which provides notice to employees entering or nearing regulated areas of the posted dangers. Third, limiting access to regulated areas restricts the number of people potentially exposed to respirable crystalline silica at levels above the PEL and ensures that those who must be exposed are properly protected, thereby limiting the serious health effects associated with such exposure.

The proposed requirements for regulated areas were included in paragraph (e) of both the proposed standard for general industry and maritime and the proposed standard for construction. Under proposed paragraph (e)(1), employers would have been required to establish and implement either a regulated area or an access control plan wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or reasonably could be expected to be, in excess of the PEL. The substantive requirements for the regulated area option were contained in proposed paragraph (e)(2) and those for access control plans were in proposed paragraph (e)(3). In the standard for general industry and maritime, OSHA has retained the requirement for employers to establish and implement regulated areas. However, the Agency has decided against requiring regulated areas in the standard for construction; an alternate provision has been included as a component of the written exposure control plan requirements for construction.

OSHA has concluded that requirements for regulated areas are appropriate for general industry and maritime, but not for construction, because the worksites and conditions and other factors, such as environmental variability normally present in the construction industry, differ substantially from those typically found in general industry. Commenters, including the National Council of La Raza, the National Institute for Occupational Safety and Health (NIOSH), the Associated General Contractors of America, the Small Business Administration's Office of Advocacy, and the Building and Construction Trades Department, AFL–CIO (BCTD), noted some of the differences between construction and general industry worksites, including that general industry establishments are typically more stable, are likely to be indoors, and are usually at a fixed location (*e.g.*, Document ID 2166, p. 3; 2177, Attachment B, p. 7; 2323, p. 1; 2349, pp. 5–6; 2371, Attachment 1, p. 42). OSHA finds that these factors make establishing regulated areas generally suitable in general industry and maritime workplace settings, and their absence in construction settings makes a regulated areas requirement generally unworkable.

Some commenters, particularly those representing unions in general industry, supported the idea of regulated areas wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or reasonably could be expected to be, in excess of the PEL (*e.g.*, Document ID 2282, Attachment 3, p. 2; 2315, p. 3; 2318, p. 10). For example, the International Brotherhood of Teamsters stated that ancillary provisions, such as regulated areas, would reduce the risk beyond the reduction that will be achieved by a new PEL alone (Document ID 2318, p. 10). Similarly, the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) expressed concerns that workers would not receive adequate protection if OSHA did not adopt a requirement for regulated areas in general industry (Document ID 2282, Attachment 3, pp. 2, 16). The United Steelworkers said that OSHA's proposed general industry and maritime standard should be revised to require employers to establish regulated areas where processes exceed the proposed PEL for respirable crystalline silica (Document ID 2336, p. 5).

Other general industry stakeholders argued that establishing regulated areas would be unworkable and infeasible, particularly in foundries (Document ID 1992, p. 10; 2149, p. 2; 2248, p. 7; 2349, p. 5; 2379, Attachment B, pp. 30–31; 3584, Tr. 2669) and in certain other sectors of general industry (Document ID 1785, p. 6; 2337, p. 1; 2348, p. 36; 2380, Attachment 2, pp. 32–33). Some of these commenters focused on how an employer would be able to determine

which parts of the facility should be designated as regulated areas. For example, the American Foundry Society (AFS) indicated that defining a regulated area would be difficult because the standard is based on employee 8-hour time weighted average (TWA) exposures, not on specific geographic areas (Document ID 2379, Attachment B, pp. 30–31). AFS explained that ''[i]f the standard allowed real time monitoring and exposure mapping as an alternative to 8 hr. TWA sampling, one might be able to construct a basis for defining regulated areas'' (Document ID 2379, Attachment B, pp. 30–31). AFS offered a specific example to illustrate its concern:

> . . . a maintenance worker who has an exposure above the PEL may work in many areas of the plant including the office. It does not make sense to turn the office into a regulated area because the maintenance worker spent some time there on the day of sampling (Document ID 2379, Attachment B, pp. 30–31; 3487, p. 21).

The scenario described by AFS is not consistent with the definition of the term ''regulated area'' that OSHA proposed nor that of the final standard. Paragraph (b) of the proposed and final standard for general industry and maritime defines regulated area to mean ''an area, demarcated by the employer where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.'' This definition makes clear that a regulated area is defined by employee exposure, not by which employee(s) might be in it. In other words, just because a particular employee's exposure assessment results indicate that the employee's exposure is above the PEL, that does not mean that employee exposure in every area that the employee visited on the day he or she was sampled exceeds, or can reasonably be expected to exceed, the PEL.

In the scenario posed by AFS, the employer would be required by paragraph (d)(1) of the standard for general industry and maritime to assess the exposure of each employee who is, or may reasonably be expected to be, exposed to respirable crystalline silica at or above the action level in accordance with either the performance option (*i.e.*, use of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposure) or the scheduled monitoring option (*i.e.*, one or more personal breathing zone air samples). As explained in the summary and explanation of *Exposure Assessment*, if real time monitoring and exposure mapping, the methods suggested by AFS, allow an employer to accurately characterize employee exposures, then the employer would be allowed to use such methods to assess employee exposures under the performance option. This exposure information would also be helpful in determining where higher exposures may be occurring.

If an employee's exposure is above the PEL, paragraph (f)(1) of the standard for general industry and maritime would require the employer to use engineering and work practices to reduce and maintain employee exposure to respirable crystalline silica. In order to control exposures, the employer would need to determine where the exposures are generated. As explained by Dr. Franklin Mirer, Professor of Environmental and Occupational Health at CUNY School of Public Health, during his testimony on behalf of the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), setting up a regulated area in a foundry is not complicated—employers must simply determine the extent of the dust cloud, possibly using measures like short-term or real-time monitoring or exposure mapping (Document ID 3578, Tr. 1003–1005).

Dr. William Bunn, who testified on behalf of the U.S. Chamber of Commerce, also offered testimony that suggests that some foundries are capable of establishing regulated areas. In response to questioning during the public hearings, Dr. Bunn spoke about the efficacy of OSHA inspections for aiding foundries in reducing silica exposures. Based on his experience as an employee of Navistar International and as a consultant to multiple automotive engine foundries, Dr. Bunn stated that there was no feasible way to attain compliance with the proposed PEL without using respiratory protection. However, Dr. Bunn emphasized that this occurred at certain specific, restricted areas that could be easily observed (Document ID 3576, Tr. 473). OSHA concludes from this testimony that where exposures above the PEL occur in foundries, they typically occur in limited areas that can be readily identified, and the provisions for establishment, demarcation, access restriction, and provision of respirators can be applied.

Edison Electric Institute stated that, given requirements for establishing regulated areas in other OSHA substance-specific standards, OSHA should consider creating uniform provisions for regulated areas, to minimize the complications that arise when multiple regulated substances begin to ''stack'' in one regulated area (Document ID 2357, pp. 32–33). OSHA recognizes that standards for asbestos, benzene, cadmium, chromium (VI), 13 carcinogens, methylenedianiline, and others also contain requirements for regulated areas; however, these requirements are not in conflict with one another. Where an employer establishes a regulated area for multiple substances, the employer can and must comply with the requirements for each applicable standard for that regulated area. Persons allowed access to the regulated area include employees who are performing tasks required by work duties subject to the regulated area requirements of another standard even if that exposure (*e.g.*, to asbestos) is unrelated to tasks that generate silica exposures. But this would be a very uncommon scenario—for the most part, multiple standards apply when exposures to multiple hazardous substances result from a single source, *e.g.*, fly ash in electric utilities contains lead, chromium (VI), silica, etc.

Other general industry commenters felt that regulated areas were unnecessary. For example, Morgan Advanced Materials asserted that regulated areas or access control programs may be appropriate for areas where the conditions may cause an immediate health effect or injury, but are not appropriate for chronic hazards like respirable crystalline silica, especially since ''. . . nearly everyone is exposed to some level of crystalline silica on a daily basis'' (Document ID 2337, pp. 1–2). OSHA rejects Morgan Advanced Materials' position because, unlike ''everyone'' who is exposed to background levels, employees who are exposed to respirable crystalline silica at levels exceeding the revised PEL are at significant risk of developing silica-related disease; this risk cannot be ignored simply because silica exposure does not cause an immediate death or injury. Regulated areas are an effective means of limiting the risk associated with respirable crystalline silica exposure, and are therefore appropriate for protecting employees.

Paragraph (e)(2) of the standard for general industry and maritime includes requirements for demarcation of regulated areas. The proposed provision on demarcation would have required employers to demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts employees to the boundary of the regulated area. The proposed provision also stipulated that the demarcation minimize the number of employees exposed to respirable crystalline silica within regulated areas. In the proposed

rule, OSHA did not specify how employers were to demarcate regulated areas. In the standard for general industry and maritime, because the Agency has adopted requirements for posting signs, OSHA has removed the language ''in any manner that adequately establishes and alerts employees to the boundary of the regulated area.''

A number of stakeholders submitted comments on the proposed provision. For example, the AFL–CIO argued that other health standards that regulate carcinogens require warning signs at regulated areas, and that OSHA provided no justification for departing from this precedent (Document ID 4204, pp. 56–57). Many other stakeholders were supportive of warning sign requirements and submitted specific language for inclusion on signs that demarcate regulated areas (Document ID 2163, Attachment 1, p. 15; 2178, pp. 2–3; 2282, Attachment 3, p. 25; 2310, Attachment 2, p. 1; 2371, Attachment 1, p. 36; 2373, p. 2; 3582, Tr. 1920–1921; 4030, Attachment 1, p. 3; 4030, Exhibit D; 4073, Exhibit 15b, p. 18). For example, BCTD and the International Union of Operating Engineers encouraged OSHA to review the discussion of regulated areas in Ontario's Guideline on Silica Construction Projects with respect to ropes and barriers (Document ID 4073, Attachment 15b; 4234, Attachment 2, p. 57). Ontario's Guideline states that:

> Ropes or barriers do not prevent the release of contaminated dust or other contaminants into the environment. However, they can be used to restrict access of workers who are not adequately protected with proper PPE, and also prevent the entry of workers not directly involved in the operation. Ropes or barriers should be placed at a distance far enough from the operation that allows the silica-containing dust to settle. If this is not achievable, warning signs should be posted at the distance where the silica-containing dust settles to warn that access is restricted to persons wearing PPE (Document ID 4073, Ex.15 b).

Others identified particular topics that should be covered by the signs without proposing language. For example, Upstate Medical University argued that all regulated areas should have warning signs addressing the hazards of silica dust (Document ID 2244, p. 4).

As is further explained in the summary and explanation of *Communication of Respirable Crystalline Silica Hazards to Employees*, OSHA agrees with these commenters with respect to the requirement for warning signs at entrances to regulated areas. Employees must recognize when they are entering a regulated area, and understand the hazards associated with the area, as well as the need for respiratory protection. Signs are an effective means of accomplishing these objectives. Therefore, OSHA has included a requirement that employers are obligated to post all entrances to regulated areas with signs that bear the following legend:

DANGER
RESPIRABLE CRYSTALLINE SILICA
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

The rulemaking record also indicates that use of signs is also consistent with general industry practices. For example, a plan developed by the National Service, Transmission, Exploration, and Production Safety Network (STEPS Network) for the hydraulic fracturing industry recommends signs to warn of potential silica exposure and the requirement for respirator use near exposure zones (Document ID 4024, Attachment 1, p. 1; Attachment 2, p. 1).

The Unified Abrasives Manufacturers Association argued that demarcation of regulated areas would require the construction of a complete physical separation between the regulated area and adjacent areas (Document ID 3398, p. 1). Aside from the requirement of specific language for posting signs, however, the standard does not specify the method of demarcation; cones, stanchions, tape, barricades, lines, or textured flooring may each be effective means of demarcating the boundaries of regulated areas. As in the proposed rule, therefore, so long as the demarcation is accomplished in a manner that minimizes the number of employees exposed to respirable crystalline silica within the regulated area, the employer will be in compliance, without necessarily installing a complete physical separation in the workplace.

Factors that OSHA considers to be appropriate considerations for employers when they are determining how to demarcate regulated areas include the configuration of the area, whether the regulated area is permanent, the airborne respirable crystalline silica concentration, the number of employees in adjacent areas, and the period of time the area is expected to have exposure levels above the PEL. Permitting employers to choose how best to demarcate regulated areas is consistent with OSHA's use of performance-based approaches where the Agency has determined that employers, based on their knowledge of the specific conditions of their workplaces, are in the best position to make such determinations.

The flexibility of this provision aims to address some of the concerns identified by commenters. For example, National Electrical Carbon Products commented that:

> The concept seems to be that there are hazardous areas where access must be restricted. In reality: there are hazardous exposures, where exposures must be controlled . . . Exposure to airborne crystalline silica, on the other hand, is most typically associated with intermittent activities that are not necessarily associated with a location (Document ID 1785, p. 6).

OSHA understands that for certain work processes, exposure may indeed be associated with an intermittent activity rather than a fixed location. In such cases where silica-generating activities are conducted only sporadically, employers may elect to demarcate a regulated area by means of movable stanchions, portable cones, barricade tape, and the like, as long as the required warning sign with prescribed hazard language is posted at all entrances to each regulated area. Similarly, in a case where work activity migrates to different areas of a worksite, these movable forms of demarcation could likewise be repositioned to indicate the regulated area as work progresses. This flexibility should also help employers with open-design facilities establish regulated areas when needed.

A few commenters expressed concern that provisions for demarcation of regulated areas may interfere with heat stress programs currently in place as well as the current sanitation standard in general industry (29 CFR 1910.141) (Document ID 2379, Appendix 1, p. 59; 3577, Tr. 751–752; 3586, Tr. 3370). The AFS stated that:

> Foundries often have areas with high heat exposures and encourage workers to drink water. The proposal [is] not clear on hygiene rules for regulated areas. The final rule must not be drafted in a way that could be interpreted to ban drinking water in a regulated area (Document ID 2379, Appendix 1, p. 59).

OSHA's standards addressing sanitation in general industry and maritime with respect to consumption of food and beverages are unchanged by this rulemaking. The standards in paragraphs 29 CFR 1910.141(g)(2) and 1917.127(c) prohibit consumption of food or beverage in any area exposed to a toxic material. OSHA appreciates the importance of providing access to drinking water, particularly in hot work environments, and recognizes that in many cases employees will need access to drinking water in order to remain

hydrated. However, as explained in more detail below, paragraph (e)(4) of the standard for general industry and maritime requires all employees within the demarcated boundaries of a regulated area to wear a respirator continually while in the area, and thereby the consumption of water within boundaries of a regulated area is not feasible. An employee will need to leave the regulated area temporarily to access water and food, in accordance with OSHA's sanitation standards.

Paragraph (e)(3) of the standard for general industry and maritime requires employers to limit access to regulated areas. As in the proposed rule, employers are required to limit access to: (A) Persons authorized by the employer and required by work duties to be present in the regulated area; (B) any person entering such an area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring procedures under paragraph (d) of this section; and (C) any person authorized by the OSH Act or regulations issued under it to be in a regulated area.

The first group, persons the employer authorizes or requires to be in a regulated area to perform work duties, includes employees and other persons whose jobs involve operating machinery, equipment, and processes located in regulated areas; performing maintenance and repair tasks on machinery, equipment, and processes in those areas; conducting inspections or quality control tasks; and supervising those who work in regulated areas. Persons allowed access to the regulated area include employees who are performing tasks required by work duties subject to the regulated area requirements of another standard even if that exposure is unrelated to tasks that generate silica exposures.

The second group is made up of persons entering a regulated area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring under paragraph (d) of the standard for general industry and maritime. As explained in the summary and explanation of *Exposure Assessment*, providing employees and their representatives with the opportunity to observe monitoring is consistent with the OSH Act and OSHA's other substance-specific health standards, such as those for cadmium (29 CFR 1910.1027) and methylene chloride (29 CFR 1910.1052).

The third group consists of persons authorized by law to be in a regulated area. This category includes persons authorized to enter regulated areas by the OSH Act, OSHA regulations, or any other applicable law. OSHA compliance officers fall into this group.

Some commenters expressed concerns about restricting access to regulated areas. For example, OSCO Industries argued that control of ingress and egress from regulated areas would be very problematic because of high traffic volumes, indicating, for example, that it may be necessary to reroute pedestrian and fork truck traffic outside the building in order to avoid the regulated area (Document ID 1992, p. 10). Similarly, a representative of the Non-Ferrous Founders' Society (NFFS) testified that smaller foundries would experience difficulty in establishing and restricting access to regulated areas (Document ID 3584, Tr. 2814).

Other commenters indicated that restricted areas were already in place at their workplaces. For example, Kenny Jordan, Executive Director of the Association of Energy Service Companies, testified that restricted areas with limited access are already used in hydraulic fracturing operations (Document ID 3589, Tr. 4066–4067). Mr. Jordan went on to describe how the presence of these restricted areas is communicated to other employees on the multiemployer worksite (Document ID 3589, Tr. 4079–4080).

OSHA finds that requirements for establishing and limiting access to regulated areas are reasonable and generally feasible for general industry and maritime workplaces. With regard to the concerns expressed by OSCO Industries about rerouting traffic to avoid regulated areas, the intent of the standard is to restrict unnecessary pedestrian and vehicle traffic in areas where exposures exceed the PEL; employees who would otherwise be exposed when traversing the regulated area will thus be better protected. Where work duties require these employees to enter the regulated area, the standard provides for access, with appropriate respiratory protection. OSHA also considers that the exposure assessment performed in accordance with paragraph (d) of the standard for general industry and maritime will provide a basis for establishing the boundaries of the regulated area, and thus establishment of regulated areas will not be as problematic as NFFS suggests.

Paragraph (e)(4) of the standard for general industry and maritime requires employers to provide each employee and the employee's designated representative entering a regulated area with an appropriate respirator in accordance with paragraph (g) of the standard. The provision also mandates that employers require each employee or employee representative to use the respirator while in the regulated area. The provision in the standard requiring use of respirators in regulated areas is identical to the proposed provision. The boundary of the regulated area indicates where respirators must be donned prior to entering, and where respirators can be doffed, or removed, upon exiting the regulated area. This provision was intended to establish a clear and consistent requirement for respirator use for all employees who enter a regulated area, regardless of the duration of their presence in the regulated area.

OSHA received comments from stakeholders in both construction and general industry, generally opposing this requirement (*e.g.*, Document ID 1785, p. 7; 2267, p. 5; 2291, p. 25; 2296, p. 26; 2319, p. 90; 2348, p. 36; 2363, p. 5; 2380, Attachment 2, pp. 32–33; 3577, Tr. 752; 3586, Tr. 3408–3417). For example, the National Association of Home Builders (NAHB) stated that the proposed requirements were overly restrictive because respiratory protection would be required even when risks are low, such as when an employee was in a regulated area for a very short period of time (Document ID 2296, p. 30). Several commenters representing general industry entities also expressed similar concerns with respect to increases in respirator usage (*e.g.*, Document ID 1785, p. 7; 2291, p. 25; 2337, p. 1; 2348, p. 36; 2380, Attachment 2, pp. 32–33; 4229, p. 25). The Asphalt Roofing Manufacturers Association (ARMA) indicated that the proposed requirement for respirator use would place a significant and unnecessary burden on ARMA member companies (Document ID 2291, p. 25). The National Association of Manufacturers (NAM) recommended that OSHA should limit requirements for respirator use to situations where entry into the regulated area will be of such frequency and duration as to constitute a hazard (Document ID 2380, Attachment 2, pp. 32–33). National Electrical Carbon Products also expressed concerns about the requirements for respirators in regulated areas, and encouraged the adoption of a time specification. They argued that the proposed requirement was inconsistent with the concept of the 8-hour TWA PEL (Document ID 1785, p. 7).

After reviewing these comments, OSHA has decided to retain the requirement for employers to provide and require the use of respirators in regulated areas in the standard for general industry and maritime. Although OSHA recognizes that some employees entering regulated areas may not be exposed above the PEL (expressed as an 8-hour TWA), many

employees who are assigned to work in these areas may remain in these locations for long enough periods of time so that they would be needlessly overexposed to respirable crystalline silica if they did not wear respirators. Furthermore, OSHA finds that allowing some employees to work in regulated areas without respiratory protection, while requiring it for others, would create confusion and compliance difficulties in the workplace. To the extent that some employees in regulated areas who may not be exposed on a particular day above the PEL are nonetheless required to wear respirators, this time-limited use of respirators should further reduce the significant risk that remains at the PEL.

In the proposed rule, OSHA also included a provision related to protective work clothing. Proposed paragraph (e)(2)(v)(A) would have required employers to either provide protective clothing or provide other means of removing excessive silica dust from contaminated clothing. Under proposed paragraph (e)(2)(v)(B), employers would have been required to ensure that clothing was removed or cleaned upon exiting a regulated area when there was potential for employees' clothing to become ''grossly contaminated'' by fine particles of crystalline silica that could become airborne and inhaled. The purpose was not to protect employees from dermal exposure to silica, but rather to protect the employee from those situations wherein contamination of clothing has the potential to contribute significantly to employee inhalation of respirable crystalline silica.

The proposed provision for protective clothing was more limited than similar provisions in other OSHA substance-specific standards. As noted in the preamble of the Notice of Proposed Rulemaking OSHA limited the proposed provision for protective clothing to regulated areas because dermal exposure to crystalline silica is not associated with adverse health effects. Nonetheless, OSHA solicited information from stakeholders regarding protective clothing for respirable crystalline silica, largely because a provision for protective clothing had been recommended by the Agency's Advisory Committee on Construction Safety and Health.

Several employees in silica-exposed industries described the extent of contamination to their clothing by silica dust and how this dust would even be brought home with them (Document ID 3571, Attachment 7, p. 1; 3581, Tr. 1595, 1599–1600; 3582, Tr. 1840). OSHA heard testimony from Dan Smith, Director of Training for the Bay Area Roofers and Waterproofers Training Center in Livermore, California and member of the National Curriculum Development Committee of the United Union of Roofers, Waterproofers and Allied Workers, which represents roughly 25,000 workers. Mr. Smith said:

> Some years back, one of my members walked into my office with a very unusual object: a plumbing trap. [He] handed it to me. First thing I noticed, it was pretty heavy, two to three pounds. He said, 'That's from my shower at home.' At the time, he had been in the tile industry, cutting tile for about 10 years. He said, 'My drain kept getting clogged. No matter what I put in there, I couldn't get it unclogged. I called the plumber. He couldn't get it unclogged. He took it off. I looked inside. It was filled with . . . what I would call reconstituted cement.' This came off of his body (Document ID 3581, Tr. 1599–1600).

UAW Local 523 President Jeff P'Poole spoke about making silicon metal out of granite with an electric arc furnace reduction process, ''. . . people come out with like raccoon eyes . . . you'll look like a coal miner at times . . .'' (Document ID 3582; Tr. 1840). Construction employee Santiago Hernandez testified that employees often have to throw away their work clothing because dust remains embedded even after washing the clothes (Document ID 3571, Attachment 7, p. 1).

OSHA received comments supporting a requirement for employer provision of work clothing, or storage, handling, removal and cleaning responsibilities for contaminated work clothing (Document ID 2212, p. 2; 2256, Attachment 2, p. 11; 2277, p. 4; 2310, Attachment 1, pp. 2–4; 2315, p. 9; 3586, Tr. 3199–3200). For example, the International Safety Equipment Association requested that OSHA require employers to provide protective garments at no cost to the employee, indicating that this would be consistent with other OSHA standards that require employers to pay for personal protective equipment (Document ID 2212, p. 2).

However, numerous comments received on the provision for protective work clothing in regulated areas were opposed to OSHA's proposed requirement for employers to either provide protective clothing or other means of removing excessive silica dust from contaminated clothing, and to ensure that clothing is removed or cleaned upon exiting a regulated area when there is potential for employees' clothing to become grossly contaminated by silica dust (Document ID 1785, p. 8; 2116, Attachment 1, p. 11; 2187, p. 6; 2195, p. 7; 2296, p. 40; 2319, pp. 90–91; 2337, p. 2; 2339, p. 8; 2357, pp. 29–30; 2363, p. 6; 3577, Tr. 713–714; 3580, Tr. 1376–1377; 3584, Tr. 2669; 4035, p. 9). Many contended that the language in the provision was vague or subjective. For example, the Tile Council of North America, the National Tile Contractors Association, and Morgan Advanced Materials argued that the term ''*grossly*'' is subjective, and its use in this context would subject the employer to the whim of the compliance inspector (Document ID 2267, p. 6; 2363, p. 6; 2337, p. 2).

The American Society of Safety Engineers (ASSE) indicated that no special clothing should be required, as crystalline silica does not present a hazard from skin contact. Instead, ASSE suggested that employers need to implement programs to assure employees whose clothing is contaminated with crystalline silica do not create exposure issues outside of the workplace (Document ID 2339, p. 8). NAHB argued that protective clothing such as coveralls would be difficult for workers in residential construction to use because coveralls frequently restrict movement, are often not durable enough for the conditions encountered in construction, and could contribute to heat stress (Document ID 2296, p. 40).

The evidence regarding the extent to which dust-contaminated clothing may exacerbate employee exposure to respirable crystalline silica is mixed. NIOSH stated that past studies have shown a significant increase in workers' respirable dust exposure from contaminated work clothing, referencing a Bureau of Mines study involving highly-exposed machine operators bagging mineral products into paper bags (Document ID 2177, Attachment B, p. 15). On the other hand, the National Industrial Sand Association (NISA) stated that:

> NISA member companies have years of experience conducting root cause analyses of exceedances of the PEL. In that experience, contaminated work clothing can be the source of such an exceedance, but such circumstances are uncommon (Document ID 2195, p. 37).

OSHA agrees that contaminated work clothing can contribute to respirable dust exposures in some circumstances, as NIOSH indicated. However, OSHA concludes that the evidence in the rulemaking record does not show that contaminated work clothing contributes appreciably to employee exposures to respirable crystalline silica in workplace conditions covered by this rule. OSHA is therefore not including a requirement for protective clothing in the rule because it is unable to determine that the use of protective clothing would

provide appreciable protection from inhalation of respirable crystalline silica in most circumstances. OSHA understands that many of the activities covered under the rule involve generation of substantial amounts of dust. However, the dust of concern in this rulemaking is composed only of respirable crystalline silica particles—those particles small enough to penetrate deep into the lungs. OSHA proposed protective clothing requirements in regulated areas in an attempt to focus on those areas in the workplace where high exposures to respirable crystalline silica occur. However, it is not clear that measures to address dust on employees' clothing are likely to have any meaningful effect on exposures to respirable crystalline silica in most workplaces covered by the rule.

Protective clothing is primarily designed to mitigate against dermal hazards, which are not the problem here; nor is dermal exposure (as opposed to respiratory exposure) the mechanism by which silica causes its adverse health effects. Therefore, special or employer-provided protective clothing would be no more protective than ordinary clothing in this context. Moreover, OSHA understands the practical difficulty that employers would encounter in attempting to determine when clothing is sufficiently contaminated to trigger a requirement for protective measures. Therefore, OSHA has not included a requirement for employers to provide protective work clothing or other means of removing silica dust from clothing in the rule. There may be instances where providing protective clothing or other means of removing excessive silica dust from clothing are feasible methods of limiting employee exposures to respirable crystalline silica; in such cases, these methods become an option for complying with the requirement to limit employee exposures to the PEL.

OSHA has also decided not to include the proposed option to establish and implement an access control plan in lieu of a regulated area in the rule. As noted above, paragraph (e)(1) of the proposed standards for general industry/maritime and construction would have required the establishment and implementation of either a regulated area or an access control plan wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or reasonably could be expected to be, in excess of the PEL. OSHA recognized that establishing regulated areas in some workplaces might be difficult. As such, the Agency proposed an option for establishing and implementing a written access control plan in lieu of a regulated area.

The option for a written access control plan contained provisions for: A competent person to identify the presence and location of areas where respirable crystalline silica exposures exceed the PEL; notifying employees and demarcating such areas; communicating with other employers on multi-employer worksites; limiting access to areas where exposures exceed the PEL; providing respirators; and addressing measures regarding contaminated work clothing. The proposed rule also included a requirement for an annual employer review and evaluation of the written access control plan, and the plan was to be made available upon request for examination and copying to employees, their representatives, and the Assistant Secretary and the Director.

The intent of the provision for establishing written access control plans in lieu of regulated areas was to provide employers with flexibility to adapt to the particular circumstances of their worksites while maintaining equivalent protection for employees. The option for establishing a written access control plan was thought to be best suited for changing or mobile worksites such as those found in construction and utilities.

The North American Insulation Manufacturers Association supported the option for a written access control plan, claiming that it is similar to current mineral wool industry practices for limiting access (Document ID 2348, p. 36). The National Concrete Masonry Association and approximately five of its member companies stated that access control plans may be effective for tasks in which personal protective equipment is needed (*e.g.*, mixer cleaning), but not for operations that cannot be performed in a controlled, limited areas (*e.g.*, general plant clean-up) (*e.g.*, Document ID 2279, p. 10; 2388, p. 9).

Commenters including American Subcontractors Association (ASA), Leading Builders of America (LBA), NAHB, and the Construction Industry Safety Coalition (CISC), thought that a written access control plan was impractical in the construction industry, stating reasons such as uncertainty about its requirements or how such plans would differ from a regulated area (*e.g.*, Document ID 2187, p. 5; 2269, p. 22; 2296, pp. 25–26; 2319, pp. 88–89). Additionally, the Communication Workers of America (CWA), UAW, and AFL–CIO felt that, given issues of enforceability, it did not appear the written access control plan would adequately protect workers and limit access to high-exposure work areas. Thus, CWA, UAW, and AFL–CIO recommended elimination of the option for a written access plan, and for the provision to be limited to a regulated areas requirement only (Document ID 2240, p. 2; 2282, Attachment 3, p. 16; 3578, Tr. 924–925). Fann Contracting, Inc. indicated that neither written access control plans nor regulated areas were conducive to outdoor, heavy highway and road and bridge construction where the entire worksite has potential for silica exposure (Document ID 2116, Attachment 1, pp. 26–27).

OSHA concludes that the option for a written access control plan may prove less protective and would be difficult to enforce, so has decided not to include the option for employers to develop and maintain written access control plans in lieu of regulated areas in the rule. OSHA no longer views a written access control plan to be a viable substitute for establishment and maintenance of regulated areas in the rule, especially in light of its decision not to include a regulated areas requirement in the standard for construction. The requirement for a competent person in paragraph (g)(4) of the standard for construction provides an alternate approach to restricting access to areas where high exposures can occur, and OSHA's expectation is that it will achieve a comparable level of protection without imposing the burden of maintaining a written access control plan.

The decision not to require regulated areas in the standard for construction reflects OSHA's acknowledgment of the impracticality of establishing and demarcating regulated areas in many construction industry workplaces. However, as described in further detail in the summary and explanation of *Written Exposure Control Plan,* OSHA has concluded that implementing a written exposure control plan, which includes a requirement to describe procedures to restrict access to work areas, is practical in construction industry workplaces. OSHA notes that a written access control plan as contemplated in the proposed rule is different from a written exposure control plan as mandated in the rule. Written exposure control plans are included in the industry consensus standards: ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica and ASTM E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities

(Document ID 1466, p. 2; 1504, p. 2). OSHA finds that written exposure control plans provide a systematic approach for ensuring proper function of engineering controls and effective work practices that can prevent overexposures from occurring. The ASTM standards do not specifically call for procedures to restrict access; however, they do call for a description of administrative controls to reduce exposures (Document ID 1466, p. 2; 1504, p. 2). An example of such an administrative control for minimizing the number of employees exposed to respirable crystalline silica would be to schedule high-exposure tasks to be conducted when others will not be in adjacent areas (Document ID 3583, Tr. 2385–2386).

Commenters from the construction industry submitted comments on the regulated area option. Some of the comments were generally supportive (Document ID 2169, p. 4; 2177, Attachment B, p. 14; 2262, pp. 43–44; 2339, p. 4). However, other stakeholders felt that OSHA's proposed requirements for regulated areas would be unworkable and infeasible in construction (*e.g.*, Document ID 2116, Attachment 1, p. 13; 2183, pp. 1–2; 2187, p. 5–6; 2269, p. 4; 2276, p. 5; 2319, pp. 89–90; 2323, p. 1; 2338, p. 3; 2345, p. 3). They expressed serious concerns with the proposed provisions for establishing and limiting access to regulated areas, often citing challenges posed by constantly changing work activities, multiple employers on the worksite, lack of employer control in outside construction projects, the possibility of an entire worksite needing to be classified as a regulated area (on small worksites), and the prevalence of silica in the natural environment, particularly in certain regions of the country (*e.g.*, Document ID 2116, pp. 13–14, 22, 27; 2183, pp. 1–2; 2319, p. 89; 2323, p. 1; 2210, Attachment 1, p. 7; 2187, pp. 5–6; 2246, p. 11; 2269, p. 22; 2296, p. 26; 3230, p. 2). For example, ASA questioned a subcontractor's ability to control the environment on a multiemployer job site, stating:

> . . . even if a trade contractor were to establish a regulated area, it may not be able to limit access or operations by individuals outside of its management or control, particularly in the absence of a representative of a general contractor or construction manager (Document ID 2187, p. 6).

The Interlocking Concrete Pavement Institute indicated that other construction trade workers labor in the same area from 10 to 90 percent of the time, and that efforts by OSHA to restrict access among trades on a job site would result in chaos (Document ID 2246, p. 11). The LBA added that, although OSHA's proposed requirements might be suitable for a single-employer setting where working conditions are somewhat consistent, they were unworkable in the construction industry (Document ID 2269, p. 8).

OSHA received feedback from employee representatives and public health advocates indicating support for a requirement that employers establish and limit access to areas where high exposures may occur in the construction industry (Document ID 2177, Attachment B, p. 14; 2371, Attachment 1, pp. 17–19; 3589, Tr. 4263; 4223, p. 102). For example, the Laborers Health and Safety Fund of North America argued that regulated areas are helpful because they provide a visible indicator that a hazardous area exists for employees in different trades who may be on the worksite but would not otherwise be aware of the potential for exposure to respirable crystalline silica in that area (Document ID 3589, Tr. 4263). NIOSH supported the need to protect workers on a construction site from exposure via regulated areas and/or a written access control plan. NIOSH also noted the importance of competent persons and how they play an integral role in establishing regulated areas (Document ID 2177, Attachment B, pp. 8–10, 14).

Several commenters representing public health organizations and unions opined that construction employers could implement regulated areas on construction sites without a great deal of difficulty (Document ID 3585, Tr. 3090–3091; 4234, Part 1, pp. 24–25). The American Industrial Hygiene Association (AIHA) suggested how an employer might determine whether a regulated area needs to be established:

> Utilization of the Table 1 as a compliance option when respirators are required means the surrounding area must be considered a regulated area or under an access control plan. This combined with the engineering controls can help address the common problem of adjacent workers being inadvertently exposed to silica particulates. The need for a regulated area or control plan would now be an objective determination by the competent person. This in turn would help identify workers or areas where inadvertent exposure may occur and consequently allow procedures to be implemented to prevent this (Document ID 2169, p. 4).

Other commenters indicated that, to an extent, regulated areas already exist on construction sites. At the public hearings, the Mason Contractors Association of America provided testimony pointing out that a vast majority of masonry work is already carried out in restricted zones, and that access to these zones by other workers is limited. They noted that access to these restricted work zones was ultimately controlled by the general contractor (Document ID 3585, pp. 2933–2934). BCTD noted that Kevin Turner of Hunt Construction Group, testifying on behalf of CISC, indicated that contractors creating a hazard on construction worksites identify their work areas to avoid putting other workers at risk, and explained how different contractors on a multi-employer site routinely establish exclusion zones to exclude other workers from hazardous areas. BCTD argued that there is no reason why such an approach would not work for areas with high silica exposure as well (Document ID 4223, p. 102–105). ASSE indicated that, while the organization recognized the potential value of establishing regulated areas where silica overexposures are anticipated, there may be valid, practical reasons for exempting short-term construction worksites from this requirement as long as alternative worker protections are in place (Document ID 3430, p. 3)

After a review of these comments submitted on the proposed rule by construction industry stakeholders, OSHA concludes that a requirement for regulated areas is not appropriate for the construction standard. OSHA proposed to require regulated areas wherever an employee's exposure to respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL. However, OSHA expects that a majority of the regulated community in construction will implement the specified exposure control methods presented in paragraph (c) of the standard for construction (*i.e.*, the controls listed in Table 1) for the purposes of reducing occupational exposure to respirable crystalline silica and to assure compliance with the standard. Employers who implement the specified exposure control methods presented in paragraph (c) of the standard for construction will not be required to assess employee exposures to respirable crystalline silica, and thus will not necessarily be aware of situations where employee exposures exceed the PEL. Furthermore, these employers who are not necessarily required to conduct an exposure assessment would thereby not have the data necessary to establish and demarcate the boundaries of regulated areas (*i.e.*, the point at which exposures no longer exceed the PEL). Therefore,

most construction employers will not have an objective basis for establishing regulated areas.

In addition, OSHA basis its decision not to require regulated areas in the standard for construction in part on its recognition that conditions at construction worksites present challenges to establishing regulated areas for respirable crystalline silica exposure due to the varied and changing nature of construction work. Various commenters representing construction interests expressed how factors such as environmental variability normally present in construction differ substantially from those typically found in general industry and maritime workplaces. These commenters noted that construction tasks are often of relatively short duration; they are commonly performed outdoors, sometimes under adverse environmental conditions; and they are normally performed at non-fixed workstations or worksites. These factors make establishment of regulated areas impractical for many construction tasks. Silica-generating tasks in construction often involve movement to different locations during the workday, and respirable crystalline silica may be subject to changes in wind currents, meaning that exposure patterns may frequently shift. Accordingly, in the typical construction project involving silica-generating tasks, it is difficult to determine appropriate boundaries for regulated areas because the work and worksite are varied and subject to environmental influences (*e.g.*, Document ID 2246, p. 11; 2269, pp. 4, 9–10; 2289, pp. 6–7; 2309, p. 3; 2327, p. 20).

OSHA finds the evidence of the particular and varying nature of construction work persuasive. Furthermore, the requirement for a competent person as part of the written exposure control plan requirements in paragraph (g)(4) of the standard for construction provides that a designated competent person on the worksite will have the responsibility to restrict access to work areas, where necessary, to limit exposures to respirable crystalline silica. OSHA concludes that this requirement will achieve the primary objectives of a regulated area.

OSHA realizes that in some cases general industry work tasks and work environments may be comparable to those found in construction. Although no exceptions have been carved out of the requirement in the standard for general industry and maritime, where the general industry or maritime employer can show compliance is not feasible, regulated areas will not have to be established insofar as infeasibility is a complete defense to an OSHA citation. *See United Steelworkers* v. *Marshall*, 647 F.2d 1189 (D.C. Cir. 1980); *Marshall* v. *West Point Pepperell, Inc.*, 588 F.2d 979 (5th Cir. 1979). As a general matter, however, OSHA's longstanding distinction between general industry (including, for these purposes, the maritime sector), on the one hand, and the construction sector, on the other hand, provides an appropriate line for delineating between those tasks where the employer generally is reasonably able to establish regulated areas where exposures to respirable crystalline silica exceed the PEL versus tasks where regulated areas are generally not practicable.

ASTM E 1132–06 and ASTM E 2625–09 do not include requirements for regulated areas. However, both industry consensus standards indicate that workers should not work in areas where visible dust is generated from crystalline silica-containing materials without the use of respiratory protection, unless proven protective measures are used or sampling shows exposure is below the exposure limit (*see* Section 4.4.3.1 in each standard) (Document ID 1466, p. 4; 1504, p. 3). OSHA considers the approach taken in its standard for construction to be consistent with the approach taken in the ASTM standards. OSHA further considers that the requirement for regulated areas in the standard for general industry and maritime better effectuates the purposes of the OSH Act because the establishment of regulated areas in those workplaces, where they are most effective, serves to limit the number of employees exposed and the level of exposure of employees who would otherwise be at significant risk of suffering adverse health effects from exposure to respirable crystalline silica. As explained above, regulated areas make employees aware of the presence of respirable crystalline silica at levels above the PEL and the need for protective measures, and serve to limit respirable crystalline silica exposure to as few employees as possible. Additionally, OSHA notes that the industry consensus standards addressing occupational exposure to respirable crystalline silica do not include requirements for protective clothing. The OSHA rule is consistent with the consensus standards in this respect also.

Methods of Compliance

Paragraph (f)(1) of the standard for general industry and maritime (paragraph (d)(3)(i) of the standard for construction) establishes a hierarchy of controls that employers must use to reduce and maintain exposures to respirable crystalline silica to or below the permissible exposure limit (PEL) of 50 $\mu g/m^3$. The rule requires employers to implement engineering and work practice controls as the primary means to reduce exposure to the PEL or to the lowest feasible level above the PEL. In situations where engineering and work practice controls are not sufficient to reduce exposures to or below the PEL, employers are required to supplement these controls with respiratory protection, according to the requirements of paragraph (g) of the standard for general industry and maritime (paragraph (e) of the standard for construction).

OSHA's long-standing hierarchy of controls policy was supported by many commenters including the National Institute for Occupational Safety and Health (NIOSH), the American Society of Safety Engineers (ASSE), the American Industrial Hygiene Association, the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), the American Public Health Association (APHA), the National Asphalt Pavement Association (NAPA), the National Utility Contractors Association, the American Road and Transportation Builders Association (ARTBA), and the International Safety Equipment Association (ISEA) (*e.g.*, Document ID 1757, p. 4; 1771, p. 1; 1797, p. 5; 1800, p. 5; 2106, p. 2; 2166, p. 3; 2173, p. 4; 2178, Attachment 1, pp. 3–4; 2181, p. 9; 2240, p. 2; 2256, Attachment 2, pp. 11–12; 2278, p. 3; 2313, p. 6; 2315, p. 3; 2329, p. 5; 2336, p. 7; 2371, Attachment 1, p. 22; 2373, pp. 3–4; ; 3468, p. 3; 3516, p. 3; 3577, Tr. 791; 3578, Tr. 1044–1045; 3579, Tr. 182–183; 3581, Tr. 1564, 1648–1651; 3583, Tr.2237, 2243–2244, 2451, 2456; 3584, Tr. 2576–2577; 3955, Attachment 1, p. 2; 3585, Tr. 3112; 3586, Tr. 3162, 3200; 3589, Tr. 4147; 1759; 4203, p. 4; 4204, pp. 64–65; 4219, pp. 16, 20; 4223, p. 86; 4227, p. 1; 4233, Attachment 1, p. 14; 4235, p. 14). Tom Ward, a bricklayer and member of the International Union of Bricklayers and Allied Craftworkers (BAC) testified:

> [The hierarchy of controls] is the first thing we are supposed to do. Whenever feasible, eliminate the hazard. PPE is and always should be the last line of defense. Switching it is going backwards . . . (Document ID 3585, Tr. 3070).

Many industry commenters, including trade associations, generally objected to OSHA's proposed application of the hierarchy of controls in the rule. These commenters included the U.S. Chamber of Commerce (the Chamber), Associated

Builders and Contractors, the Association of American Railroads (AAR), Battery Council International (BCI), the Motor and Equipment Manufacturers Association (MEMA), the Institute of Makers of Explosives (IME), the Association of Energy Service Companies, and the Precast/Prestressed Concrete Institute (PCI) (*e.g.*, Document ID 1728; 1992, pp. 10–11; 2102, p. 2; 2130, pp. 1–2; 2151, p. 1; 2211, pp. 6–7; 2213, pp. 3–4; 2276, p. 3; 2288, pp. 12–13;2289, p. 7; 2325, p. 2; 2326, p. 2; 2344, p. 2; 2361, p. 3; 2366, p. 5; 4194, pp. 12–13). These commenters asked OSHA to reconsider its preference for engineering and work practice controls and permit the use of respiratory protection, such as powered air-purifying respirators (PAPRs), instead of engineering and work practice controls to reduce exposures to respirable crystalline silica to or below the PEL. For example, the Chamber urged OSHA to support

> . . . new technology and policies favoring effective, comfortable, respirators and clean filtered air helmets, which provide full protection but are not favored by OSHA's outdated 'hierarchy of control' policy (Document ID 4194, p. 4).

Similarly, the American Foundry Society (AFS) argued that:

> OSHA's preference for controls other than respirators is based on a policy that was adopted decades ago, and fails to take into account changes in respirator technology that have resulted in improved performance, improved reliability, improved worker acceptance, and increased protection (Document ID 3487, p. 25).

Greg Sirianni, an industrial hygienist testifying for the Chamber, commented that some respiratory protection, such as PAPRs, ''should not be looked at as mere respirators, but as microenvironmental engineering controls'' (Document ID 2364, p. 12). He described several studies demonstrating the effectiveness of PAPRs with helmets/hoods (Document ID 2364, pp. 6–7). He also referenced studies showing that PAPRs reduce physiological burdens, as well as provide increased comfort, ease of use, and improved communication, when compared to traditional air-purifying respirators (Document ID 2364, pp. 8–10). Other industry commenters, including the National Association of Manufacturers (NAM), AFS, and National Mining Association, echoed Mr. Sirianni's conclusion about the effectiveness of PAPRs (Document ID 2211, pp. 6–7; 2379, Appendix 1, p. 49; 2380, Attachment 2, pp. 22–23; 3489, p. 5;). Peter Mark, Corporate Director of Safety, Health, and Environment at Grede Holdings, testified that some respirators, such as air-supplied helmets, can also provide eye and face protection (Document ID 3584, Tr. 2685–2686). The George Washington University Regulatory Studies Center argued that OSHA's hierarchy of controls eliminates the incentive to develop more effective, lower cost, and more comfortable respirators and ''distorts the development of new knowledge that could provide superior protection for employees'' (Document ID 1831, p. 15).

Other commenters pointed to the disadvantages of engineering controls. The Construction Industry Safety Coalition (CISC), NAM, PCI, and AFS noted that engineering controls are subject to human error and maintenance concerns (Document ID 2319, p. 95; 2380, Attachment 2, p. 22; 3487, p. 25; 3581, Tr. 1738, 1762; 3589, Tr. 4357). The Tile Roofing Institute (TRI), National Roofing Contractors Association (NRCA), National Association of Home Builders (NAHB), CISC, and NAM described situations where the use of engineering and work practice controls could present other hazards, such as falls (Document ID 2191, pp. 9–10; 2214, pp. 3–4; 2296, p. 28; 2319, p. 93; 3587, Tr. 3593–3594; 4225, p. 2; 4226, p. 3). OSCO Industries (OSCO) commented that where ventilation requires all doors and windows to be closed, engineering controls can put physiological and psychological strain on employees (Document ID 1992, p. 10).

NIOSH provided evidence that recent improvements in PAPRs have not eliminated all of their disadvantages. NIOSH cited several studies suggesting that psychological issues, medical disqualifications, communication impairment, hearing degradation, and visual impairment remained even for PAPRs (Document ID 4233, Attachment 1, pp. 17–20). NIOSH also noted that there are no maximum weight requirements for PAPRs, some of which can be fairly heavy (Document ID 4233, Attachment 1, p. 18). When questioned about the use of PAPRs in the brick industry, Thomas Brown, the Director of Health and Safety at Acme Brick Company, testified that:

> No, we have not used [PAPRs]. And the reason why [is] it would be almost virtually impossible to wear those type[s] of respirators and perform the tasks that they are doing (Document ID 3577, Tr. 752).

No commenter representing employees or public health organizations agreed that PAPRs have improved to the point that they have become preferable to engineering controls. For example, when asked whether PAPRs should be viewed as an alternative to engineering controls and treated on the same level in the hierarchy of controls, Frank Hearl, Chief of Staff at NIOSH, testified that, ''. . . in terms of the PAPR and other respirators, it all sort of falls into the hierarchy of controls and suffers the same problems as the other respirators in that it doesn't control the entire environment'' (Document ID 3579, Tr. 233). The Building and Construction Trades Department, AFL–CIO (BCTD) testified that PAPRs are not an adequate alternative given that they do not ''. . . control the hazards at the source for all workers'' (Document ID 3581, Tr. 1668–1669). Similarly, ISEA commented that ''. . . the association does not believe PAPRs can be used as engineering controls'' since they do not remove hazards from the workplace (Document ID 4227, p. 1).

NIOSH, public health organizations, labor unions, individual employees, trade associations, public interest organizations and employers also provided additional evidence of the discomfort and difficulties experienced by employees who wear respirators (*e.g.*, extreme temperatures, visibility restrictions, communication impairment, psychological issues, strain on respiratory and cardiac systems) (Document ID 1758; 2116, Attachment 1, p. 28; 2178, Attachment 1, p. 4; 2181, pp. 9, 12; 2262, p. 26; 2314, p. 2; 2373, p. 4; 3571, Attachment 1, p. 2; 3577, Tr. 839–841; 3579, Tr. 183–184; 3580, Tr. 1526–1527; 3582, Tr. 1872–1874, 1897, 1899–1901; 3583, Tr. 2434–2435; 3585, Tr. 3112; 3586, Tr. 3174–3175, 3180, 3250, 3252–3253; 3587, Tr. 3583–3584, 3637–3638; 4233, Attachment 1, pp. 18–19; 4235, p. 12). Other commenters, including NIOSH, the International Union of Operating Engineers (IUOE), the Brick Industry Association, TRI, NAPA, ARTBA, the Interlocking Concrete Pavement Institute, Black Roofing, the National Tile Contractors Association, Acme Brick, and iQ Power Tools also described how respirator use can exacerbate various safety and health threats to employees, such as trips, falls, ''struck by'' hazards, saw hazards, and heat stress (Document ID 2262, p. 25; 2293; 3529, p. 2; 3577, Tr. 714, 750–752; 3583, Tr. 2170, 2237, 2372, 2435–2437; 3586, Tr. 3341, 3406; 3587, Tr. 3583–3584, 3594; 3589, Tr. 4373; 4225, p. 6; 4233, Attachment 1, p. 18; 4234, Part 1 and Part 2, pp. 30–31; 4235, p. 12). IUOE, the Laborers' Health and Safety Fund of North America (LHSFNA), and Arch Masonry further noted that reliance on respirators to protect

employees from exposures to respirable crystalline silica could end the careers of employees who cannot pass the medical evaluation, but can do the work (Document ID 2262, p. 27; 2292, p. 4; 3587, Tr. 3656–3567; 3589, Tr. 4274–4275).

In addition, NIOSH and other public health professionals described how respirators are more prone to misuse or other human error, as they depend on human behavior to achieve beneficial results (Document ID 2374, Attachment 1, pp. 5–6; 3577, Tr. 848–849; 3579, Tr. 183–184). On the other hand, engineering controls are easier to monitor and maintain. As Dr. Celeste Monforton testified:

> It is illogical to suggest that diligently meeting all the laborious requirements necessary for an effective respiratory protection program for a whole crew of employees is easier than ensuring that a handful of silica-generating pieces of equipment are maintained (Document ID 3577, Tr. 849).

Various individuals and organizations detailed the lack of adequate fit testing and respiratory protection programs in practice, which can significantly impact respirator effectiveness. These included Dr. Monforton, ASSE, the National Council of La Raza, the National Consumers League (NCL), APHA, the National Council for Occupational Safety and Health, NRCA, and Arch Masonry as well as workers, including James Schultz and Allen Schultz (Document ID 2166, p. 3; 2173, p. 5; 2178, Attachment 1, pp. 3–4; 2373, pp. 3–4; 3577, Tr. 848–849; 3578, Tr. 1040–1041, 1042–1043; 3586, Tr. 3161, 3213–3214, 3236–3237, 3253–3254; 3587, Tr. 3625, 3680–3681; 3955, Attachment 1, p. 2). Workers, including James Schultz, Jonass Mendoza, Santiago Hernandez, Juan Ruiz, Norlan Trejo and Jose Granados described their negative experiences with respirator use, including the lack of fit testing, training, and proper maintenance (Document ID 3571, Attachment 2, p. 3; 3571, Attachment 3, p. 2; 3571, Attachment 5, p. 1; 3571, Attachment 7, p. 1; 3583, Tr. 2487; 3586, Tr. 3201–3202;). Dr. Laura Welch, representing BCTD, testified that in her experience, respiratory protection does not prevent employees from developing lung disease, but that engineering controls are effective (Document ID 3581, Tr. 1648–1649).

Further, NIOSH, labor organizations (*e.g.*, LHSFNA, the International Association of Sheet Metal, Air, and Rail Transportation Workers, the Operative Plasterers' and Cement Masons' International Association, the International Union of Painters and Allied Trades (IUPAT), the United Union of Roofers, Waterproofers, and Allied Workers, BAC, the United Steelworkers, BCTD, and AFL–CIO), public health organizations (*e.g.*, APHA), public interest organizations (*e.g.*, the Center for Biological Diversity, the Center for Effective Government, and NCL), and individual workers described how limiting exposure to respirable crystalline silica at its source through engineering and work practice controls best protects employees involved in dust-generating operations, as well as other employees and the public from these exposures (*e.g.*, Document ID 2178, Attachment 1, p. 4; 2253, pp. 1–2; 2329, p. 4; 2373, p. 4; 2374, Attachment 1, pp. 5–6; 3516, p. 3; 3579, Tr. 184–185, 233; 3581, Tr. 1590, 1593–1594, 1649–1651,1669, 1708–1709; 3582, Tr. 1878–1879, 1881–1883; 3583, Tr. 2455–2456; 3584, Tr. 2578–2579; 3585, Tr. 3067–3069; 4204, pp. 68, 72–74; 3589, Tr. 4232–4233; 4223, pp. 86–87; 4233, Attachment 1, pp. 11–14). For example, LHSFNA noted that using controls on jackhammers, chipping guns, hand-held grinders, and drywall sanders can reduce exposures to nearby laborers (Document ID 2253, pp. 1–2). Norlan Trejo testified that when cutting ceramic and granite, wet cutting helps protect both the employee and bystanders (Document ID 3583, Tr. 2455–2456). Sean Barrett, a terrazzo worker, testified that grinding floors in the terrazzo industry exposes everyone on the worksite if controls are not used:

> Every other trade has to walk through the cloud [of dust] to get in and out of the building to use the outhouses or to go to the coffee truck or even go home at the end of the day . . . [T]hey have no choice but to walk through the dust (Document ID 3585, Tr. 3068).

Additionally, James Schultz, a former foundry employee from the Wisconsin Coalition for Occupational Safety and Health, provided testimony about how the lack of engineering controls creates dusty conditions that can lead to other hazards. He described how dusty conditions in a foundry led to incidents where employees were struck by forklifts (Document ID 3586, Tr. 3242–3243).

Some of the same industry commenters advocating for the use of PAPRs in place of engineering controls have acknowledged the importance of engineering controls to protect employees from exposures to respirable crystalline silica. For example, AFS, in its *Guide for Selection and Use of Personal Protective Equipment and Special Clothing for Metalcasting Operations*, describes the hierarchy of controls as the basis for choosing strategies for protecting employers from exposures to airborne contaminants. The guide concludes that air-supplied hoods and PAPRs are important options when choosing respiratory or personal protection, but does not support using these in lieu of engineering controls (Document ID 2379, Appendix 6). NAM noted that they were not opposed to using engineering controls where they are feasible and effective (Document ID 3581, Tr. 1753). Greg Sirianni, an expert for the Chamber, testified that:

> . . . there are obviously benefits to engineering controls, and by all means I want the use of engineering controls when they are possible. And in certain work environments . . . you need to have something that can protect all workers in all scenarios, and engineering controls are good for most cases, but there are a lot of workers out there that need [PAPRs], and I really recommend their use (Document ID 3578, Tr. 1104–1105).

Other industry groups provided additional evidence that the hierarchy of controls is embraced and applied in practice. For example, Wayne D'Angelo of the American Petroleum Institute (API) testified that the organization supports the traditional use of the hierarchy of controls to protect employees (Document ID 3589, Tr. 4065). The National Industrial Sand Association (NISA) has built the hierarchy of controls into its *Practical Guide to an Occupational Health Program for Respirable Crystalline Silica* (Document ID 1965, Attachment 2, pp. vii, 44). The National Stone, Sand, and Gravel Association's occupational health program, which is based on NISA's program, also supports the industrial hygiene hierarchy of controls (Document ID 3583, Tr. 2312).

OSHA concludes that requiring primary reliance on engineering controls and work practices is necessary and appropriate because reliance on these methods is consistent with good industrial hygiene practice, and with the Agency's experience in ensuring that employees have a healthy workplace. The Agency finds that engineering controls: (1) Control crystalline silica-containing dust particles at the source; (2) are reliable, predictable, and provide consistent levels of protection to a large number of employees; (3) can be monitored continually and relatively easily; and (4) are not as susceptible to human error as is the use of personal protective equipment. The use of engineering controls to prevent the release of silica-containing dust particles at the source also minimizes the silica exposure of other employees in surrounding work areas who are not directly involved in the task that is generating the dust, and

may not be wearing respirators. This issue of secondary exposures to other laborers and bystanders is especially of concern at construction sites (*e.g.,* Document ID 2177, Attachment B, pp. 14–15; 2329, p. 4; 2319, p. 28, 3581, Tr. 1587–1588).

Under the hierarchy of controls, respirators can be another effective means of protecting employees from exposure to air contaminants. However, to be effective, respirators must be individually selected, fitted and periodically refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. In many workplaces, these conditions for effective respirator use are difficult to achieve. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides to some or all of the employees. For example, certain types of respirators require the user to be clean shaven to achieve an effective seal where the respirator contacts the employee's skin. Failure to ensure a tight seal due to the presence of facial hair compromises the effectiveness of the respirator.

Respirator effectiveness ultimately relies on the good work practices of individual employees. In contrast, the effectiveness of engineering controls does not rely so heavily on actions of individual employees. Engineering and work practice controls are capable of reducing or eliminating a hazard from a worksite, while respirators protect only the employees who are wearing them correctly. Furthermore, engineering and work practice controls permit the employer to evaluate their effectiveness directly through air monitoring and other means. It is considerably more difficult to directly measure the effectiveness of respirators on a regular basis to ensure that employees are not unknowingly being overexposed. OSHA therefore continues to consider the use of respirators to be the least satisfactory approach to exposure control.

In addition, use of respirators in the workplace presents other safety and health concerns. Respirators can impose substantial physiological burdens on employees, including the burden imposed by the weight of the respirator; increased breathing resistance during operation; limitations on auditory, visual, and olfactory sensations; and isolation from the workplace environment. Job and workplace factors such as the level of physical work effort, the use of protective clothing, and temperature extremes or high humidity can also impose physiological burdens on employees wearing respirators. These stressors may interact with respirator use to increase the physiological strain experienced by employees.

Certain medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee wearing the respirator at an increased risk of illness, injury, and even death. These medical conditions include cardiovascular and respiratory diseases (*e.g.,* a history of high blood pressure, angina, heart attack, cardiac arrhythmias, stroke, asthma, chronic bronchitis, emphysema), reduced pulmonary function caused by other factors (*e.g.,* smoking or prior exposure to respiratory hazards), neurological or musculoskeletal disorders (*e.g.,* epilepsy, lower back pain), and impaired sensory function (*e.g.,* a perforated ear drum, reduced olfactory function). Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees and may also cause, independent of physiological burdens, significant elevations in heart rate, blood pressure, and respiratory rate that can jeopardize the health of employees who are at high risk for cardiopulmonary disease (*see* 63 FR 1152, 1208–1209 (1/8/98)).

In addition, safety problems created by respirators that limit vision and communication must always be considered. In some difficult or dangerous jobs, effective vision or communication is vital. Voice transmission through a respirator can be difficult, annoying, and fatiguing. In addition, movement of the jaw in speaking can cause leakage, thereby reducing the efficiency of the respirator and decreasing the protection afforded the employee. Skin irritation can result from wearing a respirator in hot, humid conditions. Such irritation can cause considerable distress to employees and can cause employees to refrain from wearing the respirator, thereby rendering it ineffective.

These potential burdens placed on employees by the use of respirators were acknowledged in OSHA's revision of its respiratory protection standard, and are the basis for the requirement (29 CFR 1910.134(e)) that employers provide a medical evaluation to determine the employee's ability to wear a respirator before the employee is fit tested or required to use a respirator in the workplace (*see* 63 FR at 1152). Although experience in industry shows that most healthy employees do not have physiological problems wearing properly chosen and fitted respirators, nonetheless common health problems can cause difficulty in breathing while an employee is wearing a respirator.

While OSHA acknowledges that certain types of respirators, such as PAPRs, may lessen problems associated with breathing resistance and skin discomfort, they do not eliminate them. OSHA concludes that respirators do not provide employees with a level of protection that is equivalent to engineering controls, regardless of the type of respirator used. It is well-recognized that certain types of respirators are superior to other types of respirators with regard to the level of protection offered, or impart other advantages like greater comfort. OSHA has evaluated the level of protection provided by different types of respirators in the Agency's Assigned Protection Factors rulemaking (68 FR 34036 (06/06/03)). Even in situations where engineering controls are not sufficiently effective to reduce exposure levels to or below the PEL, the reduction in exposure levels benefits employees by reducing the required protection factor of the respirator, which provides a wider range of options in the type of respirators that can be used. For example, for situations in which dust concentrations are reduced through use of engineering controls to levels that are less than ten times the PEL, employers would have the option of providing approved half-mask respirators with an assigned protection factor (APF) of 10 that may be lighter and easier to use when compared with full-facepiece respirators.

All OSHA substance-specific health standards have recognized and required employers to observe the hierarchy of controls, favoring engineering and work practice controls over respirators. OSHA's PELs, including the previous PELs for respirable crystalline silica, also incorporate this hierarchy of controls. The Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (*see* Section II, Pertinent Legal Authority for further discussion of these cases). In addition, the industry consensus standards for crystalline silica (ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities) incorporate the hierarchy of controls. NRCA also pointed out that the ANSI Z10, Standard for Occupational Health and Safety Management Systems, supports the hierarchy of controls (Document ID 2214, p. 3) and Dr. Celeste Monforton noted that the

hierarchy of controls has been followed and adopted by safety and health regulatory agencies around the world, including Safe Work Australia, the country's tripartite health and safety body, and the Canadian Province of Ontario's Health and Safety Agency (Document ID 3577, Tr. 847–848).

As explained in Section II, Pertinent Legal Authority, the very concept of technological feasibility for OSHA standards is grounded in the hierarchy of controls. The courts have clarified that a standard is technologically feasible if OSHA proves a reasonable possibility,

> . . . within the limits of the best available evidence . . . that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations (United Steelworkers v. Marshall, 647 F.2d 1189, 1272 (D.C. Cir. 1980)).

Allowing use of respirators instead of engineering and work practice controls would be a significant departure from this framework for evaluating the technological feasibility of a PEL.

While labor groups were opposed to any exemptions from the hierarchy of controls (Document ID 3586, Tr. 3235–3237), industry commenters, including both individual employers and trade associations, urged OSHA to consider making exemptions to the hierarchy in various situations. Commenters, including the Edison Electric Institute (EEI), Dal-Tile, the Glass Association of North America (GANA), the Tile Council of North America, the Non-Ferrous Founders' Society (NFFS), PCI, and the Chamber, argued that employers need flexibility to determine when enough engineering controls have been added and when respirators can be used (Document ID 2147, p. 3; 2215, p. 6; 2276, p. 6; 2357, pp. 25–26; 2363, p. 4; 3491, p. 4; 3576, Tr. 466; 3589, Tr. 4364). NAM echoed this, arguing that employers will never know when or if they are in compliance with the requirement to incorporate all feasible engineering and work practice controls and the Agency should thus base its requirements on objective criteria, while allowing flexibility to achieve compliance (Document ID 3581, Tr. 1738). Lapp Insulators, the Indiana Manufacturing Association, Murray Energy Corporation, BCI, Rheem Manufacturing Company, MEMA, IME, CISC, AFS, NFFS, and NAM urged OSHA to permit the use of respirators to satisfy the obligation to control exposures where feasible engineering and work practice controls are insufficient to bring exposure levels to or below the PEL (Document ID 1801, pp. 3–4; 2102, p. 2; 2130, pp. 1–2; 2151, p. 1; 2213, pp. 3–4; 2319, p. 95; 2325, p. 2; 2326, p. 2; 2361, p. 3; 2380, Appendix 2, pp. 22–23; 3486, p. 2; 3491, pp. 4–5; 3581, Tr. 1752–1753; 4226, p. 2). This concern was echoed by other commenters who encouraged OSHA to permit the use of respirators in industries using large amounts of crystalline silica (*e.g.,* oil and gas operations where hydraulic fracturing is conducted), where engineering controls alone would not be likely to reduce exposures to or below the PEL (Document ID 2283, p. 3; 3578, Tr. 1090–1091).

OSHA disagrees. Instead, the Agency considers engineering controls to be the most effective method of protecting employees and allows respiratory protection only after all feasible engineering controls and work practices have been implemented or where such controls have been found infeasible. If an employer has adopted all feasible engineering controls, and no other feasible engineering controls are available, the rule would permit the use of respirators. On the other hand, if feasible engineering controls are available that would reduce respirable crystalline silica exposures that exceed the PEL, then these controls are required. Thus, OSHA has concluded these engineering controls better protect employees.

Commenters, including CISC and OSCO, urged OSHA to permit the use of respirators for short duration, intermittent, or non-routine tasks (Document ID 1992, pp. 3, 5; 2319, pp. 95, 115; 3580, Tr. 1463–1464). Others, such as the Glass Packaging Institute (GPI) and NAM, argued that OSHA should permit the use of respirators for maintenance activities (Document ID 2290, pp. 2, 3; 2380, Attachment 2, pp. 14–15; 3493, pp. 2–3). Verallia North America recommended that respirators be allowed in all refractory repairs (Document ID 3584, Tr. 2848).

Where OSHA requires respirator use in this rule, the requirement is tied to expected or recorded exposures above the PEL, not categorically to specific operations or tasks per se. The rule permits the use of respirators where exposures exceed the PEL during tasks for which engineering and work practice controls are not feasible. Some tasks, such as certain maintenance and repair activities, may present a situation where engineering and work practice controls are not feasible. For example, GPI noted that respirators are needed to address failures of any conveyance system (elevators, conveyors, or pipes), failures of dust collecting bag systems, or section head failures at glass plant facilities (Document ID 3493, p. 3). OSCO described how engineering controls are not feasible for cupola (furnace) repair work and baghouse maintenance activities (Document ID 1992, pp. 3, 5). The Agency agrees that for tasks, such as certain maintenance and repair activities, where engineering and work practice controls are not feasible, the use of respirators is permitted.

The Chamber and the American Subcontractors Association (ASA) suggested that the hierarchy of controls is not appropriate for silica exposures in construction workplaces (Document ID 2187, p. 6; 2283, p. 3). While ASSE generally supported the hierarchy of controls, it acknowledged that there might be practical issues with implementation on short-term construction worksites (Document ID 2339, p. 4). More specifically, the Mason Contractors Association of America and Holes Incorporated urged OSHA to consider the approach taken by the ASTM standard for the construction industry (ASTM E 2625–09), which provides an exception to the hierarchy for brief, intermittent silica generating tasks of 90 minutes or less per day (Document ID 3580, Tr. 1453; 3585, Tr. 2882). Conversely, BCTD argued that even for silica dust-generating tasks of short duration where respiratory protection is employed, a failure to employ engineering controls could result in dangerous exposures (Document ID 4219, p. 17). They contended that:

> There is no evidence in the record that exposures of only 90 minutes a day pose a lower risk of harm, such that respirators would provide sufficient protection. Moreover . . . the industry failed to prove that it is infeasible—or even difficult—to use engineering controls in most silica-generating tasks (Document ID 4223, p. 88).

OSHA finds, as discussed above, that primary reliance on respirators to protect employees is inappropriate when feasible engineering and work practice controls are available. This is as true for the construction industry, as it is for other industries with respirable crystalline silica exposures. Even where employees are conducting intermittent silica generating tasks for 90 minutes or less per day, if the exposures are above the PEL and feasible engineering and work practice controls are available, they must be applied. Further, although an exemption for employees conducting silica generating tasks for 90 minutes or less per day is included in the ASTM standard for the construction industry, the standard also includes the hierarchy of controls, as well as task-based methods of compliance based on engineering and work practice controls

that are feasible and available for many construction tasks (ASTM E 2625–09). This approach is consistent with the specified exposure control methods for construction in paragraph (c)(1) described in the summary and explanation of Specified Exposure Control Methods. OSHA concludes that requiring the use of all feasible engineering and work practice controls in the construction industry, even for tasks of short duration generating respirable crystalline silica, is reasonably necessary and appropriate to protect employees from exposures to respirable crystalline silica.

AFS, NISA, GANA, EEI, the North American Insulation Manufacturers Association (NAIMA), and the Asphalt Roofing Manufacturers Association urged OSHA to consider allowing employers to use respirators to achieve compliance for operations where exposures exceed the PEL for 30 days or less per year (Document ID 4229, p. 11; 2195, pp. 7, 38–39; 2215, pp. 9–10; 2291, pp. 2, 18; 2348, Attachment 1, pp. 17, 26–28, 40; 2357, p. 26; 2379, Appendix 1, pp. 48, 68–69; 3487, pp. 22–23). Similarly, NAM proposed that OSHA could establish a maximum number of days a year when respirators can be used in place of engineering controls (Document ID 2380, Attachment 2, pp. 24–25).

Many of the examples mentioned by the commenters supporting this exemption described maintenance and repair activities, such as baghouse cleaning and furnace rebuilds. As discussed above, some tasks, such as certain maintenance and repair activities, may present a situation where engineering and work practice controls are not feasible. OSHA agrees that, for tasks of this nature where engineering and work practice controls are not feasible, the use of respirators is permitted. Permitting employers to use respirators instead of feasible engineering and work practice controls for exposures occurring for 30 days or less per year does not best effectuate the purpose of the rule—to protect employees from exposures to respirable crystalline silica. Thus, the Agency concludes that the hierarchy of controls is appropriate whenever feasible engineering and work practice controls are available.

The American Composite Manufacturers Association suggested that small businesses be exempt from the hierarchy of controls (Document ID 3588, Tr. 3933–3936). Bret Smith urged OSHA to allow small entities to use respiratory protection temporarily to allow time to prepare for the costs of implementation (Document ID 2203). OSHA does not agree that there should be a distinction between the protection employees receive in a small business or a large business. Protecting the safety and health of employees is part of doing business. Thus, exposures to respirable crystalline silica above the PEL, wherever they occur, must first be controlled using all feasible engineering and work practice controls available, before turning to respiratory protection. For the reasons previously discussed, implementing and maintaining a comprehensive respiratory protection program is a considerable undertaking for many employers, and likely even more so for small businesses. If employers are unable to properly train and fit employees and maintain the equipment, respirators will not effectively protect employees from exposures to respirable crystalline silica.

NAM proposed that OSHA adopt language to allow respirators to be used when exposures are below a specified level:

> Where airborne exposures to RCS on a time-weighted-average basis are below XX milligrams per cubic meter, employers may require the use of respirators in accordance with the requirements of 1910.134. Where exposures exceed this level, employers are required to adopt engineering and administrative controls to reduce exposures (Document ID 2380, Attachment 2, pp. 24–25).

They specifically provided the example of 5 mg/m^3 (*i.e.,* 5,000 µg/m^3), the respirable dust PEL, which would permit the use of respirators that provide a protection factor of 100 to achieve compliance with the PEL of 50 µg/m^3.

As discussed above, this approach is in conflict with the concept of technological feasibility for OSHA standards. Technological feasibility is determined based on the ability of a typical firm to develop and install engineering controls and work practice controls that can meet the PEL without regard to the use of respirators. The approach advanced by NAM would permit the use of respirators to achieve the PEL, even where exposures reached 100 times the PEL. If technological feasibility were based solely on the ability of respirators to meet the PEL, OSHA could determine that a much lower PEL would indeed be feasible. Further, a failure of respiratory protection in situations where exposures reach 100 times the PEL could result in extremely dangerous exposures.

Therefore, OSHA rejects the various comments recommending upsetting the long-established hierarchy of controls. Because engineering and work practice controls are capable of reducing or eliminating a hazard from the workplace, while respirators protect only the employees who are wearing them and depend on the selection and maintenance of the respirator and the actions of employees, OSHA holds to the view that engineering and work practice controls offer more reliable and consistent protection to a greater number of employees, and are therefore preferable to respiratory protection. Thus, the Agency continues to conclude that engineering and work practice controls provide a more protective first line of defense than respirators and must be used first when feasible.

Engineering controls. The engineering controls that are required by the standard can be grouped into four categories: (1) Substitution; (2) isolation; (3) ventilation; and (4) dust suppression. Depending on the sources of crystalline silica dust and the operations conducted, a combination of control methods may reduce silica exposure levels more effectively than a single method.

Substitution refers to the replacement of a toxic material with another material that reduces or eliminates the harmful exposure. OSHA considers substitution to be an ideal control measure if it replaces a toxic material in the work environment with a non-toxic material, thus eliminating the risk of adverse health effects.

As indicated in Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA), employers use substitutes for crystalline silica in a variety of operations. For example, some employers use substitutes in abrasive blasting operations, repair and replacement of refractory materials, operations performed in foundries, and in the railroad transportation industry. Commenters, such as NIOSH, John Adams, Vice President of the American Federation of Government Employees Local 2778, Kyle Roberts, and the National Automobile Dealers Association (NADA) also identified several situations where substitute materials and products were available or used in place of silica-containing products, including: The use of plastic curbs in place of concrete curbs to repair a highway overpass; the use of materials containing aluminum oxide instead of crystalline silica in dental labs; the use of aluminum pellets instead of sand in hydraulic fracturing operations; the availability of silica-free OEM and auto-refinish paint systems; and the availability of silica-free body fillers and silica-free abrasives for auto

body repair work (Document ID 1763, p. 2; 1800, p. 5; 2177, Attachment B, pp. 37–38; 2358, p. 4).

Commenters also identified many situations where no substitute materials and products were available to replace silica-containing materials and products. For example, Grede Holdings and AFS noted that there were no substitutes for sand for most foundry applications (Document ID 2298, p. 2; 2379, Appendix 1, pp. 14–16; 3486, p. 4). The General Contractors Association of New York, ASA, CISC, and NAHB noted that the construction industry cannot select alternate materials to avoid silica exposure, since nearly all construction materials and products contain silica (Document ID 2187, p. 6; 2314, pp. 1–2; 2296, pp. 7, 35; 2319, pp. 93–34). AAR and the American Short Line and Regional Railroad Association noted that substitute ballast materials with lower silica content cannot be used because they introduce safety hazards for employees and the public (Document ID 2366, pp. 5–6). GANA and NAIMA noted that silica is indispensable to the flat glass industry (Document ID 2215, p. 5; 2348, Attachment 1, pp. 8–10). NAM noted that viable alternatives of lower silica content are not available for some products made by their members (Document ID 3581, Tr. 1728). The Porcelain Enamel Institute noted that there are no proven replacements for mill-added crystalline silica for wet-applied enamel systems, given that the technical advantages offered by silica cannot be practically and economically achieved with other materials (Document ID 2281, p. 3).

The American College of Occupational and Environmental Medicine (ACOEM), the Mount Sinai-Irving J. Selikoff Centers for Occupational and Environmental Medicine, and Samantha Gouveia urged OSHA to more explicitly encourage the use of substitution where feasible (Document ID 1771, p. 1; 2080, pp. 4–5; 2208).

Commenters also expressed concerns about the safety of substitutes (Document ID 2080, pp. 4–5; 2187, p. 6; 2278, pp. 3–4). ACOEM suggested that OSHA only endorse the use of substitutes when they have been demonstrated to be safe in short- and long-term inhalation toxicology studies and urged OSHA to request that NIOSH conduct a periodic assessment that evaluates substitutes to determine which ones have been found to be safe based upon results of inhalation toxicity and epidemiologic studies (Document ID 2080, pp. 4–5). Dr. George Gruetzmacher, an industrial hygiene engineer, urged OSHA to encourage the use of alternative materials to silica when feasible, but only when the substitute has been demonstrated to be safe in short- and long-term inhalation toxicology studies or to prohibit the substitution of materials which have not been demonstrated to be less toxic by inhalation (Document ID 2278, pp. 3–4).

While OSHA finds that substitution can be an ideal control measure in certain circumstances, the Agency recognizes that this approach may not be feasible or safer in many others. Because some alternatives to silica or silica-containing materials may present health risks, OSHA is not implying that any particular alternative is an appropriate or safe substitute for silica. In its technological feasibility analyses, the Agency identified information about situations where substitution may be an available control strategy. OSHA strongly encourages employers to thoroughly evaluate potential alternatives, where available, to determine if a substitute can mitigate employees' exposure to respirable crystalline silica without posing a greater or new significant hazard to employees. Additionally, when substituting, employers must comply with Section 5(a)(1) of the OSH Act (29 U.S.C. 654(a)(1)), which prohibits occupational exposure to ''recognized hazards that are causing or are likely to cause death or serious physical harm,'' and with applicable occupational safety and health standards. For example, with respect to chemical hazards, OSHA's hazard communication standard imposes specific requirements for employee training, safety data sheets, and labeling (*see* 29 CFR 1910.1200).

Isolation, *i.e.,* separating workers from the source of the hazard, is another effective engineering control employed to reduce exposures to crystalline silica. Isolation can be accomplished by either containing the hazard or isolating workers from the source of the hazard. For example, to contain the hazard, an employer might install a physical barrier around the source of exposure to contain a toxic substance within the barrier. Isolating the source of a hazard within an enclosure restricts respirable dust from spreading throughout a workplace and exposing employees who are not directly involved in dust-generating operations. Or, alternatively, an employer might isolate employees from the hazard source by placing them in a properly ventilated cab or at some distance from the source of the respirable crystalline silica exposure.

Ventilation is another engineering control method used to minimize airborne concentrations of a contaminant by supplying or exhausting air. Two types of systems are commonly used: Local exhaust ventilation (LEV) and dilution ventilation. LEV is used to remove an air contaminant by capturing it at or near the source of emission, before the contaminant spreads throughout the workplace. Dilution ventilation allows the contaminant to spread over the work area but dilutes it by circulating large quantities of air into and out of the area. Consistent with past recommendations such as those included in the chromium (VI) standard, OSHA prefers the use of LEV systems to control airborne toxics because, if designed properly, they efficiently remove contaminants and provide for cleaner and safer work environments.

Dust suppression methods are generally effective in controlling respirable crystalline silica dust, and they can be applied to many different operations such as material handling, rock crushing, abrasive blasting, and operation of heavy equipment (Document ID 1147). Dust suppression can be accomplished by one of three systems: Wet dust suppression, in which a liquid or foam is applied to the surface of the dust-generating material; airborne capture, in which moisture is dispensed into a dust cloud, collides with particles, and causes them to drop from the air; and stabilization, which holds down dust particles by physical or chemical means (lignosulfonate, calcium chloride, and magnesium chloride are examples of stabilizers).

The most common dust suppression controls are wet methods (*see* Chapter IV of the FEA). Water is generally an inexpensive and readily available resource and has been proven an efficient engineering control method to reduce exposures to airborne crystalline silica-containing dust. Dust, when wet, is less able to become or remain airborne.

Work practice controls. Work practice controls systematically modify how employees perform an operation, and often involve employees' use of engineering controls. For crystalline silica exposures, OSHA's technological feasibility analysis shows that work practice controls are generally applied complementary to engineering controls, to adjust the way a task is performed (*see* Chapter IV of the FEA). For work practice controls to be most effective, it is essential that employees and supervisors are trained to be fully aware of the exposures generated by relevant workplace activities and the impact of the engineering controls installed. Work practice controls are preferred over the use of personal protective equipment, since work practice controls can address

the exposure of silica at the source of emissions, thus protecting nearby employees.

Work practice controls can also enhance the effects of engineering controls. For example, to ensure that LEV is working effectively, an employee would position the LEV equipment so that it captures the full range of dust created, thus minimizing silica exposures. For many operations, a combination of engineering and work practice controls reduces silica exposure levels more effectively than a single control method.

The requirement to use engineering and work practice controls is consistent with ASTM E 1132–06 and ASTM E 2625–09, the national consensus standards for controlling occupational exposure to respirable crystalline silica in general industry and in construction, respectively. Each of these standards has explicit requirements for the methods of compliance to be used to reduce exposures below exposure limits. These voluntary standards specifically identify several controls, which include use of properly designed engineering controls such as ventilation or other dust suppression methods and enclosed workstations such as control booths and equipment cabs; requirements for maintenance and evaluation of engineering controls; and implementation of certain work practices such as not working in areas where visible dust is generated from respirable crystalline silica containing materials without use of respiratory protection. For employers in general industry and maritime, as well as those in construction following paragraph (d) for tasks not listed in Table 1 or where the employer does not fully and properly implement the engineering controls, work practices, and respiratory protection described in Table 1, OSHA similarly requires the use of engineering and work practices controls to reduce employee exposures to or below the PEL; however, this is a performance requirement and does not specify any particular engineering and work practice controls that must be implemented.

Paragraph (f)(2)(i) of the standard for general industry and maritime (paragraph (g)(1) of the standard for construction) requires that employers establish and implement a written exposure control plan. Paragraphs (f)(2)(i)(A)–(C) (paragraphs (g)(1)(i)–(iv) of the standard for construction) specify the contents for written exposure control plans. Paragraph (f)(2)(ii) (paragraph (g)(2) of the standard for construction) specifies requirements for the employer to review the plan at least annually and update it as needed. Paragraph (f)(2)(iii) (paragraph (g)(3) of the standard for construction) requires the employer to make the plan available to employees, employee representatives, OSHA, and NIOSH. Details about the written exposure control plan, including comments from stakeholders and OSHA's responses to those comments, are included in the summary and explanation of *Written Exposure Control Plan*.

SECALs. In the NPRM, OSHA asked stakeholders to provide input as to whether the Agency should establish separate engineering control air limits (SECALs) for certain processes in selected industries. In OSHA's cadmium standard (29 CFR 1910.1027 (f)(1)(ii), (iii), and (iv)), the Agency established SECALs where compliance with the PEL by means of engineering and work practice controls was infeasible. For these industries, a SECAL was established at the lowest feasible level that could be achieved by engineering and work practice controls. The PEL was set at a lower level, and could be achieved by any allowable combination of controls, including respiratory protection. A similar exception was included in OSHA's chromium (VI) standard (29 CFR 1910.1026) for painting aircraft and large aircraft parts.

OSHA received feedback from several commenters who supported establishing SECALs (*e.g.,* Document ID 2082, p. 8; 2379, Appendix 1, p. 61; 2380, Attachment 2, p. 23). For example, AFS argued for a SECAL of 150 or 200 μg/m^3 for foundries, with a PEL of 100 μg/m^3. AFS indicated that many foundries now operate under a formal or informal arrangement with OSHA that allows use of respirators as an acceptable control to achieve compliance with the current PEL after implementing all feasible engineering controls (Document ID 2379, Appendix 1, p. 61). ORCHSE Strategies stated that the use of SECALs could provide more definitive expectations for employers based on the feasibility for engineering controls in specific operations (Document ID 2277, p. 2). The United Automobile, Aerospace and Agricultural Implement Workers of America recommended that the PEL be even lower than OSHA proposed (25 μg/m^3), and suggested that SECALs could be established for those industries for which 25 μg/m^3 is not feasible (Document ID 2282, p. 16).

Other commenters did not favor establishing SECALs. CISC stated that it did not support the concept of SECALs, but that CISC would continue to examine whether a SECAL was appropriate for the construction industry (Document ID 2319, p. 128). NIOSH did not support the use of SECALs and stated that the requirement to meet the PEL for silica generating processes should be maintained (Document ID 2177, Attachment B, p. 16).

OSHA stresses that, where incorporated in a standard, a SECAL is intended for application to discrete processes and operations within an industry, rather than application to an entire industry, as some supporters of SECALs seemed to suggest. For example, in OSHA's cadmium standard, OSHA established SECALs for certain plating and other processes in a few affected industries. OSHA did not receive evidence to support establishing a SECAL for any discrete task or operation within a particular industry in the respirable crystalline silica rule. OSHA therefore has not established SECALs in the rule.

Abrasive blasting. Abrasive blasting requirements remain the same as proposed, except for minor editorial changes. Paragraph (f)(3) of the standard for general industry and maritime (paragraph (d)(3)(ii) of the standard for construction) requires the employer to comply with paragraph (f)(1) of the standard for general industry and maritime (paragraph (d)(3)(i) of the standard for construction) where abrasive blasting is conducted using crystalline silica-containing blasting agents, or where abrasive blasting is conducted on substrates that contain crystalline silica. Thus, for abrasive blasting, employers must follow the hierarchy of controls applicable to other tasks covered by the rule.

In this provision addressing abrasive blasting, the proposed standard referred to ''where abrasive operations are conducted,'' but for simplicity, this standard refers to ''where abrasive blasting is conducted.'' OSHA intends this change to be editorial only, and does not intend a substantive change from the proposed requirements.

In addition, paragraph (f)(3) of the standard for general industry and maritime indicates that the employer must comply with the requirements of 29 CFR 1910.94 (Ventilation), 29 CFR 1915.34 (Mechanical paint removers) and 29 CFR 1915 Subpart I, as applicable, where abrasive blasting is conducted using crystalline silica-containing blasting agents, or where abrasive blasting is conducted on substrates that contain crystalline silica. Paragraph (d)(3)(ii) of the standard for construction indicates that the employer must comply with the requirements of 29 CFR 1926.57 (Ventilation) in such circumstances.

OSHA's general industry (29 CFR 1910.94) and construction ventilation standards (29 CFR 1926.57), as well as the standards for mechanical paint removers (29 CFR 1915.34) and personal protective equipment for shipyard employment (29 CFR 1915 subpart I) provide requirements for respiratory protection for abrasive blasting operators and others involved in abrasive blasting. This rule includes cross-references to these standards. Employers using abrasive blasting need to consult these referenced standards to ensure that they comply with their provisions for personal protective equipment and ventilation, and other operation-specific safety requirements.

ISEA urged OSHA to add a reference to the APF table at 29 CFR 1910.134(d)(3)(i)(A) in the general industry and construction standards for ventilation, and to require that if the employer has no sampling data to support the use of an abrasive blasting respirator with an APF of 25, the employer must select a respirator with an APF of 1,000 (Document ID 2212, p. 1). The 3M Company similarly questioned the respirator requirements under the ventilation standards, arguing that without considering the performance (APF) of the respirator, some employees could be overexposed to silica (Document ID 2313, pp. 1, 5–6). Charles Gordon, a retired occupational safety and health attorney, commented that even with the reference to the ventilation standards, the provision is not protective enough. He encouraged the Agency to require the most protective abrasive blasting hood and respirators and require the best work practices (Document ID 2163, Attachment 1, p. 19).

Given the high levels of hazardous dust generated during abrasive blasting, OSHA has concluded, for reasons discussed in its technological feasibility analyses for construction and for certain general industry sectors like foundries and shipyards that perform abrasive blasting in their operations, that respiratory protection will continue to be necessary to reduce silica exposure below the PEL, even with engineering and work practice controls in place (see the discussion of abrasive blasting in Chapter IV of the FEA). This standard also takes respirator use into account by cross-referencing the specific respirator requirements already in place for abrasive blasting. Employers are also required to comply with the requirements of 29 CFR 1910.134 whenever respiratory protection is required by this section. Under 29 CFR 1910.134, the employer is required to select and provide an appropriate respirator based on the respiratory hazards to which the employee is exposed and is required to use the APF table at 29 CFR 1910.134(d)(3)(i)(A). This includes note four of the APF table, which requires the employer to have evidence to support an APF of 1000 for helmet/hood respirators. In addition, paragraph (d) of the standard for general industry and maritime and paragraph (d)(2) of the standard for construction require employers to assess the exposure of each employee who is or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level, which will provide employers with information to make appropriate respirator selection decisions. OSHA concludes that these requirements, including the referenced provisions in other OSHA standards, will adequately protect employees from exposures to respirable crystalline silica during abrasive blasting.

Many commenters, including NIOSH, labor unions, public health organizations, trade associations, occupational health medical professionals, and public interest organizations, urged OSHA to ban the use of silica sand as an abrasive blasting agent (Document ID 2167; 2173, p. 4; 2175, pp. 7–8; 2177, Attachment B, p. 37; 2178, Attachment 1, p. 3; 2212, p. 1; 2240, p. 2; 2244, p. 2; 2256, Attachment 2, pp. 12–13; 2282, Attachment 3, pp. 2, 18; 2341, p. 3; 2371, Attachment 1, p. 31; 2373, p. 3; 3399, p. 6; 3403, p. 7; 3577, Tr. 779–780, 785, 790; 3586, Tr. 3319–3320, 3163; 3588, Tr. 3752; 4204, p. 81; 4223, pp. 104–106). Some noted that 4 countries (Great Britain, Germany, Sweden, and Belgium), several U.S. military departments, and 23 state Departments of Transportation have already banned the practice (Document ID 2167; 2175, pp. 7–8; 2178, Attachment 1, p. 3; 2256, Attachment 2, pp. 12–13; 2212, p. 1; 2282, Attachment 3, p. 18; 2371, Attachment 1, p. 31; 2373, p. 3; 3399, p. 6; 4204, p. 76).

Fann Contracting, Dr. Kenneth Rosenman, an expert in occupational and environmental disease, and Novetas Solutions noted the broad trend of abrasive blasting operations moving away from sand (Document ID 2116, Attachment 1, pp. 31–32; 3577, Tr. 858; 3588, Tr. 3992–3993). The American Federation of State, County and Municipal Employees reported that several local Maryland unions no longer use silica-based blasting agents and have substituted other materials, such as aluminum shot (Document ID 2106, p. 2). Sarah Coyne, a former painter and current Health and Safety Director for IUPAT, discussed how their signatory contractors have largely transitioned from silica sand to coal slag for abrasive blasting (Document ID 3581, Tr. 1644). API noted that many oil and gas companies have limited or eliminated respirable crystalline silica exposure in sandblasting operations by using media options that do not contain silica (Document ID 2301, Attachment 1, p. 5). NADA also noted that product substitution has minimized potential exposures to airborne crystalline silica-containing media (Document ID 2358, p. 4). The Interstate Natural Gas Association of America stated that members utilize other abrasives to the extent feasible, including fused glass in limited applications (Document ID 2081, p. 2).

As OSHA indicated in its NPRM, the use of silica sand for abrasive blasting operations is decreasing (Document ID 1420). This reduction might reflect the use of alternative blasting media, the increased use of high-pressure water-jetting techniques, and the use of cleaning techniques that do not require open sand blasting. Several substitutes for silica sand are available for abrasive blasting operations, and current data indicate that the abrasive products with the highest U.S. consumptions are: Coal slag, copper slag, nickel slag, garnet, staurolite, olivine, steel grit, and crushed glass. Several commenters (Adam Webster, Charles Gordon, and the Association of Occupational and Environmental Clinics) also noted the general availability of alternative abrasive blast media, including baking soda, water, dry ice, coal/copper slag, glass beads, walnut shells, and carbon dioxide (Document ID 2163, p. 19; 2167; 3399, p. 6). Additional alternatives are discussed and evaluated in Chapter IV of the FEA. On the other hand, PCI commented that the use of alternative abrasive blast media was precluded in the precast concrete structures industry, since many alternatives will not meet aesthetic requirements, are not aggressive enough to provide the desired finished, or are simply cost prohibitive (Document ID 2276, p. 9). Furthermore, CISC warned about possible hazards associated with the substitutes for silica sand (Document ID 2319, p. 37). PCI and Novetas Solutions cautioned that coal and copper slags, commonly used as a substitute for silica sand in abrasive blasting, contain hazardous substances such as beryllium that cause adverse health effects in employees (Document ID 2276, p. 9; 3588, Tr. 3992–4004). Meeker *et al.* (2006) found elevated levels of exposure to arsenic, beryllium, and other toxic metals among painters using three

alternative blasting abrasives (Document ID 3855).

A NIOSH study compared the short-term pulmonary toxicity of several abrasive blasting agents (Document ID 1422). This study reported that specular hematite and steel grit presented less short-term in vivo toxicity and respirable dust exposure in comparison to blast sand. Overall, crushed glass, nickel glass, staurolite, garnet, and copper slag were similar to blast sand in both categories. Coal slag and olivine showed more short-term in vivo toxicity than blast sand and were reported as similar to blast sand regarding respirable dust exposure. This study did not examine long-term hazards or non-pulmonary effects.

Additionally, another NIOSH study monitored exposures to several OSHA-regulated toxic substances that were created by the use of silica sand and substitute abrasive blasting materials (Document ID 0772). The study showed that several substitutes create exposures or potential exposures to various OSHA-regulated substances, including: (1) Arsenic, when using steel grit, nickel slag, copper slag and coal slag; (2) beryllium, when using garnet, copper slag, and coal slag; (3) cadmium, when using nickel slag and copper slag; (4) chromium, when using steel grit, nickel slag, and copper slag; and (5) lead, when using copper slag. Since these studies were performed, OSHA has learned that specular hematite is not being manufactured in the United States due to patent-owner specification. In addition, the elevated cost of steel has a substantial impact on the availability to some employers of substitutes like steel grit and steel shot.

Evidence in the rulemaking record indicates that elevated silica exposures have been found during the use of low-silica abrasives as well, even when blasting on non-silica substrates. For example, the use of the blasting media Starblast XL (staurolite), which contains less than one percent quartz according to its manufacturer, resulted in a respirable quartz level of 1,580 $\mu g/m^3$. The area sample (369-minute) was taken inside a containment structure erected around two steel tanks. The elevated exposure occurred because the high levels of abrasive generated during blasting in containment overwhelmed the ventilation system (Document ID 0212). This example emphasizes the impact of control methods in specific working environments. In order to reduce elevated exposures to or as close as feasible to the PEL in situations like these, employers need to examine the full spectrum of available controls and how these controls perform in specific working conditions.

After considering the arguments for and against prohibition, OSHA concludes that prohibiting the use of silica sand as an abrasive blasting agent is not appropriate. In so concluding, the Agency considered whether such a prohibition is an effective risk mitigation measure, as well as the technological feasibility of substitutes. The Agency finds that many of the silica sand substitutes used in abrasive blasting can create hazardous levels of toxic dust other than silica, as documented in studies conducted by NIOSH on the toxicity of silica sand substitutes for abrasive blasting; NIOSH found that many, including coal slag, garnet, copper and nickel slags, olivine, and crushed glass, produced lung damage and inflammatory reactions in rodent lung similar to that of silica sand, indicating that use of such materials would present lung disease risks to employees (Document ID 3857; 3859). OSHA further finds that additional toxicity data are necessary before the Agency can reach any conclusions about the hazards of these substitutes relative to the hazards of silica. Given the concerns about potential harmful exposures to other substances that the alternatives might introduce in a workplace, as well as the potential for continued exposure to respirable crystalline silica, OSHA concludes that banning the use of silica sand as an abrasive blasting agent would not necessarily effectively mitigate risk. OSHA also concludes, as detailed in the FEA, that the general prohibition of silica sand in abrasive blasting is not technologically or economically feasible. Thus, the Agency has decided against a ban or limitation on the use of silica sand as an abrasive blasting agent in the rule.

BCTD urged OSHA to ban the use of silica sand as an abrasive blasting agent, but said that if banning the use of silica sand as an abrasive blasting agent was not possible, OSHA should prohibit the use of dry silica sand as an abrasive blasting agent (Document ID 2371, Attachment 1, p. 31). However, PCI noted that wet blasting with silica sand cannot be used to finish concrete surfaces (Document ID 2276, p. 9). CISC noted the problems associated with excessive water application on some worksites and argued that different environments and conditions had not been analyzed to determine the effectiveness of wet methods for abrasive blasting (Document ID 2319, p. 36).

OSHA finds that a separate requirement for the use of wet blasting methods when silica sand is used as a blasting agent is neither necessary nor appropriate. Under paragraph (f)(1) of the standard for general industry and maritime (paragraph (d)(3)(i) of the standard for construction), employers are required to use engineering and work practice controls, which include wet methods, to reduce and maintain employee exposure to respirable crystalline silica at or below the PEL, unless the employer can demonstrate that such controls are not feasible. Therefore, where employee exposures exceed the PEL from abrasive blasting with silica sand, employers must implement wet blasting methods whenever such methods are feasible and would reduce exposures, even if implementing this control does not reduce exposures to or below the PEL. By not specifically mandating the use of wet methods whenever sand is used as a blasting agent, the rule gives employers who cannot feasibly use wet methods flexibility to determine what controls to implement in order with comply with the PEL.

Charles Gordon argued for a partial ban on the use of silica sand as an abrasive blasting agent:

> Abrasive blasting with crystalline silica should be banned in confined spaces and in the maritime industry. That is where acute silicosis was most common and where it is hardest to protect adjacent workers.
>
> In all other areas and operations, the employer must consult MSDS's for substitutes for crystalline silica. If it is reasonable to conclude that a substitute for crystalline silica is a safer blasting media and will lead to a reasonable surface, then the employer must adopt the substitute. If the employer concludes that there is no safer reasonable substitute for crystalline silica, then the employer must keep a brief written record of that determination (Document ID 2163, Attachment 1, pp. 18–19).

While OSHA has declined to ban abrasive blasting with crystalline silica in any setting, the Agency considers that the process of selecting, evaluating, and adopting safer blasting agent substitutes where feasible, is consistent with the analysis required under paragraph (f)(1) of the standard for general industry and maritime (paragraph (d)(3)(i) of the standard for construction). As part of complying with this paragraph, employers must consider whether substitutes for crystalline silica abrasive blasting agents are available. Safer, effective, and feasible substitutes, where available, should be included as part of the package of feasible engineering and work practice controls required to reduce employee exposure to respirable crystalline silica to or below the PEL. The Agency expects that the requirements in the rule will incentivize

employer evaluation and adoption of substitute materials where substitution is appropriate for the task and shown to be safe, while avoiding substitutions that pose comparable or greater risk and maintaining flexibility for employers to determine what controls to implement in order to comply with the PEL.

CISC questioned the application of the hierarchy of controls to abrasive blasting, given the Agency's acknowledgement that respiratory protection will still be necessary in many situations even after implementing engineering and work practice controls (Document ID 2319, p. 37). As discussed above, the Agency maintains its position that adherence to the hierarchy of controls, which includes, where appropriate and feasible, substitutes for silica sand, wet blasting, LEV, proper work practices and housekeeping practices that reduce dust emissions, is essential to help reduce the extremely high exposures to respirable crystalline silica experienced by abrasive blasting workers and workers who may be near them. The FEA describes how extremely high exposures associated with dry abrasive blasting were significantly reduced where controls, such as wet blasting and non-silica containing abrasive blast media, were used (see Chapter IV of the FEA for further discussion). By using engineering controls to reduce these exposures, employees will be able to wear less restrictive respirators and will be better protected if their respiratory protection fails. Engineering controls also help protect others on the worksite from exposure to respirable crystalline silica. Therefore, requiring the use of controls, even where respiratory protection will also be required, is reasonably necessary and appropriate to protect employees from exposures to respirable crystalline silica.

The requirements in the rule for abrasive blasting are consistent with ASTM E 1132—06 and ASTM E 2625—09, the national consensus standards for controlling occupational exposure to respirable crystalline silica in general industry and in construction, respectively. Each of these standards clarifies that the hierarchy of controls (*i.e.,* using alternative materials, wet suppression systems, or exhaust ventilation, where feasible, to reduce exposures) applies to abrasive blasting and refers to the existing requirements under OSHA's ventilation standards (29 CFR 1910.94 and 29 CFR 1926.57).

Employee rotation. OSHA proposed, but is not including in the final rule, a provision specifying that the employer must not rotate employees to different jobs to achieve compliance with the PEL. The Agency proposed this prohibition because silica is a carcinogen, and OSHA considers that any level of exposure to a carcinogen places an employee at risk. With employee rotation, the population of exposed employees increases. A prohibition on rotation has been included in other OSHA health standards that address carcinogens, such as the standards for asbestos (29 CFR 1910.1001), chromium (VI) (29 CR 1910.1026), 1,3-butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), cadmium (29 CFR 1910.1027), and methylenedianiline (29 CFR 1910.1050). However, other standards addressing chemicals that were associated with non-cancer health effects, such as the standards for lead and cotton dust (29 CFR 1910.1025 and 29 CFR 1910.1043), do not include a prohibition on employee rotation to achieve the PEL. In response to a recommendation by the Small Business Advocacy Review Panel, OSHA solicited comment in the NPRM on the prohibition of employee rotation to achieve compliance with the PEL (78 FR 56273, 56290 (9/12/13)).

A prohibition on employee rotation to achieve compliance with the PEL was supported by EEI, Dr. George Gruetzmacher, and James Schultz (Document ID 2278, p. 4; 2357, p. 30; 3586, Tr. 3200). However, many commenters representing employers from the concrete, brick, tile, construction, electric utility, and foundry industries, over 20 trade associations, ASSE, and academics from the George Washington University Regulatory Studies Center urged OSHA to reconsider this prohibition (*e.g.,* Document ID 1785, p. 8; 1831, p. 15; 1992, p. 11; 2023, p. 7; 2024, p. 3; 2075, p. 3; 2102, p. 2; 2116, Attachment 1, pp. 34–35; 2119, Attachment 3, p. 7; 2145, pp. 5–6; 2147, p. 4; 2150, p. 2; 2154, Attachment 3, p. 7; 2185, pp. 6–7; 2195, p. 39; 2213, p. 4; 2215, p. 11; 2222, p. 2; 2241, p. 2; 2245, p. 3; 2255, p. 3; 2276, p. 10; 2279, p. 10; 2288, p. 12; 2296, p. 42; 2305, pp. 11, 15; 2309, p. 3; 2322, p. 14; 2326, p. 3; 2339, p. 4; 2348, Attachment 1, p. 36; 2355, p. 2; 2359, Attachment 1, p. 11; 2370, p. 2; 2379, Appendix 1, p. 69; 2380, Attachment 2, p. 21; 2384, p. 10; 2391, p. 2; 3245, p. 2; 3275, p. 2; 3489, p. 4; 3491, p. 4; 3578, Tr. 1035–1036, 1044; 3729, p. 3; 4194, p. 12; 4213, p. 7; 4226, p. 2).

Some commenters misunderstood the prohibition on employee rotation to achieve compliance with the PEL, or believed that the provision could be misunderstood by the regulated community. These commenters were concerned that the prohibition would preclude the use of rotation for other reasons, such as limiting exposure to physical hazards (*e.g.,* noise, vibration, repetitive motion stresses), providing cross-training, improving productivity, preventing fatigue, and filling in for other employees. OSHA explained in the NPRM that the proposed provision was not intended as a general prohibition on employee rotation. However, commenters including National Electrical Carbon Products, OSCO, the Ohio Cast Metals Association, PCI, and AFS expressed concerns that using employee rotation for these other reasons could be misinterpreted as a violation of the prohibition (*e.g.,* Document ID 1785, p. 8; 1992, p. 11; 2119, Attachment 3, p. 7; 2276, p. 10; 3489, p. 4;). NISA also asked the Agency to clarify that rotation may be performed for purposes other than achieving compliance with the PEL (Document ID 2195, p. 39).

NISA and the Chamber argued that if the risks of silicosis are subject to a threshold, then rotation to maintain exposures at low levels could only be protective (Document ID 2195, p. 39; 2288, p. 12; 4194, p. 12). ASSE argued that job rotation may be warranted as an alternative to burdensome engineering and administrative controls or PPE for tasks that involve some levels of exposure to silica, but are performed on an infrequent basis (Document ID 2339, p. 4; 3578, Tr. 1035–1036, 1044). ASSE, as well as Dal-Tile, noted that since silica is a ubiquitous substance and present in many raw materials, virtually all employees would be exposed to some level of respirable crystalline silica. Therefore, they argued that a prohibition on rotation in this circumstance does not make sense (Document ID 2147, p. 4; 2339, p. 4). In addition, AFS indicated that rotation as an administrative control is permitted by Canadian provinces with exposure limits for respirable crystalline silica (Document ID 4035, p. 14). OSHA also notes that the industry consensus standards for respirable crystalline silica, ASTM E 1132–06 and ASTM E 2625–09, expressly permit employee rotation as an administrative control to limit exposures (Document ID 1466, p. 4; 1504, pp. 3, 7).

OSHA does not consider employee rotation to be an acceptable alternative to avoid the costs associated with implementation of engineering and administrative controls, nor does the Agency consider that pervasive exposures to respirable crystalline silica justify allowing rotation. OSHA has nonetheless concluded that there may be situations where employee rotation

may be an acceptable measure to limit the need for respiratory protection. For example, OSHA has determined that the majority of employers covered by the rule will be in construction, and expects that most construction employers will implement the controls listed on Table 1 in paragraph (c) of the standard for construction. A number of tasks listed on Table 1 require respiratory protection, in addition to engineering and work practice controls, when performed for more than four hours per shift. Where the employer has implemented the engineering and work practice controls specified in Table 1, OSHA accepts the rationale that it may be reasonable to rotate employees to avoid exceeding the four-hour threshold that would trigger a requirement for respirator use. As discussed earlier in this section, respirator use can restrict visibility, impair communication, contribute to heat stress, strain the respiratory and cardiac systems, and exacerbate other safety and health hazards, such as trip and fall hazards. Under such circumstances, rotation of employees to limit use of respiratory protection may serve to reduce overall risks to employees. Rotation may also allow employees to continue to work if they are unable to pass the medical evaluation for respirator use, but are otherwise capable of performing the work.

OSHA also recognizes that a provision prohibiting employee rotation to achieve the PEL has little practical application for purposes of enforcement. Because the prohibition is limited to rotation for the sole purpose of achieving the PEL, an employer can provide any other reason to justify employee rotation. As described above, there are many legitimate reasons for an employer to rotate employees. As a result, OSHA has almost never cited employers for violating provisions prohibiting employee rotation for achieving the PEL. For the 7 standards that contain these provisions, which have been in effect for periods ranging from 8 to 29 years, Federal OSHA has only cited one of these provisions on one occasion.

For the reasons described above, OSHA has determined that a prohibition on employee rotation to achieve the PEL is not reasonably necessary or appropriate for the silica rule. The Agency recognizes that this determination differs from the determinations made in previous rulemakings addressing carcinogens. This is not intended as a reversal of OSHA's prior practice of prohibiting employee rotation to achieve the PEL for carcinogens, nor a precedent that will control future rulemakings, which necessarily will be based on different rulemaking records. Nevertheless, in this rule OSHA expects that the majority of employers covered by the rule will implement all feasible engineering and work practice controls to achieve the PEL (as the rule requires), and rotation will generally be used to limit use of respiratory protection that is triggered by working more than four hours in conditions where exposures are expected above the PEL even with the full implementation of engineering and work practice controls. OSHA finds that these factors justify omitting the prohibition on rotation from this rule. Therefore, the prohibition, which was included in the proposed rule, is not included in the final rule.

Respiratory Protection

Paragraph (g) of the standard for general industry and maritime (paragraph (e) of the standard for construction) establishes requirements for the use of respiratory protection, to which OSHA's respiratory protection standard (29 CFR 1910.134) also applies. Specifically, respirators are required under the rule: Where exposures exceed the PEL during periods necessary to install or implement engineering and work practice controls; where exposures exceed the PEL during tasks, such as certain maintenance and repair tasks, for which engineering and work practice controls are not feasible; and during tasks for which all feasible engineering and work practice controls have been implemented but are not sufficient to reduce exposure to or below the PEL. The standard for general industry and maritime also requires respiratory protection during periods when an employee is in a regulated area. The standard for construction also requires respiratory protection where specified by Table 1 of paragraph (c), but does not include a requirement to establish a regulated area, and thus does not contain a provision requiring the use of respirators in regulated areas.

These provisions of the rule for the required use of respirators are consistent with those proposed and are generally consistent with other OSHA health standards, such as methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). They reflect the Agency's determination that, as discussed in the summary and explanation of *Methods of Compliance*, respirators are inherently less reliable than engineering and work practice controls in reducing employee exposure to respirable crystalline silica. OSHA therefore is allowing reliance on respirators to protect against exposure to respirable crystalline silica only in specific circumstances where engineering and work practice controls are in the process of being installed or implemented (and thus are not yet fully operational), are not feasible, or cannot by themselves reduce exposures to the PEL. In those circumstances, OSHA's hierarchy of controls contemplates requiring the use of respirators as a necessary supplement to engineering, work practice, and administrative controls.

Paragraph (e)(1) of the standard for construction is revised from the proposed standard in order to clarify where respiratory protection is required. Paragraph (e)(1)(i) of the standard for construction provides that, for employers following the specified exposure control methods approach set forth in paragraph (c) of the standard for construction, respiratory protection is required under the standard where specified by Table 1. Table 1 in paragraph (c) of the standard for construction specifies respirator use for certain listed tasks; employers whose employees are engaged in those tasks have the option of following Table 1 in order to comply with the standard. The specific respiratory protection and minimum assigned protection factors (APF) for the tasks listed on Table 1 are discussed in the summary and explanation of *Specified Exposure Control Methods*. Paragraph (e)(1)(ii) of the standard for construction establishes where respirators are required for employees who are not performing tasks listed on Table 1 or where the engineering controls, work practices, and respiratory protection described in Table 1 are not fully and properly implemented (including where the employer chooses to follow paragraph (d) rather than follow paragraph (c)). Specifically, respirators are required in each of the situations described in paragraphs (e)(1)(ii)(A)–(C).

Paragraph (g)(1)(i) of the standard for general industry and maritime (paragraph (e)(1)(ii)(A) of the standard for construction) requires the use of respirators in areas where exposures exceed the PEL during periods when feasible engineering and work practice controls are being installed or implemented. OSHA recognizes that respirators may be needed to achieve the PEL under these circumstances. During these times, employees will have to use respirators for temporary protection until the hierarchy of controls has been implemented, at which point respirators will not be needed, provided the PEL is no longer exceeded. Employers must follow the

requirements for exposure assessment (*see* the summary and explanation of *Exposure Assessment*) to determine the extent of employee exposures once engineering and work practice controls are installed or implemented. While there is not an established time for exposure assessments to occur after the installation or implementation of controls, employers are required to reassess exposures whenever a change in control equipment may reasonably be expected to result in new or additional exposures above the action level. Employers must also ensure that employee exposures are accurately characterized, so they would need to reassess exposures after the installation or implementation of controls in order to meet this obligation.

OSHA anticipates that engineering controls will be in place by the dates specified in paragraphs (l)(2) and (l)(3) of the general industry and maritime standard (paragraph (k)(2) of the standard for construction) (*see* the summary and explanation of *Dates* for discussion of these requirements). However, the Agency realizes that in some cases employers may commence operations, install new or modified equipment, or make other workplace changes that result in new or additional exposures to respirable crystalline silica after the dates specified. In these cases, a reasonable amount of time may be needed before appropriate engineering controls can be installed and proper work practices implemented. When employee exposures exceed the PEL in these situations (see the summary and explanation of *Exposure Assessment* for an explanation of the requirements to assess employee exposure to respirable crystalline silica), employers must provide their employees with respiratory protection and ensure its use.

Paragraph (g)(1)(ii) of the general industry and maritime standard (paragraph (e)(1)(ii)(B) of the standard for construction) requires respiratory protection in areas where exposures exceed the PEL during tasks in which engineering and work practice controls are not feasible. OSHA anticipates that there will be few situations where no feasible engineering or work practice controls are available to limit employee exposure to respirable crystalline silica. However, the Agency recognizes that it may be infeasible to control respirable crystalline silica exposure with engineering and work practice controls during certain tasks, such as maintenance and repair tasks, and permits the use of respirators in these situations. For example, maintenance and repair to address temporary failures in operating systems or control systems to achieve the PEL such as failures of conveyance systems (elevators, conveyors, or pipes), failures of dust collecting bag systems, and section head failures at glass plant facilities as well as cupola (furnace) repair work and baghouse maintenance activities, may present a situation where engineering and work practice controls are not feasible and the use of respirators is permitted (Document ID 3493, p. 3; 1992, pp. 3, 5). In situations where respirators are used as the only means of protection, the employer must be prepared to demonstrate that engineering and work practice controls are not feasible.

Paragraph (g)(1)(iii) of the standard for general industry and maritime (paragraph (e)(1)(ii)(C) of the standard for construction) requires the use of respirators for supplemental protection in circumstances where feasible engineering and work practice controls alone are not sufficient to reduce exposure levels to or below the PEL. The employer is required to install and implement all feasible engineering and work practice controls, even if these controls alone cannot reduce employee exposures to or below the PEL. Whenever respirators are used as supplemental protection, the burden is on the employer to demonstrate that engineering and work practice controls alone are insufficient to achieve the PEL.

Paragraph (g)(1)(iv) of the standard for general industry and maritime requires employers to provide respiratory protection during periods when an employee is in a regulated area. Paragraph (e) of the standard for general industry and maritime requires employers to establish a regulated area wherever an unprotected employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL. OSHA included the provision requiring respirator use in regulated areas to make it clear that each employee is required to wear a respirator when present in a regulated area, regardless of the duration of time spent in the area. Because of the potentially serious results of exposure, OSHA has concluded that this provision is necessary and appropriate because it would limit unnecessary exposures to employees who enter regulated areas, even if they are only in a regulated area for a short period of time. The standard for construction does not include a requirement to establish a regulated area and thus, does not contain a similar provision in the respiratory protection section of the standard. Further discussion about this can be found in the summary and explanation of *Regulated Areas* and *Written Exposure Control Plan.*

OSHA proposed to require the use of respiratory protection when specified by the written access control plan—an option given to employers in the proposed rule as an alternative to establishing regulated areas. The Agency is not including an access control plan option in the rule (*see* discussion in the summary and explanation of *Regulated Areas*). Thus, without an option for an employer to develop a written access control plan, there is no reason to require respirators pursuant to a written access control plan.

Commenters, including Charles Gordon, a retired occupational safety and health attorney, and the American Industrial Hygiene Association recommended that OSHA require employers to provide employees with respirators upon request in certain situations where they are not required under the rule (*e.g.,* exposures below the PEL, Table 1 tasks for which respirators are not required) (Document ID 2163, Attachment 1, p. 16; 2169, p. 5). Dr. George Gruetzmacher, an industrial hygiene engineer, suggested that OSHA require respiratory protection and a respiratory protection program at the action level (Document ID 2278, p. 4).

While the Agency considers the level of risk remaining at the PEL to be significant, OSHA is not including a provision in this rule permitting employees to request and receive a respirator in situations where they are not required under the rule, nor is OSHA requiring respiratory protection and a respiratory protection program at the action level. There has been significant residual risk below the PEL in many previous health standards, but OSHA has only rarely included provisions permitting employees to request and receive a respirator to mitigate this risk (cotton dust (29 CFR 1910.1043(f)(1)(v)), lead (29 CFR 1910.1025(f)(1)(iii)), cadmium (29 CFR 1910.1027(g)(1)(v))) and the Agency has never established a requirement for respiratory protection and a respiratory protection program at a standard's action level.

OSHA anticipates that most construction employers covered by the rule will choose to implement the control measures specified in paragraph (c) of the standard for construction. Employers who implement the specified exposure control methods will not be required to assess employee exposures to respirable crystalline silica. Therefore, many employers covered by

the rule will not be aware if their employees are exposed to respirable crystalline silica at or above the action level. In order to impose a requirement for employers to provide respirators to employees exposed at or above the action level, OSHA would first need to require employers to assess the exposures of all employees in order to determine which employees are exposed at or above the action level. As discussed in the summary and explanation of *Specified Exposure Control Methods*, OSHA has concluded that such an exposure assessment requirement is not necessary for employers who implement the controls listed on Table 1.

With regard to permitting employees to request respirators for Table 1 tasks where respiratory protection is not specified, OSHA has relied on its technological feasibility analyses to determine which tasks can be performed at or below the PEL most of the time with the use of engineering and work practice controls only (*i.e.,* without respirators), and has concluded that employers who implement the controls listed on Table 1 for these tasks will provide equivalent overall protection for their employees as employers who perform exposure assessment and follow the alternative exposure control methods option provided in paragraph (d). If an employer follows Table 1 and Table 1 does not require use of a respirator, the employee's exposure will generally be below the PEL. There may be exceptions, but this is no different than when monitoring is conducted—monitoring two or four times a year does not perfectly characterize exposures, and there will be situations where exposures exceed the PEL even when good faith monitoring efforts by the employer indicate that exposures would be below the PEL.

If respirators were mandated at the action level or available upon employee request in situations where they are not required under the rule, employers would need to have respirators available at all times. Moreover, they would need to establish and implement a full respiratory protection program for all employees exposed to silica—a considerable undertaking for many employers that involves not only the purchase and retention of suitable respirators but an ongoing program of training, fit-testing, and maintenance. OSHA concludes that ''on request'' respirator use or requiring respiratory protection at the action level is not a practical or responsible approach to occupational safety and health regulation, and requiring such an investment in respirators would divert resources from the development and implementation of engineering controls that could more effectively reduce exposure levels to or below the PEL. Thus, OSHA's approach for reducing employee exposure to respirable crystalline silica in this and all other standards for air contaminants is to focus on engineering controls, rather than additional requirements for respiratory protection. For these reasons, OSHA has determined that a requirement for employers to provide respirators to employees upon request in situations where they are not required under the rule, or a requirement to provide respirators to employees exposed at or above the action level, is not reasonably necessary and appropriate for this respirable crystalline silica rule.

At the same time, OSHA does not prohibit employers from supplying or employees from using respirators outside the requirements of the rule. Therefore, although this rule does not include a provision providing employees with a right to request and receive respirators where not required by the rule, or requiring respiratory protection at the action level, employers may continue to provide respirators at the request of employees or permit employees to use their own respirators in situations where respirator use is not required, as provided for in the respiratory protection standard (29 CFR 1910.134(c)(2)(i)). OSHA's understanding, however, is that such use beyond what is required in a comprehensive OSHA standard is not a common occurrence, and the Agency does not expect non-mandated respirator use to proliferate with respect to this rule, as might well be the case if a provision requiring employers to provide respirators ''on request'' was written into the rule and would certainly be the case if the action level were used as the trigger for respirator use.

Industry commenters, including the Construction Industry Safety Coalition, OSCO Industries, American Foundry Society, National Association of Manufacturers, Glass Packaging Institute, American Composite Manufacturers Association, Small Business Administration's Office of Advocacy, U.S. Chamber of Commerce, and American Subcontractors Association, urged OSHA to consider discarding the hierarchy of controls and permitting the use of respirators in lieu of engineering and work practices controls in various circumstances, including: During short duration tasks performed intermittently (Document ID 1992, pp. 3, 5; 2319, p. 115); where exposures exceed the PEL for 30 days or less per year (Document ID 4229, p. 11); where exposures are below the respirable dust PEL of 5 mg/m^3 (Document ID 2380, Attachment 2, p. 24); for unanticipated maintenance issues (Document ID 3493, pp. 2–3); for small businesses (Document ID 3588, Tr. 3933–3936); for construction employers (Document ID 2187, p. 6; 2283, p. 3; 2349, p. 5); and for industries using large amounts of crystalline silica (*e.g.,* oil and gas operations where hydraulic fracturing is conducted) (Document ID 2283, p. 3; 3578, Tr. 1091). These comments are discussed in the summary and explanation of *Methods of Compliance.* As indicated in that section, OSHA's longstanding hierarchy of controls policy reflects the common assessment among industrial hygienists and the public health community that respirators are inherently less reliable than engineering and work practice controls in reducing employee exposure to air contaminants like respirable crystalline silica, and therefore, except in limited circumstances, they should not be allowed as an alternative to engineering and work practice controls, which are more reliable in controlling exposures. Thus, the Agency has not included additional situations where respirators are required in the respiratory protection paragraph, but as previously discussed, recognizes that, in some circumstances, such as certain maintenance and repair activities, engineering and work practice controls may not be feasible and the use of respiratory protection would be required.

Paragraph (g)(2) of the general industry and maritime standard (paragraph (e)(2) of the standard for construction) requires the employer to implement a comprehensive respiratory protection program in accordance with OSHA's respiratory protection standard (29 CFR 1910.134) whenever respirators are used to comply with the requirements of the respirable crystalline silica standard. As contemplated in the NPRM, a respiratory protection program that complies with the respiratory protection standard will ensure that respirators are properly used in the workplace and are effective in protecting employees. In accordance with that standard, the program must include: Procedures for selecting respirators for use in the workplace; medical evaluation of employees required to use respirators; fit-testing procedures for tight-fitting respirators; procedures for proper use of respirators in routine and reasonably

foreseeable emergency situations; procedures and schedules for respirator maintenance; procedures to ensure adequate quality, quantity, and flow of breathing air for atmosphere-supplying respirators; training of employees in respiratory hazards to which they might be exposed and the proper use of respirators; and procedures for evaluating the effectiveness of the program (78 FR 56274, 56467 (9/12/13)).

Many employers commented that they already have respiratory protection programs in place to protect employees from exposures to respirable crystalline silica (Document ID 1964; 2183, p. 1; 2276, p. 5; 2292, p. 2; 2301, Attachment 1, p. 5, 37; 2338, p. 2; 2366, p. 3; 3577, Tr. 711; 3583, Tr. 2386–2387). The International Union of Bricklayers and Allied Craftworkers and the International Union of Operating Engineers also indicated that their members' employers have established respiratory protection programs (Document ID 2329, p. 7; 3583, Tr. 2342, 2367).

The American Association of Occupational Health Nurses, Ameren Corporation, 3M Company, and Dr. George Gruetzmacher supported the reference to the respiratory protection standard (Document ID 2134; 2278, p. 3; 2313, p. 6; 2315, p. 4). For example, the 3M Company, which manufactures respirators, stated:

> 3M believes that by not requiring separate, individual respiratory protection provisions for respirable crystalline silica, the . . . rule should enhance consolidation and uniformity of the 1910.134 respirator requirements and could result in better compliance concerning the use of respiratory protection. Many of our customers use respirators to help protect workers from exposures to multiple contaminants and the reference in the respirable crystalline silica standard to the requirements of 1910.134 brings uniformity that could likely result in better compliance and protection for workers with exposures to silica and other materials (Document ID 2313, p. 6).

Expressing an opposing view, the National Stone, Sand, and Gravel Association commented that the respiratory protection paragraph was duplicative of existing requirements in 29 CFR 1910.134 (Document ID 2327, Attachment 1, p. 11).

OSHA concludes that referencing the requirements in the respiratory protection standard is important for ensuring that respirators are properly used in the workplace and are effective in protecting employees. Simply cross-referencing these requirements merely brings the applicable requirements to the attention of the employer; the cross-reference does not add to the employer's existing legal obligations, but it makes it more likely that the employer covered by this standard will meet all its obligations with regard to providing respirators when required to do so. Thus, the Agency has incorporated in the rule the reference to the respiratory protection standard that was proposed.

A representative of a local union and individual employees recommended specific respirators that they believed should be used to protect employees exposed to respirable crystalline silica (Document ID 1763, p. 3; 1798, p. 6; 2135). OSHA is not singling out silica-specific respirators but concludes instead that, for purposes of consistency and to ensure that the appropriate respirator is used, the provisions of the respiratory protection standard should apply to substance-specific standards unless there is convincing evidence that alternative respirator selection requirements are justified. The commenters who recommended specific respirators did not provide any evidence to support their recommendations. As no basis has been established for distinguishing respirator requirements for respirable crystalline silica from other air contaminants, OSHA finds it appropriate to adopt its usual policy of requiring employers to follow the provisions of the respiratory protection standard.

Paragraph (e)(3) of the standard for construction states that, for the tasks listed in Table 1 in paragraph (c), if the employer fully and properly implements the engineering controls, work practices, and respiratory protection described in Table 1, the employer shall be considered to be in compliance with paragraph (e)(1) of the standard for construction and with the requirements for selection of respirators in paragraphs (d)(1)(iii) and (d)(3) of 29 CFR 1910.134. Employers following Table 1 must still comply with all other provisions of 29 CFR 1910.134. Paragraphs (d)(1)(iii) and (d)(3) of 29 CFR 1910.134 require the employer to evaluate respiratory hazards in the workplace, identify relevant workplace and user factors, and base respirator selection on these factors. Because Table 1, in specifying the required respiratory protection and minimum APF for a particular task, has already done this, employers following Table 1 are considered to be in compliance with paragraphs (d)(1)(iii) and (d)(3) of 29 CFR 1910.134 for exposure to respirable crystalline silica. While not required for employers fully and properly implementing Table 1, paragraph (d)(3)(i)(A) of the respiratory protection standard (29 CFR 1910.134), which includes a table that can be used to determine the type or class of respirator that is expected to provide employees with a particular APF, can help employers determine the type of respirator that would meet the required minimum APF specified by Table 1. For example, Table 1 requires employers to provide employees with respiratory protection with an APF of 10 for some of the listed tasks. An employer could consult the table in 29 CFR 1910.134(d)(3)(i)(A) to find the types of respirators (*e.g.,* half-mask air-purifying respirator) that provide at least an APF of 10.

Unions, labor groups, and others urged OSHA to include a provision in the rule that allows employees to choose a powered air-purifying respirator (PAPR) in place of a negative pressure respirator (Document ID 2106, p. 3; 2163, Attachment 1, pp. 15–16; 2173, p. 5; 2244, p. 4; 2253, p. 7; 2256, Attachment 2, pp. 13–14; 2336, p. 7; 2371, Attachment 1, pp. 33–34; 3581, Tr. 1668–1669; 3955, Attachment 1, p. 2; 4204, pp. 78–79). They asserted that employees are more likely to get better protection from PAPRs, since they are more comfortable and thus, more likely to be used. They also argued that this will allow employees who may encounter breathing resistance or other difficulty in wearing a negative pressure respirator the ability to continue working in a job where silica exposures cannot feasibly be controlled below the PEL using engineering and work practice controls, without revealing their health status or health condition to their employer. They noted that previous health standards, such as the standards for asbestos (29 CFR 1910.1001(g)(2)(ii)) and cadmium (29 CFR 1910.1027(g)(3)(ii)), include provisions that allow employees to request and obtain a PAPR without revealing their health status or health condition to their employer.

In some cases, employers are already providing PAPRs to employees who request them. The North American Insulation Manufacturers Association reported that some member companies provide PAPRs upon employee request in certain circumstances, including accommodating religious practices and where the work is physically taxing (Document ID 4213, pp. 4–5). James Schultz, a former foundry employee from the Wisconsin Coalition for Occupational Safety and Health, testified that he was able to get his employer to provide a PAPR in some, but not all, instances when he requested one (Document ID 3586, Tr. 3201).

OSHA has long understood that it is good industrial hygiene practice to provide a respirator that the employee

considers acceptable. Under the respiratory protection standard, employers must allow employees to select from a sufficient number of respirator models and sizes so that the respirator is acceptable to and correctly fits the user (29 CFR 1910.134 (d)(1)(iv)). In addition, fit testing protocols under the respiratory protection standard require that an employee has an opportunity to reject respirator facepieces that the employee considers unacceptable (*see* 29 CFR 1910.134 Appendix A). The Agency also recognizes that in some circumstances employees may prefer PAPRs over other types of respirators. However, the rulemaking record does not provide a sufficient basis for OSHA to conclude that a requirement for employers to provide PAPRs upon request would lead to any meaningful additional benefit for employees exposed to respirable crystalline silica.

With regard to employees who have difficulty breathing when using a negative pressure respirator or cannot wear such a respirator, the respiratory protection standard requires employers to provide a PAPR if the employee's health is at increased risk if a negative pressure respirator is used (29 CFR 1910.134(e)(6)(ii)). Under the medical surveillance provisions of this rule, as well as the medical determination provisions of the respiratory protection standard (29 CFR 1910.134(e)(6)), the PLHCP's written medical opinion for the employer must contain any recommended limitations on the employee's use of respirators. Thus, including a provision in this rule that provides employees the ability to choose a PAPR in place of a negative pressure respirator would not appreciably add a benefit to what is already provided pursuant to required medical determinations. Therefore, OSHA finds that a provision specific to this rule permitting employees to request and receive a PAPR in place of a negative pressure respirator is neither necessary nor appropriate in this rule.

These requirements are consistent with ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, the national consensus standards for controlling occupational exposure to respirable crystalline silica in general industry and in construction, respectively. Each of these standards requires respirators to be used in work situations in which engineering and work practice controls are not sufficient to reduce exposures of employees to or below the PEL. Like the consensus standards, where the use of respirators is required, the standards that comprise this rule require employers to establish and enforce a respiratory protection program, as specified in 29 CFR 1910.134.

Housekeeping

Paragraph (h) of the standard for general industry and maritime (paragraph (f) of the standard for construction) requires employers to adhere to housekeeping practices. This is a new paragraph in the rule, but it is derived from the proposed requirements for cleaning methods (included in the Methods of Compliance paragraph in the proposed rule) and revised in response to further analysis and public comments. The requirements apply to all employers covered under this rule, including where the employer has fully and properly implemented the control methods specified in Table 1 in the standard for construction.

OSHA proposed a requirement that accumulations of crystalline silica be cleaned by high-efficiency particulate air (HEPA)-filter vacuuming or wet methods where such accumulations could, if disturbed, contribute to employee exposure that exceeds the PEL. The proposed rule would also have prohibited the use of compressed air, dry sweeping, and dry brushing to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to exposures exceeding the PEL. OSHA included these provisions in the proposed rule because evidence shows that use of HEPA-filtered vacuums and wet methods instead of dry sweeping, dry brushing and blowing compressed air effectively reduces worker exposure to respirable crystalline silica during cleaning activities. For example, a study of Finnish construction workers compared respirable crystalline silica exposure levels during dry sweeping to exposure levels when using alternative cleaning methods. Compared with dry sweeping, estimated worker exposures were about three times lower when workers used wet sweeping and five times lower when they used vacuums (Document ID 1163).

Some commenters, including the International Union of Bricklayers and Allied Craftworkers (BAC), the United Steelworkers (USW), the Building and Construction Trades Department, AFL–CIO (BCTD), the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), BlueGreen Alliance (BGA), and Upstate Medical University, expressed support for the proposed requirement to use HEPA-filtered vacuums and wet methods and to prohibit the use of compressed air and dry sweeping for cleaning activities (*e.g.,* Document ID 2282, Attachment 3, pp. 2, 18–19; 2329, p. 6; 2336, pp. 8–10; 2371, Comment 1, pp. 32–33; 2176, p. 3; 2244, p. 4). For example, UAW stated that the prohibitions on the use of compressed air and dry sweeping constitute sound industrial hygiene and are necessary to ensure that dust is controlled (Document ID 2282, Attachment 3, p. 18). Similarly, BCTD argued that the record firmly supports the use of HEPA-filtered vacuums and wet methods in lieu of compressed air and dry sweeping. BCTD pointed to specific studies referenced in OSHA's Preliminary Economic Analysis (PEA) that it believes demonstrate that performing housekeeping duties using compressed air or dry sweeping is a major source of silica exposure in a number of work operations (Document ID 2371, p. 34). BCTD also noted and agreed with studies in the PEA that recommend reducing silica exposure by eliminating these practices and instead relying on HEPA-filtered vacuums and wet methods (Document ID 2371, p. 34). Based on this evidence, BCTD agreed with the inclusion of the cleaning provisions. However, as discussed more extensively below, BCTD, and many of the other commenters that supported these provisions, argued that OSHA should expand the requirement to apply to cleaning whenever silica dust is present, not only where employee exposure could exceed the PEL (*e.g.,* Document ID 2240, p. 3; 2256, Attachment 2, p. 13; 2282, Attachment 3, p. 2; 4204, p. 77).

The National Institute for Occupational Safety and Health (NIOSH) also supported OSHA's proposed requirement to use wet methods and HEPA-filtered vacuums and prohibit the use of dry sweeping and compressed air during cleaning activities. In its written comments and testimony during the hearings, NIOSH cited U.S. Bureau of Mines research indicating that dry sweeping can increase respirable dust exposures, and provided several recommendations, including using water to wash down facilities that may have silica contamination, and using portable or centralized vacuum systems to clean off equipment (Document ID 2177, Attachment B, p. 38; 3579, p. 142).

Other commenters, such as Ameren, Acme Brick, the American Iron and Steel Institute (AISI), Fann Contracting, Inc., Leading Builders of America (LBA), Edison Electric Institute (EEI),

the National Association of Home Builders (NAHB), Eramet and Bear Metallurgy Company, Accurate Castings, the Asphalt Roofing Manufacturers Association (ARMA), the Small Business Administration's Office of Advocacy, the Glass Association of North America (GANA), the National Association of Manufacturers (NAM), the American Foundry Society (AFS), the Ohio Cast Metals Association (OCMA), the Tile Council of North America (TCNA), the North American Insulation Manufacturers Association (NAIMA), the Non-Ferrous Founders Society (NFFS), the National Concrete Masonry Association (NCMA), and the American Society of Safety Engineers (ASSE), objected to the proposed provisions (*e.g.,* Document ID 2023, pp. 5–6; 2082, pp. 5–7; 2116, Attachment 1, pp. 9–10, 32–33; 2261, p. 3; 2269, pp. 4, 22–23; 2291, pp. 2, 13, 18–20, 27; 2296, pp. 9, 41–42; 2315, p. 8; 2339, p. 9; 2349, pp. 4–5; 2357, pp. 7, 24–25; 2381, p. 2; 3432, p. 3; 3492, p. 2; 2119, Attachment 3, p. 7; 2215, p. 9; 2248, p. 8; 2279, pp. 7–8; 2348, Comment 1, p. 37; 2363, p. 3; 3490, p. 3; 3581, Tr. 1726–1727; 4213, p. 5). Many of these commenters cited problems with the use of wet methods or HEPA-filtered vacuums in particular circumstances, or noted specific circumstances where they believed dry sweeping or using compressed air was necessary.

For example, AISI indicated that using wet methods in areas of steel making facilities where molten metal is present creates the potential for a significant and immediate safety hazard from steam explosions (Document ID 2261, p. 3; 3492, p. 2). The National Concrete Masonry Association argued that wet methods cannot generally be used in concrete block and brick plants:

> In general, wet methods to control dust are NOT appropriate in the concrete masonry as a replacement for dry-sweeping . . . Not only do wet floors create fall hazards, any dust or debris that contains cement dust will react and harden in the presence of water, creating additional problems in concrete block production facilities (Document ID 2279, pp. 7–8).

EEI and Ameren indicated that the use of wet methods can also cause fly ash to harden (Document ID 2357, pp. 24–25; 2315, p. 8).

NAHB indicated that use of wet methods in residential construction would damage many surfaces and could lead to structural problems, indoor air quality degradation, and the development of molds (Document ID 2296, p. 37). It argued that there are many circumstances in residential construction where dry sweeping is the only alternative for cleanup activities (Document ID 2296, pp. 41–42). LBA indicated that HEPA-filter vacuums will not collect large debris and that, during the collection process, dirt will clog the HEPA filter, preventing cleaning. It stressed that dry sweeping must be used (Document ID 2269, pp. 4, 22–23). Ameren and EEI argued that dry sweeping should be allowed because wet methods cannot be used around certain electrical equipment and when temperatures are below freezing (Document ID 2315, p. 8; 2357, pp. 7, 24–25). Fann Contracting said that it is necessary to dry sweep at the end of the milling process when milling roadways in order to clean the loose leftover material. It indicated that if water is used, it would create a thin layer of mud on the bottom of the milled trench, which would interfere with the paving process (Document ID 2116, Attachment 1, pp. 9–10, 32–33).

Commenters representing foundries argued that wet methods and HEPA-filtered vacuuming were not appropriate for cleaning in foundries. For example, Accurate Castings explained that wet methods would result in water going into the shell sand mold and would eventually lead to an explosion when molten metal enters the mold. It stressed that it must use compressed air for these applications (Document ID 2381, p. 2). Similarly, ESCO Corporation commented that it cannot use water in foundries due to potential for fire and explosion hazards. ESCO Corportation stressed that it also must use compressed air to clean castings (Document ID 3372, pp. 2–3). AFS also argued that the use of wet methods in foundries increases the likelihood of explosions as well as tripping hazards (Document ID 3490, p. 3). OCMA argued that vacuums can cause damage to molds and using wet methods would damage equipment, make floors slippery, and cause explosions (Document ID 2119, Attachment 3, p. 7). NFFS argued that compressed air is ''the only viable means of cleaning complex or intricate castings'' (Document ID 2247, p. 8; 2248, p. 8). AFS argued that a ban on dry sweeping would require the vacuuming of hundreds of tons per week in many foundry operations, and that collecting this amount of sand with a vacuum system is not feasible. AFS also expressed concern that the proposed rule would prohibit use of operator-driven power (dry) sweepers in foundries, arguing that power sweepers substantially reduce the release of fugitive dust from aisles and other vehicle traffic areas and that these machines cannot be replaced with wet sweepers because the quantity of material handled would gum up the sweeping mechanism with sludge (Document ID 2379, Attachment B, pp. 33–34).

Several commenters indicated that compressed air is needed to clean difficult to reach places (*e.g.,* Document ID 2215, p. 9; 2279, pp. 7–8; 3581, Tr. 1726; 2023, p. 5; 2348, Comment 1, p. 37; 3544, pp. 15–16; 4213, pp. 5; 2119, Attachment 3, p. 7). For example, GANA stressed that it is ''not technologically feasible to prohibit completely the use of compressed air for clean-up,'' because tight spaces and hard-to-reach crevices can only be cleaned using compressed air (Document ID 2215, p. 9). NAM testified to the need to use compressed air in space-restricted situations and where there is a potential for explosions when using water and there are no other alternatives (Document ID 3581, Tr. 1726). Acme Brick also indicated that compressed air must be used in tight spaces or under equipment because these areas cannot be accessed by brooms or vacuums (Document ID 2023, p. 5).

After reviewing the evidence in the record, OSHA concludes that use of wet methods and HEPA-filter vacuums, as proposed, is highly effective in reducing respirable crystalline silica exposures during cleaning and that compressed air, dry sweeping, and dry brushing can contribute to employee exposures. However, OSHA finds convincing evidence that wet methods and HEPA-filtered vacuums are not safe and effective in all situations. Therefore, the Agency has revised the proposed language to take these situations into account. Paragraph (h)(1) of the standard for general industry and maritime (paragraph (f)(1) for construction) allows for the use of dry sweeping and dry brushing in the limited circumstances where wet methods and HEPA-filtered vacuuming are not feasible. Paragraph (h)(2) of the standard for general industry and maritime (paragraph (f)(2) for construction) allows employers to use compressed air for cleaning where the compressed air is used in conjunction with a ventilation system that effectively captures the dust cloud created by the compressed air, or where no alternative method is feasible. These limited exceptions will encompass the situations described above by commenters, and give them the necessary flexibility in permitting the use of compressed air, dry sweeping, or dry brushing in situations where wet methods or HEPA-filtered vacuums are infeasible, or where the dust cloud created by use of compressed air is

captured and therefore does not present a hazard to employees. Thus, in situations where wet methods or HEPA-filtered vacuuming would not be effective, would cause damage, or would create a hazard in the workplace, the employer is not required to use these cleaning methods. OSHA concludes that these limited exceptions balance the need to protect employees from exposures caused by dry sweeping, dry brushing, and the use of compressed air with stakeholder concerns about the need to use such methods under certain circumstances.

Although OSHA is allowing for dry sweeping and dry brushing and the use of compressed air for cleaning clothing and surfaces under these limited circumstances, the Agency anticipates that these circumstances will be extremely limited. The ''unless'' clause indicates that the employer bears the burden of showing that wet methods are not feasible in a particular situation, and OSHA expects that the vast majority of operations will use wet methods that minimize the likelihood of exposure. Where the employer uses dry sweeping, therefore, the employer must be able to demonstrate that HEPA-filtered vacuuming, wet methods, or other methods that minimize the likelihood or exposure are not feasible. Similarly, where compressed air is used to clean clothing and surfaces without a ventilation system designed to capture the dust cloud created, the employer must be able to demonstrate that no alternative cleaning method is feasible.

OSHA has also revisited the triggers for these provisions based on stakeholder comments. Some stakeholders disagreed with triggering these provisions based on the PEL. For example, the American Federation of State, County, and Municipal Employees (AFSCME), the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), BCTD, BAC, UAW, USW, and others argued that dry sweeping and use of compressed air should be prohibited at any exposure level, not just where the use of such measures contributes to exposures that exceed the PEL (*e.g.,* Document ID 2142, p. 3; 2257, Attachment 2, p. 13; 2282, Attachment 3, pp. 18–19; 2329, p. 6; 2336, p. 10; 2371, Comment 1, pp. 32–33). AFL–CIO stated:

> OSHA has determined that exposure at the PEL still poses a significant risk to workers. All feasible efforts should be made to reduce those risks. OSHA should follow the well-established approach in its other health standard[s] and prohibit practices of dry sweeping, [use of] compressed [air] and require HEPA-filter[ ] vacuuming or wet methods whenever silica dust is present (Document ID 2257, Attachment 2, p. 13).

Similarly, AFSCME indicated that there is no reason why cleaning methods need to be tied to the PEL. It argued that requiring that all accumulations be dealt with in a uniform way would provide clarity for employers and employees alike (Document ID 2142, p. 3). BCTD argued that OSHA's proposed requirements would be unenforceable because they are tied to overexposure (Document ID 2371, Attachment 1, p. 33). Finally, AFL–CIO also recommended that OSHA expand the proposed requirements to require that accumulations of dust be kept as low as practicable. It noted that this requirement has appeared in previous OSHA health standards that regulate exposure to dusts, such as asbestos (29 CFR 1910.1001), lead (29 CFR 1910.1025), and cadmium (29 CFR 1910.1027).

On the other hand, the Precast/Prestressed Concrete Institute (PCI) argued that a general prohibition on the use of compressed air, dry brushing, and dry sweeping to clean areas where silica-containing material has accumulated is too broad, and not directly related to a particular exposure risk. It maintained that the use of compressed air and dry sweeping should be permitted as long as silica exposures are below the PEL (Document ID 4029, Cover Letter 1, p. 3). Similarly, the National Tile Contractors Association (NTCA) and TCNA both recommended that the proposed language be changed to read as follows:

> To the extent practical compressed air, dry sweeping, and dry brushing shall not be used to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL (Document ID 2267, p. 3; 2363, p. 3).

After consideration of these comments, OSHA has decided to revise the trigger for the housekeeping provisions in the rule to apply to situations where dry sweeping, dry brushing or use of compressed air could contribute to employee exposure to respirable crystalline silica, regardless of whether that exposure exceeds the PEL. OSHA finds this change is necessary because the risk of material impairment of health remains significant at and below the revised PEL of 50 μg/m^3, including at the new action level of 25 μg/m^3. By triggering the housekeeping provisions wherever the use of dry sweeping, dry brushing, and compressed air could contribute to employee exposures, OSHA aims to minimize this risk. The Agency concludes that the limited exceptions discussed above not only balance the concerns of employers with the need to protect employees, but align the rule with the realities of the workplace, which do not always lend themselves to the method that produces the lowest silica exposure.

OSHA has decided not to include an affirmative requirement to clean accumulations of crystalline silica that could, if disturbed, contribute to employee exposure that exceeds the PEL. In addition, the Agency has determined that it is not appropriate for the respirable crystalline silica rule to require accumulations of dust to be kept at the lowest level practicable. As noted above, OSHA recognizes that exposure to respirable crystalline silica is hazardous at concentrations below the PEL. However, crystalline silica is ubiquitous in many work environments. Crystalline silica is a component of the soil and sand at many construction sites and other outdoor workplaces, and may be present in large quantities at many other workplaces such as foundries and oil and gas drilling sites where hydraulic fracturing is performed. For purposes of cleaning, the employer may not be able to distinguish large crystalline silica particles from the fine particles which can, if airborne, be respirable. In many cases, the employer may not be able to distinguish crystalline silica particles from other workplace dusts. Because of these factors, many unique to respirable crystalline silica, OSHA is convinced that the best approach to address potentially hazardous exposures from cleaning is by requiring proper housekeeping practices to minimize exposure to respirable crystalline silica.

OSHA also received a number of miscellaneous comments on the proposed provisions, including suggestions for items the Agency should or should not include in the final rule and questions about the application of the proposed provisions to particular situations. For example, ARMA argued that OSHA should not require HEPA filters on central vacuum systems that discharge outdoors or into a non-occupied area, such as a baghouse (Document ID 2291, pp. 19–20). GPI also indicated it uses central vacuum systems, and argued that OSHA should allow for vacuum systems that discharge outside the facility (Document ID 2290, pp. 4–5). OSHA agrees that a prohibition on central vacuum systems that discharge respirable crystalline silica outside of the workplace is unnecessary, because such systems do not contribute to employee exposure. OSHA clarifies that the rule therefore

allows for use of vacuum systems that discharge respirable crystalline silica outside of the workplace. These requirements are similar to housekeeping requirements in other OSHA health standards, such as the standards for lead (29 CFR 1910.1025) and cadmium (29 CFR 1910.1027). Discharge of respirable crystalline silica from such systems may be subject to environmental regulations; *see* Section XIV, Environmental Impacts.

Occupational & Environmental Health Consulting Services (OEHCS) urged OSHA to require vacuums that meet the definition of a Portable High-Efficiency Air Filtration (PHEAF) device (Document ID 1953, Comment 1, pp. 4–6). This suggested revision would involve a requirement for field testing of portable air filtration devices using a laser particle counter to ensure that HEPA filters function as intended. OEHCS argued that, in many cases, HEPA filters do not perform effectively in the field due to inadequate, damaged, or deteriorating sealing surfaces; replacement filters that do not fit correctly; filter cabinets that are damaged; filters that are punctured; and other problems (Document ID 1953, Comment 1, p. 2). OEHCS further indicated that it is participating in an ongoing, multi-year research effort with the National Institutes of Health to test HEPA-filtered equipment (Document ID 1953, Comment 1, p. 2). However, OEHCS did not provide documentation to support the use and effectiveness of meeting the requirements and definition of this device, nor is there other evidence in the rulemaking record supporting such a requirement. OSHA encourages employers to ensure that HEPA filters function as intended in the field. However, lacking adequate documentation and support in the record, OSHA has concluded that it is not appropriate to include a requirement that HEPA vacuums meet the PHEAF standards in the rule.

OSHA also received a few comments related to the use of compressed air, dry sweeping, and dry brushing to clean clothing. Specifically, NIOSH and ASSE maintained that there are ways that clothing can be safely cleaned using compressed air. The two organizations advocated for the use of clothes cleaning booths, also referred to as mobile air showers (Document ID 2177, Attachment B, pp. 15, 38; 3403, p. 5; 2339, p. 9). This technology uses compressed air to clean clothes by blowing dust from an employee's clothing in an enclosed booth. Dust is blown out of the employee's breathing zone and is captured by a filter. NIOSH argued that the booths adequately capture the dust and prevent exposure to employees and the environment (Document ID 3403, p. 5). OSHA recognizes that this technology may be useful for cleaning dust off of clothing, and the rule does not prohibit the use of such systems. Clothes cleaning booths that use compressed air to clean clothing are permitted under the rule, as long as the compressed air is used in conjunction with a ventilation system that effectively captures the dust cloud created by the compressed air. The provision has been modified from that proposed to clearly allow the use of compressed air in conjunction with a ventilation system that effectively captures the dust cloud that is created, preventing it from entering the employee's breathing zone.

In addition, the American Subcontractors Association (ASA) offered a comment related to dry brushing. It argued that the term ''dry brushing'' could be misunderstood, and that an employer could receive a citation if an employee reflexively brushes visible dust off clothing (Document ID 2187, p. 6). OSHA's intent in the proposed rule was to restrict dry brushing activity that was comparable to dry sweeping, such as using a brush as a tool to clean clothing or surfaces. OSHA clarifies that the rule does not prohibit employees from using their hands to remove small amounts of visible dust from their clothing.

Finally, OSHA received comments on how often or at what point employers need to clean up dust in their facility. For instance, HalenHardy, a firm that provides products and services to limit exposures to dangerous dusts, argued that there should be some visible evidence of silica dust in order to require cleaning (Document ID 3588, Tr. 3920–3922). NCMA commented that dry sweeping can produce dust and indicated that best practices suggest that it is important to prevent the dust or debris from reaching the floor. If not cleaned regularly, this can lead to buildups of dust on the floor (Document ID 2279, p. 7).

The proposed rule would have required accumulations of crystalline silica to be cleaned by HEPA-filtered vacuuming or wet methods where such accumulations could, if disturbed, contribute to employee exposure to respirable crystalline silica that exceeds the PEL. As explained above, OSHA's final rule does not require employers to clean up dust. However, OSHA agrees that housekeeping is an important work practice to be used to limit employee exposures. And, as discussed in Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis, some employers will need to perform housekeeping in order to limit employee exposures to the PEL. In recognition of this fact and because some cleaning methods can contribute to employee exposure, OSHA has included housekeeping as one of the items employers must address in their written exposure control plans (*see* the summary and explanation of *Written Exposure Control Plan*).

Moreover, for employers following the general industry and maritime standard and, in construction, for tasks not listed in Table 1, or where the employer does not fully and properly implement the control methods described in Table 1, the rule requires employers to assess the exposure of each employee who is or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level. Where exposure assessment reveals that an employee's exposure exceeds the PEL, the rule requires employers to use engineering and work practice controls to reduce and maintain employee exposure to or below the PEL, unless the employer can demonstrate that such controls are not feasible. Good housekeeping is one such work practice control that employers should consider. And, as NCMA suggests, employers may choose to clean up dust regularly as a best practice.

In addition, paragraph (c) of the standard for construction includes several housekeeping provisions that apply to employers who choose to follow Table 1. For instance, paragraphs (c)(1)(vii) and (c)(1)(viii) of the standard for construction require employers whose employees are engaged in a task using handheld or stand-mounted drills (including impact and rotary hammer drills) or dowel drilling rigs for concrete to use a HEPA-filtered vacuum when cleaning holes. Similarly, under paragraph (c)(1)(xiii), when using a walk-behind milling machine or floor grinder indoors or in an enclosed area, milling debris must be cleaned up using a HEPA-filtered vacuum prior to making a second pass over an area. This prevents the milling debris from interfering with the seal between machine and floor and minimizes the gap. Additionally, it prevents debris from being re-suspended and acting as another source of exposure.

If an employer chooses to follow paragraph (c) of the standard for construction, then the employer must implement any applicable housekeeping measures specified in Table 1. An employer who does not do so has not fully and properly implemented the controls identified on Table 1 and, thus, will be required to assess and limit the

exposure of employees in accordance with paragraph (d). For example, if an employer has an employee who is using a handheld or stand-mounted drill, the employee must use a HEPA-filtered vacuum when cleaning holes. Any method for cleaning holes can be used, including the use of compressed air, if a HEPA-filtered vacuum is used to capture the dust. If a HEPA-filtered vacuum is not used when cleaning holes, then the employer must assess and limit the exposure of that employee in accordance with paragraph (d).

While the paragraph on housekeeping (paragraph (f) of the construction standard) also applies when employers are following paragraph (c), the employer must ensure that all of the engineering controls and work practices specified on Table 1 are implemented. For example, paragraph (f)(2)(i) of the construction standard permits the use of compressed air when used in conjunction with a ventilation system that effectively captures the dust cloud. However, to fully and properly implement the controls on Table 1, an employer using compressed air when cleaning holes drilled by handheld or stand-mounted drills or dowel drilling rigs for concrete must use a HEPA-filtered vacuum to capture the dust, as specified in paragraphs (c)(1)(vii) and (c)(1)(viii), not just a ventilation system as specified in paragraph (f)(2)(i).

The housekeeping requirements of the rule are generally consistent with the provisions of the industry consensus standards, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities. Both consensus standards specify that compressed air shall not be used to blow respirable crystalline silica-containing materials from surfaces or clothing, unless the method has been approved by an appropriate Regulatory agency (4.4.3.3. and 4.4.3.2, respectively). Both consensus standards also list HEPA vacuums, water spray, and wet floor sweepers among available means to reduce exposure to dust (4.4.3.6. and 4.4.3.5, respectively). In addition, ASTM E 1132–06 includes restrictions on dry sweeping (4.4.3.2).

Written Exposure Control Plan

Paragraph (f)(2) of the standard for general industry and maritime (paragraph (g) of the standard for construction) sets forth the requirements for written exposure control plans, which describe methods used to identify and control workplace exposures, such as engineering controls, work practices, and housekeeping measures. OSHA did not propose a requirement for a written exposure control plan, but raised it as an issue in the preamble of the Notice of Proposed Rulemaking (NPRM) in Question 53 under *Methods of Compliance* (78 FR 56273, 56289 (9/12/13)). Written exposure control plans are included in ASTM International (ASTM) standards, E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica (Section 4.2.6) and E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities (Section 4.2.5), and in a draft standard by the Building and Construction Trades Department, AFL–CIO (BCTD) (Document ID 1466, p. 2; 1504, p. 2; 1509, pp. 3–4).

The only written plan that OSHA proposed was an access control plan, which was an alternative approach to establishing regulated areas; it described methods for identifying areas where exposures exceeded the permissible exposure limit (PEL), limiting access to those areas, communicating with others on the worksite, and providing personal protective equipment (PPE) to individuals entering those areas. Several stakeholders commented on the proposed written access control plans, whether or not the rule should contain a written plan, and their preference for the type of written plan.

A number of commenters questioned the practicality of a written access control plan in workplaces with continually changing tasks, conditions, or materials, which they argued can lead to the need for multiple plans and subsequent costs. The National Stone, Sand, and Gravel Association (NSSGA) commented that written access control plans and establishing boundaries are not feasible in many workplaces, such as aggregate facilities or large construction sites, because of varying silica amounts in materials (Document ID 2327, Attachment 1, p. 20). The Construction Industry Safety Coalition (CISC) stated that a written access control plan is impractical in construction and especially difficult and costly for small businesses because a different plan would need to be developed for each project, as a result of changing materials, tasks, and environmental conditions (Document ID 2319, pp. 5–6, 91–92). Associated Builders and Contractors, Inc. (ABC), Associated General Contractors of America, and American Society of Safety Engineers (ASSE) expressed similar concerns about constantly changing conditions on construction sites (Document ID 2289, pp. 6–7; 2323, p. 1; 4201, p. 2). The National Federation of Independent Business and Leading Builders of America also expressed concerns about time and resource burdens that a requirement for a written access control plan would impose on construction companies or small businesses (Document ID 2210, Attachment 1, p. 7; 2269, p. 22). ABC and CISC further stated that a written access control plan is not needed if employees are trained (Document ID 2289, pp. 6–7; 4217, p. 25).

CISC noted that section 4.2.5 of the ASTM standard E 2625–09 limits the need for a written exposure control plan to areas where overexposures are persistent, and contemplated that it is not needed when the PEL may be exceeded on a particular day because of conditions such as weather or silica content in a material. CISC stated that OSHA's requirement for a regulated area or written access control plan when exposures can reasonably be expected to exceed the PEL deviated from section 4.2.5 of the ASTM standard (Document ID 2319, p. 89; 1504, p. 2). OSHA clarifies that a written access control plan, which describes specified methods for limiting access to high-exposure areas, is different from a written exposure control plan, which can address specified protections for controlling exposure other than limiting access to high-exposure areas.

Commenters representing industry, labor, and employee health advocate groups addressed the issue of what, if any, type of written plan should be required and what level of respirable crystalline silica exposure should trigger that requirement. Some industry representatives favored a written access control plan over a regulated area, while others opposed a written exposure control plan. For example, in comparing regulated areas and the written access control plan, Edison Electric Institute favored the flexibility of the written access control plan and stated that it might use that option in larger areas or for activities that can change over time. It opposed a written exposure control plan, asserting that the training required by OSHA's hazard communication standard (HCS) was sufficient to keep employees informed (Document ID 2357, pp. 33, 37). The Non-Ferrous Founders' Society expressed concerns about costs if a consulting industrial hygienist would need to be hired to develop a written access control plan (Document ID 2248, p. 13). The National Association of Home Builders (NAHB) stated that some of its members would

prefer a written access control plan over regulated areas, while other members expressed concern that developing a written access control plan might be difficult for many small companies. NAHB also commented that many small companies would not have the knowledge to develop a written exposure control plan and would have to hire a professional to develop it. NAHB opposed a written exposure control plan, stating that a standard checklist was adequate for protecting employees from exposure (Document ID 2296, pp. 40 and 41). On the other hand, National Electrical Carbon Products (NECP) commented that if OSHA required a written plan, NECP would prefer an exposure control plan rather than an access control plan. It stated that OSHA's proposed access restrictions do not relate to the goal of ensuring compliance with the PEL (Document ID 1785, pp. 6–7).

Commenters from labor organizations and employee health advocate groups supported the inclusion of a written exposure control plan. For example, BCTD stated that the proposed written access control plan could be used as a starting point for the development of a written exposure control plan, which it said should be required for every employer that has employees who may be exposed to respirable crystalline silica (Document ID 2371, Attachment 1, pp. 14–16). International Union of Operating Engineers (IUOE), Public Citizen, American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), and International Union of Bricklayers and Allied Craftworkers (BAC) also supported a requirement for a written plan for all covered employers and not just those with regulated areas or exposures exceeding the PEL (Document ID 2262, p. 42; 2249, p. 3; 4204, p. 62; 4219, pp. 25–26; 4223, p. 119).

Other commenters, such as ASSE, favored a written exposure control plan for suspected or documented overexposure scenarios (Document ID 2339, p. 8). The National Industrial Sand Association (NISA) originally opposed a written exposure control program in its prehearing comments (Document ID 2195, p. 38). However, in its post-hearing comments, it supported one, stating that formulating and writing down an exposure control program would ensure that an employer thinks through the engineering and administrative controls required to achieve compliance in situations with persistent overexposures. NISA also stated that the plan would help employers defend against potential liability by documenting due care (Document ID 4208, pp. 20–21).

The American Foundry Society (AFS) disagreed with the need for a separate written exposure control plan and instead called for planning as part of other business initiatives. It supported written exposure control plans in enforcement situations. AFS favored an approach similar to that in the ASTM standard. AFS stated that the ASTM's approach, which involves identifying and analyzing dust sources in scenarios with overexposures to determine effective controls, was more effective in reducing exposures than requiring controls to be installed by a certain date (Document ID 2379, Appendix 1, pp. 61–62; 4229, p. 26).

Advocates of written exposure control plans explained why they supported those plans. The National Institute for Occupational Safety and Health (NIOSH) stated that written exposure control plans could be a simple mechanism for ensuring performance of maintenance checks and, for construction employers, maintaining Table 1 conditions (Document ID 2177, Attachment B, pp. 16–17). Dr. Paul Schulte, Director of the Education and Information Division at NIOSH, testified that ''. . . a written plan would greatly improve reliability of the protection provided.'' (Document ID 3403, p. 5). AFL–CIO, NISA, and BCTD agreed (Document ID 4204, p. 61; 4208, pp. 20–21; 4223, p. 74). Eileen Betit, representing BCTD, testified:

> Written exposure control plans are important for identifying operations that will result in exposures, the specific control measures, and how they will be implemented and the procedures for determining if controls are being properly used and maintained. Such plans also facilitate the communication of this information to other employers on multi-employer worksites so that they, in turn, can take steps to protect their employees. Without such plans, there's no assurance that employers and employees will take a systematic and comprehensive approach to identifying, controlling, and sharing information about silica exposures on job sites (Document ID 3581, Tr. 1569–1570).

The United Steelworkers (USW), Public Citizen, the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), and AFL–CIO also supported a requirement for a written exposure control plan as a method to continually, systematically, or comprehensively identify or control exposures (Document ID 2336, p. 9; 2249, p. 2; 2282, Attachment 3, p. 17; 4204, p. 60). NIOSH, Public Citizen, and BAC also stated that written exposure control plans are a useful way to communicate protections to employees (Document ID 2177, Attachment B, pp. 16–17; 2249, p. 3; 2329, p. 5).

BlueGreen Alliance, UAW, USW, and AFL–CIO also supported a written plan because requiring the written plan would be consistent with the many other OSHA substance-specific standards that include written plans or programs (Document ID 2176, p. 3; 2282, Attachment 3, p. 17; 3584, Tr. 2540; 4204, p. 62). In addition, commenters observed that other U.S. and Canadian regulatory agencies require written plans. Frank Hearl, Chief of Staff at NIOSH, stated that the Mine Safety and Health Administration requires a dust control plan to be filed at coal mines (Document ID 3579, Tr. 235–236). In addition, AFL–CIO and BCTD noted that written dust or silica control plans are included in a proposed standard for the Canadian Province of British Columbia and a standard promulgated in the Canadian Province of Newfoundland (Document ID 4204, p. 61; 4223, p. 73 Fn. 14; 4072, Attachment 38, pp. 6–7, Attachment 41, p. 7).

BCTD stated that a requirement for a written exposure control plan would not be unduly burdensome to employers because creating such plans is an extension of planning functions in construction (Document ID 4223, pp. 74–80). In fact, several hearing participants testified that written safety or hazard control plans are already being developed and used in the construction industry (Document ID 4223, pp. 74–80; 3580, Tr. 1383–1385; 3583, Tr. 2267–2268, 2385; 3585, Tr. 3093–3094; 3587, Tr. 3560). For example, Kevin Turner, Director of Safety at Hunt Construction Group and representing CISC testified: ''. . . we require a site-specific safety plan which addresses the hazards dealt with in that [particular] contractor's scope of work.'' (Document ID 3580, Tr. 1383).

In addition, written plans are consistent with general industry practices. For example, the National Service, Transmission, Exploration, and Production Safety Network (STEPS Network), whose members are involved in the oil and gas industry, recommends a written plan that describes how exposures to respirable crystalline silica will be reduced or prevented (Document ID 4024, Attachment 2, p. 1). Member companies of the National Ready Mix Concrete Association, who hire third-party contractors to chip out their drum mixers, follow strict written practices and procedures to ensure that exposures do not exceed the PEL. Specifically, they require the contractors to submit to them a company-approved safety and health policy and procedures and plans (Document ID 2305, pp. 8–9). AFL–CIO

submitted to the record a silica dust control plan developed by Sonic Drilling (Document ID 4072, Attachment 11).

BCTD stressed that preparing a written exposure control plan does not have to be burdensome and, along with BAC and AFL–CIO, pointed to online tools that are available to help users create written exposure control plans, such as the CPWR-Center for Construction Research and Training (CPWR) tool, available free of charge, on the silica-safe.org Web site (Document ID 2329, p. 5; 4204, p. 61; 4223, pp. 80–81; 4073, Attachment 5a and 5b). AFL–CIO and BCTD also pointed to guidance products and model exposure control plans from the Canadian Province of British Columbia as additional resources for assisting users in developing written exposure control plans (Document ID 4204, p. 61; 4223, p. 81; 4072, Attachment 14, 19, 20). Industry associations are another resource to help employers prepare written plans. For example, Anthony Zimbelman, general contractor, representing NAHB, testified that his industry association teaches courses and helps businesses develop safety plans (Document ID 3587, Tr. 3559–3560).

OSHA finds the evidence on the benefits of a written exposure control plan—as distinct from the proposed written access control plan—convincing and has concluded that a requirement for a written exposure control plan is needed for both the standard for general industry/maritime and the standard for construction because the plan will improve employee protections. OSHA agrees with commenters who stated that a written plan should not be limited to scenarios where the PEL is exceeded. Therefore, OSHA concludes that it is appropriate for the rule to require a written exposure control plan, instead of a written access control plan that would only apply to restricting access to areas where exposures to respirable crystalline silica exceed the PEL. Requiring a written exposure control plan for all employers covered by the rule is more protective than the ASTM approach of only requiring written exposure control plans for persistent overexposures. Even if exposures are below the PEL due to the use of engineering controls or work practices, a systematic approach for ensuring proper function of engineering controls and effective work practices is crucial for ensuring that those controls and practices remain effective. Thus, OSHA finds that a written exposure control plan is integral to preventing overexposures from occurring.

OSHA agrees with NISA that requiring employers to articulate conditions resulting in exposure and how those exposures will be controlled will help to ensure that they have a complete understanding of the controls needed to comply with the rule. OSHA expects a written exposure control plan will be instrumental in ensuring that employers comprehensively and consistently protect their employees. Even in cases where employees are well trained, the written plan can help to ensure that controls are consistently used and become part of employees' routine skill sets. Employers could opt to use the plans to ensure that maintenance checks are routinely performed and optimal conditions are maintained. In addition, OSHA concludes the written plans are a useful method for communicating protections to employees.

Requiring a written plan maintains consistency with the majority of OSHA substance-specific standards for general industry and construction, such as lead (29 CFR 1910.1025 and 1926.62) and cadmium (29 CFR 1910.1027 and 1926.1127), which require written compliance plans. A requirement for a written exposure control plan is also consistent with Canadian standards. In addition, it is generally consistent with industry practices, as evidence in the record indicates that some employers in general industry and construction are already developing and using written plans. OSHA concludes that even for small businesses, preparing a written exposure control plan based on identifying and controlling respirable crystalline silica hazards will not be unduly burdensome, because of the widespread availability of tools and guidance from groups such as CPWR and the Canadian government. In addition, OSHA anticipates that industry associations will provide guidance on developing written exposure control plans for respirable crystalline silica.

Contrary to the concerns indicated by comments from representatives from the construction industry, OSHA does not intend or expect that employers will need to develop a new written plan for each job or worksite. Many of the same tasks will be conducted using the same equipment and materials at various worksites. For example, a stationary masonry saw used outdoors to cut concrete will perform similarly in any outdoor setting. Most construction employers are expected to use the specified exposure control methods in Table 1 of paragraph (c), which will help them identify tasks and controls to be included in the written exposure control plan. Table 1 does not usually specify different controls for different types of crystalline silica-containing materials, thus supporting the conclusion that a new plan does not need to be continually developed. Table 1 does list some conditions, such as time performing tasks or use of equipment in enclosed areas, that would require respirator use in addition to the specified controls; those different scenarios can be indicated in the written exposure control plan, as applicable. Therefore, the written exposure control plan does not have to be limited by materials, tasks, and conditions for a particular job site and can include all materials, tasks, and conditions typically encountered. In many cases there will be no need to modify the written plan just because the location has changed. However, the plan must address all materials, tasks, and conditions that are relevant to the work performed by a particular company. OSHA is including in the docket a sample written exposure control plan for a bricklaying company for reference.

OSHA concludes that it is appropriate to include a requirement for a written exposure control plan in the respirable crystalline silica standards for general industry/maritime and construction. Therefore paragraph (f)(2)(i) of the standard for general industry and maritime (paragraph (g)(1) of the standard for construction) requires the employer to establish and implement a written exposure control plan that contains at least the elements specified in paragraphs (f)(2)(i)(A)–(C) of the standard for general industry and maritime (paragraph (g)(1)(i)–(iv) of the standard for construction). This provision not only requires that a written exposure control plan be established but also implemented. OSHA does not consider it sufficient to develop a plan and have a copy of it on a shelf. It must be followed in the day-to-day performance of tasks identified.

OSHA considered existing written exposure control plans, such as the ASTM plans, and commenter suggestions to determine what should be included in a written exposure control plan. Section 4.2.5 of ASTM standard E 2625–09 concerning construction and demolition provides:

> In areas where overexposures are persistent, a written exposure control plan shall be established to implement engineering, work practice, and administrative controls to reduce silica exposures to below the PEL, or other elected limit, whichever is lower, to the extent feasible. Conduct a root cause analysis for all exposures in excess of the PEL that cannot be accounted for. Root cause analysis

involves investigating cause(s) for the excessive exposure, providing remedies, and conducting follow-up sampling to document that exposures are below the PEL (Document ID 1504, p. 2).

The exposure control plan described in section 4.2.6 of ASTM standard E 1132–06 is substantively consistent with the approach described by section 4.2.5 of ASTM standard E 2625–09 (Document ID 1466, p. 2; 1504, p. 2).

Several stakeholders commented on what should be included in provisions for a written exposure control plan. ASSE described an approach similar to that in the ASTM standards, and AFS preferred the ASTM approach during enforcement actions (Document ID 2339, p. 8; 2379, Appendix 1, pp. 61–62).

NIOSH stated that the exposure control plan could be based on OSHA's *Job Hazard Analysis* approach (Document ID 2177, Attachment B, p. 16; OSHA document 3071, Revised 2002). The OSHA job hazard analysis form calls for descriptions of tasks, hazards, hazard controls, and rationale and comments (OSHA document 3071, Revised 2002, Appendix 3). Similarly, NISA recommended that written exposure control programs convey an understanding of work processes and their appropriate controls for managing exposures (Document ID 4208, p. 21).

Some labor unions, such as AFL–CIO and BCTD, recommended more extensive requirements for a written exposure control or compliance program that included identification of exposures and controls, in addition to exposure assessment methods or results, and descriptions of the respiratory protection, medical surveillance, and training programs (Document ID 2371, Attachment 1, pp. 16–17; 4204, p. 62; 4223, p. 82).

Commenters such as Public Citizen, USW, UAW, and BCTD all agreed that the value of a written exposure control plan is that it allows for consistent identification and control of respirable crystalline silica hazards (Document ID 2249, p. 2; 2336, pp. 8–9; 2282, Attachment 3, p. 17; 3581, Tr. 1569–1571; 4204, p. 60). OSHA affirms that the purpose of the written exposure control plan is the consistent identification and control of respirable crystalline silica hazards, and it is basing the requirements for a written exposure control plan on that purpose.

As discussed more fully below, the written exposure control plan required under this rule for respirable crystalline silica is similar to the ASTM standards in most, but not all, respects. The major difference between the written plans in the ASTM standards and in this rule is that written exposure control plans in this rule are not limited to overexposure scenarios.

OSHA thus considered the ASTM standards and commenter suggestions to develop requirements for a written exposure control plan. The Agency also considered which aspects of the proposed written access control plan should be retained or modified. Therefore, the requirement for a written exposure control plan evolved from comments on OSHA's proposed written access control plan and in response to OSHA raising the possible inclusion of a written exposure control plan as an issue.

Requirements for the written exposure control plan. Paragraphs (f)(2)(i)(A)–(C) of the standard for general industry and maritime (paragraphs (g)(1)(i)–(iv)) of the standard for construction) identify the elements to be addressed in a written exposure control plan. Requirements for the written exposure control plan are performance-based to allow employers to tailor written exposure control plans to their particular worksites. The following discussion describes the minimum requirements for the written exposure control plan and the evidence that supports those requirements. It also recommends general information to include for each section of the plan.

Paragraph (f)(2)(i)(A) of the standard for general industry and maritime (paragraph (g)(1)(i)) of the standard for construction) requires a description of tasks involving exposures to respirable crystalline silica. The proposed written access control plan called for identification of areas where respirable crystalline silica exposure may exceed the PEL. Communication Workers of America (CWA), Public Citizen, USW, AFL–CIO, NISA, and BCTD recommended that the written exposure control plan describe tasks, operations, or work processes that result in exposures to respirable crystalline silica (Document ID 2240, p. 2; 2249, p. 3; 2336, p. 9; 4204, p. 62; 4208, p. 21; 4223, p. 82). A description of tasks involving exposures to respirable crystalline silica is consistent with the first step of the root cause analysis in the ASTM exposure control plans, which involves investigating sources of overexposures (Document ID 1466, p. 2; 1504, p. 2). It is also consistent with the identification of tasks and hazards in the OSHA *Job Hazard Analysis* approach that is recommended by NIOSH as a model for a respirable crystalline silica written exposure control plan (Document ID 2177, Attachment B, p. 16; OSHA Document 3071, Revised 2002, Appendix 3).

Paragraph (f)(2)(i)(A) of the standard for general industry and maritime (paragraph (g)(1)(i) of the standard for construction) reflects OSHA's agreement with commenters that it is important for employers to consistently identify tasks resulting in exposure to ensure that appropriate employee protections are applied when needed. The identification of tasks with potential respirable crystalline silica exposure is no longer limited to exposures above the PEL, as it was in the proposed written access control plan. This is more protective because it identifies all tasks that could contribute to employee exposures, thereby furthering the purpose of the rule.

In preparing this section of the written plan, employers must list all tasks that employees perform that could expose them to respirable crystalline silica dust. This section of the written plan could include a description of factors that affect exposures, such as types of silica-containing materials handled in those tasks (*e.g.,* concrete, tile). It could also describe factors such as weather (*e.g.,* wind, humidity) and soil compositions (*e.g.,* clay versus rock) (Document ID 3583, Tr. 2350–2352, 2356–2360; 4234, Part 2, pp. 37–38). Another factor that could affect exposure and protective requirements and thus could be described in the written plan is the location of the task, for instance, whether the task is performed in an enclosed space (Document ID 2177, Attachment B, pp. 16–17). For example, the Table 1 entry for walk-behind saws with integrated water delivery systems indicates that a respirator is only required when the equipment is used indoors or in an enclosed area.

Paragraph (f)(2)(i)(B) of the standard for general industry and maritime (paragraph (g)(1)(ii) of the standard for construction) requires a description of engineering controls, work practices, and respiratory protection used to limit employee exposure to respirable crystalline silica for each task. CWA, Public Citizen, USW, AFL–CIO, NISA, and BCTD requested that the written plan describe controls for managing exposures. Engineering and work practice controls were specifically mentioned by Public Citizen, USW, AFL–CIO, and BCTD (Document ID 2240, p. 2; 2249, pp. 3–4; 2336, p. 9; 4204, p. 62; 4208, p. 21; 4223, p. 82). AFL–CIO further recommended that the written plan describe jobs where respiratory protection is required (Document ID 4204, p. 62). BCTD also requested that the written plan describe procedures for implementing the controls and for determining if the

controls are being used and maintained correctly (Document ID 4223, p. 82). NIOSH stated that a written exposure control plan can be a simple mechanism for ensuring that maintenance checks are conducted and Table 1 conditions are maintained (Document ID 2177, Attachment B, pp. 16–17).

Paragraph (f)(2)(i)(B) of the standard for general industry and maritime (paragraph (g)(1)(ii) of the standard for construction) reflects OSHA's agreement that the written exposure control plan must address controls, work practices, and respiratory protection used to manage exposures for each task identified in paragraph (f)(2)(i)(A) of the standard for general industry and maritime (paragraph (g)(1)(i) of the standard for construction). The purpose of this requirement is to ensure that exposures to respirable crystalline silica hazards are consistently controlled. Therefore, written exposure control plans must include information such as types of controls used (*e.g.,* dust collector with manufacturer's recommended air flow and a filter with 99 percent efficiency), effective work practices (*e.g.,* positioning local exhaust over the exposure source), and if required, appropriate respiratory protection (*e.g.,* a respirator with an assigned protection factor (APF) of 10) for each task. The requirement is consistent with the exposure control plans in the ASTM standards that address implementation of engineering controls and work practices to reduce respirable crystalline silica exposures (Document ID 1466, p. 2; 1504, p. 2). It is also consistent with OSHA's *Job Hazard Analysis* approach, which is recommended by NIOSH as a model for the exposure control plan and calls for a description of controls (Document ID 2177, Attachment B, p. 16; OSHA document 3071, Revised 2002, Appendix 1 and 3).

OSHA also agrees with NIOSH and BCTD about the necessity of addressing the proper implementation and maintenance of controls for each task. This is reflected in paragraph (c) of the standard for construction, in the Table 1 requirements to operate or maintain tools according to manufacturers' instructions. Proper implementation and maintenance of controls is also necessary to meet the PEL under paragraph (c) of the standard for general industry and maritime and paragraph (d)(1) of the standard for construction for construction employers who choose or are required to follow the alternative exposure control methods. Therefore, to help ensure compliance with the rule, the employer, in this section of the written exposure control plan, could indicate signs that controls may not be working effectively (*e.g.,* dust is visible, no water is delivered to the blade). The plan could also include a description of procedures the employer uses for verifying that controls are functioning effectively (*e.g.,* pressure checks on local exhaust ventilation) and schedules for conducting maintenance checks.

OSHA finds the written exposure control plan especially important for construction employers who use the specified exposure control methods in Table 1 of paragraph (c). For them, the description of engineering controls, work practices, and respiratory protection is especially necessary to ensure adequate protection of employees and the use of controls according to the manufacturer's instructions, since employers are not required to conduct exposure assessments to verify that controls are working properly. In cases where the employer owns a particular type of equipment and it is repeatedly used at different job sites, describing the manufacturer's instructions for operating the dust controls in a written exposure control plan will demonstrate that the employer has a complete understanding of and is applying those specifications needed to control dust emissions. Describing those specifications in the written exposure control plans will also serve as a convenient reference for employees.

As an example, in completing this section of the written plan, an employer whose employees use a Stihl® Model TS 410 saw to cut concrete could consult the user's manual to list or summarize those instructions in his or her written exposure control plan. Based on the user's manual, this section of the plan could indicate that (1) before using a Stihl® Model TS 410 saw for cutting concrete, the employee must examine the diamond cutting wheel for signs of excessive wear, damage, or ''built-up edges'' (*i.e.*, a pale, grey deposit on the top of the diamond segments that clogs and blunts them) and (2) while cutting, the employee must use a water flow rate no less than 0.6 liters (20 fluid ounces) per minute, stop and rinse the screen on the water connection if no or too little water is delivered while cutting, and not cut into the ballast layer of road surfaces to avoid excessive wear on the cutting wheel (Document ID 3998, Attachment 12a, pp. 9, 21–23). The specified exposure control methods in Table 1 indicate that the employee must wear a respirator with an APF of 10 when using this saw outdoors for more than 4 hours a day, and this type of information must be included in this section, if applicable.

Paragraph (f)(2)(i)(C) of the standard for general industry and maritime (paragraph (g)(1)(iii) of the standard for construction) requires a description of the housekeeping measures used to limit employee exposure to respirable crystalline silica. BCTD requested that the exposure control plan describe housekeeping methods (Document ID 2371, Attachment 1, pp. 16–17). Similarly, CWA and USW recommended that the written plan describe procedures for preventing the migration of silica, and USW further noted that the plan should address keeping surfaces visibly clean (Document ID 2240, p. 2; 2336, p. 9). USW also requested that the written exposure control plan describe procedures for removing, laundering, storing, cleaning, repairing, or disposing of protective clothing and equipment (Document ID 2336, p. 9).

Paragraph (f)(2)(i)(C) of the standard for general industry and maritime (paragraph (g)(1)(iii)) of the standard for construction) reflects OSHA's agreement that housekeeping needs to be addressed in the written exposure control plan because some cleaning methods can contribute to employee exposure to respirable crystalline silica. OSHA intends this requirement to help ensure that employers identify and implement appropriate cleaning methods so that employees are protected from respirable crystalline silica dust that can become airborne while performing housekeeping activities. Ensuring safe housekeeping methods helps to consistently control exposures and hazards related to respirable crystalline silica. Housekeeping is another type of work practice to be used to limit employee exposures, and thus, it is consistent with the written exposure control plans in the ASTM standards, which call for implementing work practices to decrease exposures (Document ID 1466, p. 2; 1504, p. 2). It is also consistent with OSHA's *Job Hazard Analysis* approach, which is recommended by NIOSH as a model for the exposure control plan and calls for a description of controls (Document ID 2177, Attachment B, pp. 16–17; OSHA document 3071, Revised 2002, Appendix 1 and 3).

OSHA concludes that requiring the written exposure control plan to include a description of housekeeping methods is important because acceptable housekeeping methods can vary among different companies. As described more fully in the summary and explanation of *Housekeeping*, certain housekeeping practices, such as wet sweeping, are infeasible in some work scenarios.

Therefore, OSHA modified proposed prohibitions on cleaning activities, such as dry sweeping or compressed air, to indicate that those housekeeping methods can be used if there are no other feasible methods. However, to comply with the rule, employers must ensure that wet sweeping, HEPA-filtered vacuuming, or other appropriate cleaning methods are used wherever feasible, if dry sweeping or dry brushing could contribute to employee exposure to respirable crystalline silica. It is therefore important for the employer to specify in the written exposure control plan the housekeeping practices the employer uses to limit employee exposures and any special protections that are needed when a particular housekeeping method is used.

To ensure that cleaning methods used comply with paragraph (h) of the standard for general industry and maritime (paragraph (f) of the standard for construction), this section of the written plan could include a description of acceptable and prohibited cleaning methods used by the employer to minimize generation of airborne dust and special instructions regarding cleaning methods (*e.g.*, using local exhaust ventilation if compressed air must be used). Hygiene-related subjects, such as not using compressed air to clean clothing, could also be addressed in this section of the written exposure control plan.

Paragraph (g)(1)(iv) of the standard for construction requires a description of the procedures used to restrict access to work areas, when necessary, to limit the number of employees exposed to respirable crystalline silica and the levels to which they are exposed, including exposures generated by other employers or sole proprietors. No such requirement is included in the written exposure control plan provision for general industry and maritime. The reasons for the differing requirements in the two standards are discussed below.

The proposed written access control plans for general industry and maritime and construction called for procedures for notifying employees about the presence and location of areas where respirable crystalline silica concentrations are or can be reasonably expected to exceed the PEL and for demarcating those areas from the workplace if needed. Also included in the proposed access control plan were provisions for limiting access to areas where respirable crystalline silica exposures may exceed the PEL, in order to minimize the numbers of employees exposed and employee exposure levels.

AFL–CIO and BCTD recommended that written plans describe procedures that employers will use to limit exposure to employees who are not performing respirable crystalline silica-related tasks (Document ID 4204, p. 63; 4223, p. 82). Similarly, BAC stated that the written plan should contain provisions for a regulated area (Document ID 2329, p. 5). USW requested the written plan address labeling of areas with potential respirable crystalline silica exposure (Document ID 2336, p. 14).

Paragraph (g)(1)(iv) of the standard for construction reflects OSHA's agreement that written exposure control plans must address limiting exposure to construction employees who are not engaged in respirable crystalline-silica-related tasks. However, as explained in the summary and explanation of *Regulated Areas,* regulated areas are not required in the standard for construction because most employers are expected to rely on the specified exposure control methods in Table 1 of paragraph (c) and, therefore, will not have air monitoring data to estimate boundaries of the regulated area. In the summary and explanation of *Regulated Areas,* OSHA also acknowledges the impracticality of demarcating regulated areas in many construction scenarios. Nonetheless, it remains crucial that access to high-exposure areas and employee exposure levels be limited at construction worksites. A written description of the employer's plan for limiting access is another tool the employer has that helps to consistently control hazards.

The exposure control plans in the ASTM standards do not specifically call for procedures used to restrict access. However, they do call for a description of administrative controls used to reduce exposures (Document ID 1466, p. 2; 1504, p. 2). An example of an administrative control that can be used to minimize the number of employees exposed to respirable crystalline silica is scheduling high-exposure tasks when others will not be in the area (Document ID 3583, Tr. 2385–2386). For example, Anthony Zimbelman stated that when granite countertops are being installed, silica dust may be generated when drilling holes for plumbing fixtures or grinding to make adjustments, but the installers are usually the only employees at the job site at that time (Document ID 3521, pp. 6–7). CISC stated that in lieu of developing a written access control plan, employers could instruct employees to stay out of areas where dust is generated or, if employees have to be in those areas, to avoid dust clouds (Document ID 2319, pp. 91–92). OSHA considers the CISC recommendation to be an additional example of administrative controls for limiting access or exposures that could be addressed in the written exposure control plan. Similarly, a written exposure control plan could include guidance requiring employees to maintain a safe distance from dust created by the use of explosives in demolition and to stay out of the affected area until the dust sufficiently dissipates; this would also serve as an acceptable administrative control. Therefore, a requirement for the written plan in the construction standard to address minimizing the number of employees exposed and their exposure levels is consistent with the exposure control plans in the ASTM standards.

OSHA concludes that the written exposure control plan for the construction standard must address restricting access of those employees who are not engaged in tasks that generate respirable crystalline silica (*i.e.,* bystanders). Therefore, as noted above, paragraph (g)(1)(iv) of the standard for construction requires a description of the procedures used to restrict access to work areas, when necessary, to limit the number of employees exposed and their exposure levels, including exposures generated by other employers or sole proprietors (*i.e.,* self-employed individuals). Restricting access is necessary where respirator use is required under Table 1 or an exposure assessment reveals that exposures are in excess of the PEL. The competent person, who is designated by the employer to implement the written exposure control plan under paragraph (g)(4) of the standard for construction, could further identify situations where limiting access is necessary. For example, limiting access may be necessary when an employer or sole proprietor exposes another company's employees to respirable crystalline silica levels that could reasonably be considered excessive (*e.g.,* above the PEL).

Such a situation might occur when an employee engaged in a Table 1 task with fully and properly implemented controls is exposed to clearly visible dust emissions by an employee or sole proprietor who is performing a task not listed on Table 1, is not fully and properly implementing Table 1 controls, or is performing a Table 1 task requiring a higher level of respiratory protection. In that case, the competent person would assess the situation to determine if it presents a reasonably anticipated hazard, and if it does, take immediate and effective steps to protect employees by implementing the procedures described in the written exposure control plan. Actions by the competent

person could include reminding employees to stay out of the areas where respirable crystalline silica is being generated or repositioning employees so that they will not be exposed to respirable crystalline silica.

This approach is consistent with current industry practices. For example, Anthony Zimbelman testified that in his experience, implementing a safety plan was sufficient to protect employees in situations where subcontractors that are not required to comply with the Occupational Safety and Health (OSH) Act are working alongside employees. Mr. Zimbelman further testified that in the home building industry, this situation does not happen often and contractors would stop working with a subcontractor who does not comply with OSHA standards (Document ID 3587, Tr. 3547–3549). OSHA expects that excessive exposures created by sole proprietors not covered by the respirable crystalline silica rule will be an infrequent occurrence because, as CISC indicated in its post-hearing brief, employers and general contractors will likely demand that everyone on the site follow regulatory requirements (Document ID 4217, Appendix B, p. 16). OSHA thus expects that the employers or their competent persons will work with general contractors of construction sites to avoid high exposures of employees working alongside others generating respirable crystalline silica. For example, the competent person could ask the general contractor to schedule high-exposure tasks when employees will not be in the area.

OSHA is not retaining the proposed requirement in the written access control plan that the employer describe how employees will be notified about respirable crystalline silica exposures and how areas will be demarcated. The requirements of the written exposure control plan are more performance-oriented to permit each employer to address unique scenarios of worksites. Demarcation (*i.e.,* direct access control), notifying or briefing employees, and scheduling high-exposure tasks when others are not around, are likely to be the most common methods of restricting access. Demarcating areas is not required because, as noted above, it is not applicable to many construction scenarios. However, if it is possible to demarcate areas, such as by posting a warning sign, and that is the employer's chosen method for limiting access or exposures, it must be described in this section of the written exposure control plan. If notifying or briefing employees is the method chosen to limit access or exposures, the procedures for doing that must be described under this section of the written exposure control plan.

As noted above, the standard for general industry and maritime does not require the written exposure control plan to address how access to high-exposure areas or employee exposures will be limited. As described in more detail in the summary and explanation of *Regulated Areas,* OSHA concludes that establishing regulated areas is reasonable and generally feasible in general industry and maritime workplaces. Therefore, the standard for general industry and maritime clearly specifies establishment of regulated areas that are demarcated and have warning signs posted at the entrances to those areas (paragraph (e)(1) and (2)(i) and (ii)). With the procedure clearly laid out in the standard, there is no reason to address it in the written exposure control plan. However, employers can address more than the minimum requirements for a written exposure control plan, and general industry and maritime employers always have the option of describing methods for limiting access in their written exposure control plan.

The proposed written access control plan called for a description of the methods that employers at multi-employer sites would use to notify other employers about the presence and location of areas where respirable crystalline silica may exceed the PEL and any precautionary methods needed to protect employees. AFL–CIO, BAC, and BCTD commented that written plans should provide for a method of communication at multi-employer sites (Document ID 4204, pp. 62–63; 4219, pp. 25–27; 4223, pp. 83–84). BCTD stated that a requirement for a written plan to describe methods of communication at multi-employer sites was not sufficient and requested that employers also be required to give their written plan to a general contractor or other ''controlling employer'' at a multi-employer construction site. The controlling employer would be required to share that information with other employers or use the plan to coordinate activities to reduce exposures to employees (Document ID 4223, pp. 118–123). AFL–CIO and BAC endorsed BCTD's approach and/or recommended a similar method for using the written exposure control plan to communicate at multi-employer worksites (Document ID 4204, p. 63; 4219, pp. 25–27). Similarly, ASSE stated that employers who generate respirable crystalline silica exposures at multi-employer sites should inform the general contractor or host employer about the need for access control and work cooperatively with the general contractor or host employer to ensure compliance and notify other employers at the site (Document ID 2339, p. 8).

In contrast, NSSGA commented that the HCS already requires employers to establish methods for communicating hazards to employees of other employers (Document ID 2327, Attachment 1, p. 11). NAHB commented that ''. . . the imposition of multi-employer burdens in the proposed rule is inconsistent with the clear wording of § 1910.12(a) requiring a construction employer to protect 'each of *his employees* engaged in construction work' (Emphasis added)'' (Document ID 2296, pp. 27–28). OSHA disagrees that a requirement to communicate the presence of crystalline silica to other employers contradicts the 29 CFR 1910.12(a) requirement that employers protect their employees. Communication among employers about areas where respirable crystalline silica exposures may exceed the PEL will provide each employer with the information needed to protect its own employees.

OSHA nonetheless concludes that the written exposure control plan need not specify communication methods at multi-employer sites, or require that employers share their written exposure control plans at multi-employer sites. Communication at multi-employer worksites is already addressed in the HCS. As part of the written hazard communication program required under the HCS, employers who use hazardous chemicals in such a way that employees of other employers may be exposed must include specific information in the written hazard communication program. This includes methods the employer will use to inform the other employers of any precautionary measures that need to be taken to protect employees (29 CFR 1910.1200(e)(2)(ii)). Because the provisions for a written hazard communication program under the HCS already require employers to share relevant information on hazards and protective measures with other employers in multi-employer workplaces, OSHA does not find it necessary to restate a requirement for sharing of information between employers in the respirable crystalline silica rule. However, as discussed above, written exposure control plans are useful for communicating information, and employers may decide that they are a convenient way for sharing information with other employers at multi-employer workplaces.

Additional provisions that were part of the proposed access control plan but

are not required for the written exposure control plan are procedures for providing employees and their designated representatives an appropriate respirator, protective clothing, or a means for cleaning clothing when entering areas where exposures exceed the PEL or where clothing could become grossly contaminated with finely divided material. OSHA is not requiring the written exposure control plan to address this subject because procedures related to providing employees with appropriate respirators, such as selection of respirators, medical evaluations, and training, must already be described in a written respiratory protection program (29 CFR 1910.134(c)(1)). In most cases, the designated representative, who requires entry into a regulated area or an area with restricted access for purposes such as observing air monitoring, is likely to have access to appropriate respiratory protection and be medically cleared to wear it (*see* summary and explanation of *Exposure Assessment*). As OSHA determined in the summary and explanation of *Exposure Assessment,* requirements of the written respiratory protection program related to providing an appropriate respirator would also apply to the designated representative in the very rare case where the representative does not have a respirator. Protective clothing is not addressed in the written exposure control plan because it is not required by the rule. Recommendations concerning cleaning of clothing, such as not using compressed air, could be addressed as part of housekeeping measures or work practice controls.

Some commenters requested that written plans address additional topics and requirements. For example, Public Citizen, BCTD, and AFL–CIO, requested that the written exposure control plan describe exposure assessment methods or programs (*e.g.,* air monitoring or objective data) and results (Document ID 2249, pp. 3–4; 2371, Attachment 1, p. 16; 4204, p. 62; 4223, p. 82). Public Citizen indicated that this should include detailed descriptions of analytical methods and air sampling protocols or objective exposure assessment methods, and BCTD stated that employers using Table 1 could indicate the portion of Table 1 upon which they are relying (Document ID 2249, pp. 3–4; 4223, p. 82). BCTD and AFL–CIO recommended that the written plan address respiratory protection, medical surveillance, and training programs, including documentation that employees have received respiratory fit testing, medical evaluations or examinations, and training (Document ID 4204, p. 62; 4223, p. 82). Public Citizen requested that the plan be prepared by a technically qualified person if the employer lacks the expertise to prepare and implement the plan (Document ID 2249, p. 4). ASSE preferred that the plans be developed by a certified safety professional or certified industrial hygienist (CIH) (Document ID 2339, p. 8). NAHB expressed concern about costs if small companies had to hire safety consultants or industrial hygienists to develop the plan (Document ID 2296, p. 41).

OSHA disagrees with commenters that the written exposure control plan needs to address these topics. The major purpose of a written exposure control plan is to ensure that respirable crystalline silica hazards are consistently identified and controlled. OSHA concludes that this purpose is best served if the written plan is limited to information useful for the employer or the employer's designated representative who will conduct inspections on job sites to ensure that employees are adequately and consistently protected. Requiring a written exposure control plan to contain information that is not directly relevant to identifying and controlling hazards at job sites would needlessly increase the burdens to employers preparing the written plans and could make the plans cumbersome for them to use on job sites. In addition, OSHA does not see the need for including a description of the respiratory protection program because employers are already required to develop a written respiratory protection program under the respiratory protection standard (29 CFR 1910.134(c)). Recordkeeping requirements are clearly specified for fit testing and medical evaluations in the respiratory protection standard (29 CFR 1910.134) and for medical examinations and exposure assessments in this rule. The respirable crystalline silica rule does not require employers to keep training records. As explained in more detail in the summary and explanation of *Recordkeeping,* the rule does not require training records because employers must instead ensure that employees demonstrate knowledge and understanding of training subjects and in addition, such a requirement would increase paperwork burdens for employers and would not be consistent with the HCS and most OSHA standards.

Therefore, OSHA is neither requiring nor precluding employers to include in written exposure control plans descriptions of exposure assessment methods and results or information on respiratory protection, medical surveillance, and training programs. Requiring information, such as highly technical details on analytical methods, would increase the likelihood that small employers would need to hire a safety and health professional to develop the plans, thus increasing the costs and burdens to those employers. Although OSHA encourages companies to seek professional assistance when needed to develop the plans, requiring a plan that is so complex that many employers would not develop it themselves defeats the advantage of employers gaining an increased understanding of the rule by articulating its requirements. The additional information may be useful as part of a compliance plan, and employers have the option to develop such a plan if they find it helpful.

Paragraph (f)(2)(ii) of the standard for general industry and maritime (paragraph (g)(2) of the standard for construction) requires the employer to review and evaluate the effectiveness of the written exposure control plan at least annually and update it as necessary. A similar requirement was included in the proposed written access control plan. Public Citizen requested revisions of written exposure control plans as needed, including after annual review of exposure assessment methods (Document ID 2249, p. 4). OSHA agrees with Public Citizen that the written exposure control plan needs to be periodically reviewed and updated as needed because work conditions can change (*e.g.,* the employer purchases a new type of equipment). As discussed above, a written exposure control plan will not likely need to be updated often because employees tend to use the same equipment to perform the same tasks at many locations. However, a yearly review is needed to ensure that all current scenarios are captured in the plan.

Paragraph (f)(2)(iii) of the standard for general industry and maritime (paragraph (g)(3) of the standard for construction) requires that the employer make the written exposure control plan readily available for examination and copying, upon request, to each employee covered by this section, his or her designated representative, the Assistant Secretary (*i.e.,* OSHA), or the Director (*i.e.,* NIOSH). A similar requirement was included in the proposed written access control plan. Public Citizen, USW, BCTD, and AFL–CIO requested a requirement to make written exposure control plans available upon request by employees or their representatives (Document ID 2249, p. 4;

2336, p. 9; 2371, Attachment 1, p. 17; 4204, p. 63). NIOSH, Public Citizen, and BAC also stated that written exposure control plans are a useful way to communicate protections to employees (Document ID 2177, Attachment B, pp. 16–17; 2249, p. 3; 2329, p. 5). OSHA agrees with commenters that a written exposure control plan is an effective method for communicating protections to employees and their designated representatives. Making the written plan readily available to employees and their designated representatives upon request empowers and protects employees by giving them and their representatives the information to question employers if controls are not fully and properly implemented or maintained. Similarly, making written exposure control plans readily available to OSHA or NIOSH allows them to verify effectiveness of employee protections.

BCTD also requested that the rule require employers to address in their written plans how temporary workers will be protected and that the rule require staffing agencies and employers who use temporary staff to share their written exposure control plans (Document ID 4223, pp. 83–84). OSHA disagrees with BCTD that the rule needs to include a requirement for host employers and temporary staffing agencies to share their written exposure control plans with each other. However, OSHA agrees with the importance of ensuring that temporary workers receive the protections they are entitled to under the OSH Act. As BCTD noted in its comments, OSHA addresses the issue of temporary employee protections in its July 15, 2014, memorandum titled *Policy Background on the Temporary Worker Initiative* (Document ID 4223, p. 84). The policy memorandum indicates that both the host and staffing agency are responsible for the health and safety of temporary employees and encourages compliance officers to review written contracts between the staffing agency and host employer to determine if they have fully addressed employee health and safety. For example, the policy memorandum indicates that host employers are well suited for assuming responsibility for compliance related to workplace hazards, while staffing agencies may be best positioned to provide medical surveillance. The memorandum also states that although the host employer has the primary responsibility for assessing hazards and complying with occupational safety and health rules in his or her workplace, staffing agencies must also ensure that they are not sending employees to workplaces where the employees would be inadequately protected from or trained about hazards. A temporary staffing agency could review a host employer's written exposure control plan to verify that the employer has identified hazards and is implementing the appropriate controls. Staffing agencies and host employers would have the option to supplement their written contract with a written exposure control plan if that is useful for them. OSHA is not requiring that host employers and staffing agencies share written exposure control plans for respirable crystalline silica because sharing information is an issue that affects all OSHA safety and health regulations and is therefore most efficiently addressed through general policy statements.

Competent Person (Construction). In paragraph (b) of the standard for construction, OSHA defines competent person as an individual who is capable of identifying existing and foreseeable respirable crystalline silica hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The definition also specifies that the competent person have the knowledge and ability necessary to fulfill the responsibilities set forth in paragraph (g). In paragraph (g)(4) of the standard for construction, the employer is required to designate a competent person to make frequent and regular inspections of job sites, materials, and equipment to implement the written exposure control plan.

OSHA included a competent person requirement in the draft general industry/maritime and construction standards presented for review to the Small Business Regulatory Enforcement Fairness Act (SBREFA) review panel. In the draft standards submitted for SBREFA review, duties of the competent person included evaluating workplace exposures and the effectiveness of controls, implementing corrective measures to maintain exposures at or below the PEL, establishing and maintaining boundaries of regulated areas, and evaluating alternate media for abrasive blasting operations. Small entity representatives (SERs) from the construction industry who reviewed the SBREFA draft standard found the requirements for a competent person hard to understand, reasoning that (1) the competent person required a high skill level, (2) a large proportion of their employees would need to be trained, and (3) the requirements would be costly and difficult to comply with (78 FR at 56443–56444).

OSHA's Advisory Committee on Construction Safety and Health (ACCSH), made up of representatives of employees, employers, and state and federal governments, recommended that the Agency retain a competent person requirement in the proposed construction standard because many OSHA standards include that requirement, it is an accepted approach for construction, many small construction employers do not have full-time health and safety staff, it can ensure that designated employees get training on hazards and proper use of controls, and it can increase confidence that controls and PPE are being used and maintained correctly (Document ID 4073, Attachment 14g, pp. 2–3).

OSHA included a competent person provision in the proposed standards, but the only duty that OSHA proposed for the competent person was identifying areas where respirable crystalline silica concentrations are, or could reasonably be expected to be, in excess of the PEL when the employer chose to develop a written access control plan in lieu of establishing regulated areas. OSHA proposed this limited competent person duty because the Agency thought that provisions of the proposed standard, such as requirements for engineering controls and work practices to reduce and maintain employee exposure to respirable crystalline silica at or below the PEL, would effectively communicate the requirements of the rule, without involvement of a designated competent person. However, the Agency was aware that competent person requirements have been included in other health and safety standards and that some parties thought such requirements would be useful in the silica rule (78 FR at 56443–56444). Therefore, OSHA requested comments regarding the appropriateness of the limited competent person requirement, whether a competent person provision should be included, and if the proposed duties for a competent person should be modified or deleted (78 FR at 56288).

Many commenters representing labor unions and employee health advocate groups disagreed with OSHA proposing to include only a limited role for the competent person in construction. Commenters such as NIOSH, the Laborers' Health and Safety Fund of North America (LHSFNA), ASSE, IUOE, and BCTD supported an expanded competent person role because many construction companies are small and cannot afford safety or health professionals, but as NIOSH stated, small companies can have trained and authorized employees ensure employee protections (Document ID 3403, p. 4;

3589, Tr. 4256–4257; 4201, pp. 2–3; 4025, Attachment 1, p. 2; 4223, pp. 107–109). OSHA estimates that approximately 93 percent of construction companies covered by the respirable crystalline silica standard have fewer than 20 employees (see Chapter III of the Final Economic Analysis and Final Regulatory Flexibility Analysis). In further explaining why a competent person is needed in construction, Dr. Schulte testified:

> The need for expanding the duties of the silica-competent person is especially important when employers plan to rely on Table 1 because it is less likely that an industrial hygienist will visit the project to evaluate the job, collect air samples, or check the effectiveness of controls. Effectiveness deteriorates when controls or personal protective equipment (PPE) are not maintained; this performance degradation may not be obvious to workers using the devices (Document ID 3403, p. 4).

The American Industrial Hygiene Association (AIHA), IUOE, and BCTD agreed that a competent person is needed to ensure that Table 1 controls are functioning effectively (Document ID 3578, Tr. 1030; 3583, Tr. 2347; 4223, pp. 109–110). BCTD stated:

> . . . because the technology for controlling silica exposures largely consists of equipment that is attached to or directed at the tools the workers use in their silica-generating tasks, the manner in which it is deployed and maintained is critical to its success. Thus, whether these controls are effective depends on successfully combining the engineering controls with work practices: Accurately assessing the potential exposures, selecting the proper control for the job, using the equipment properly, and making sure the equipment is functioning effectively. All of this must be done on an on-going basis (Document ID 4223, p. 109).

Exposure variability in construction is another reason that commenters cited in support of expanded competent person duties. For example, ASSE commented that varying silica exposures can occur as a result of wind pattern and geological changes as contractors move from one site to another or to a new area at the same site (Document ID 4201, p. 2). LHSFNA explained that a competent person can help to reduce exposure variability by identifying major sources of variability and ensuring that controls are used and maintained effectively (Document ID 4207, p. 4). Similarly, NIOSH stated that a competent person could reduce exposure variability by recognizing sources of variability, such as tasks done in an enclosed area or equipment that is not working correctly (Document ID 3579, Tr. 175–176, 194–195). In explaining how a competent person could reduce exposure variability, Kyle Zimmer, Director of Health and Safety for IUOE Local 478, testified that the competent person could respond to changing conditions by repositioning equipment so that employees are upwind of the dust created, adjusting water controls based on environmental factors, or addressing an unexpected encounter of a concrete sub-base during asphalt milling (Document ID 3583, Tr. 2351–2352).

Commenters also addressed a competent person's role regarding bystanders (*i.e.,* employees working nearby other employees who are engaged in tasks that generate respirable crystalline silica but are not themselves engaged in those tasks). BCTD commented that the potential for bystander exposure is another reason why competent persons are needed in construction (Document ID 4223, p. 110). Hearing participants described how a competent person could minimize bystander exposure. For example, Travis Parsons, Senior Safety and Health Specialist for LHSFNA, stated that the competent person could ensure communication about exposures being generated between employees from different trades working at the same construction site (Document ID 3589, Tr. 4232). Donald Hulk, Safety Director for Manafort Brothers, Inc. and representing IUOE, testified that a sufficiently trained competent person would be able to recognize when secondary exposures could occur, and in those situations, subcontractors might be able reschedule activities to avoid bystander exposures (Document ID 3583, Tr. 2385–2386).

Another reason why commenters stated that a competent person is needed in construction is because they thought that employers are not adequately recognizing respirable crystalline silica-related health hazards. As evidence that employers do not believe that respirable crystalline silica is an issue, Chris Trahan, CIH, representing BCTD, pointed to the volume of testimony claiming that declining silicosis mortality rates are evidence that silicosis is not a problem and that respirable crystalline silica is an ''alleged carcinogen.'' Ms. Trahan disagreed with these commenters and said their testimony demonstrates the hurdles that the industry must overcome before silica is recognized as a hazard and controlled (Document ID 3581, Tr. 1641–1642; 4223, pp. 108–109). LHSFNA claimed that most contactors have not adequately addressed respirable crystalline silica-related health hazards because of the long latency of silica-related disease compared to the common short tenure of employment at any one company. LHSFNA commented that this blunted the ability of workers' compensation to provide an incentive for disease prevention (Document ID 4207, p. 3). In support of the importance of a competent person for preventing disease, LHSFNA and BCTD pointed to the following statement in the AIHA White Paper on competent persons (Document ID 3589, Tr. 4199; 4223, p. 106).

> A key component in preventing overexposure to silica and subsequent disease is to have at least one individual on the jobsite who is capable of recognizing and evaluating situations where overexposure may be occurring; who knows how to evaluate the exposure potential; and who can make an initial recommendation on how to control that exposure. This is the role of the silica competent person (Document ID 4076, p. 3).

Commenters stressed that the competent person is a well-known concept in construction. LHSFNA and BCTD commented that requiring a competent person under the silica regulation maintains consistency with 19 OSHA construction standards (Document ID 4207, p. 3; 4223, p. 107). Standards requiring a competent person include asbestos (29 CFR 1926.1101), lead (29 CFR 1926.62), and cadmium (29 CFR 1926.1127) (Document ID 4223, p. 107). In addition, NIOSH and LHSFNA commented that competent person provisions are commonly included in American National Standard Institute (ANSI) standards for construction (Document ID 2177, Attachment B, p. 8; 3589, Tr. 4200). NIOSH further said that it and its state partners routinely recommend the need for, and role of, designated competent persons in investigation reports conducted under NIOSH's Fatality Assessment and Control Evaluation program (Document ID 2177, Attachment B, p. 8).

The competent person requirement is also consistent with construction industry practices. For example, Donald Hulk testified that at Manafort Brothers construction sites, a highly trained person has the authority to ensure that best practices are implemented (Document ID 3583, Tr. 2380). Anthony Zimbelman testified that owners or competent persons of subcontracting companies conduct assessments and develop procedures for controlling dust before remodeling or construction of homes (Document ID 3587, Tr. 3538–3539). Safety Director Francisco Trujillo from Miller and Long, Inc. testified ''. . . we have competent persons for almost everything . . .'' and explained that competent persons are required to

evaluate the adequacy of protective equipment when dust collection systems are used because of the limitations of those systems and changing site conditions (Document ID 3585, Tr. 2963–2964, 2980).

Specific duties for a competent person were recommended by a diverse group of commenters, including AIHA, NIOSH, National Asphalt Pavement Association (NAPA), IUOE, National Rural Electric Cooperative Association (NRECA), retired occupational safety and health attorney Charles Gordon, LHSFNA, and BCTD (Document ID 2169, p. 5; 2177, Attachment B, pp. 9–10, 14; 2181, pp. 10–11; 2262, pp. 38–39, 42–43; 2365, pp. 19–20; 3588, Tr. 3800–3801; 3589, Tr. 4197–4201; 4223, pp. 106–114). BCTD, which had among the most extensive recommendations, noted that OSHA standards for lead, asbestos, and cadmium specify duties for a competent person (Document ID 4223, p. 112). For the respirable crystalline silica standard, BCTD requested that the employer designate a competent person to be on site whenever work covered by the standard is being conducted to ensure that the employer's written exposure control plan is implemented, and to:

> . . . use the written exposure control plan to identify locations where silica is present or is reasonably expected to be present in the workplace prior to the performance of work. In addition the competent person's duties shall include ensuring: (1) The employer has assessed the exposures as required by this section; (2) where necessary, regulated areas are established and access to and from those areas is limited to authorized persons; (3) the engineering controls and work practices required by this standard, including all elements of Table 1 (if it is being used), are fully and properly implemented, maintained in proper operating condition, and functioning properly; (4) employees have been provided with appropriate PPE, including respiratory protection, if required; and (5) that all employees exposed to silica have received the appropriate silica training . . . (Document ID 4223, p. 113).

NIOSH recommended similar duties in addition to indicating that the competent person should assure proper hygiene to prevent employees from taking home silica dust on clothing and to conduct daily checks of engineering controls and respirators in abrasive blasting operations involving sand (Document ID 2177, Attachment B, pp. 9–10, 14). IUOE stated that the competent person could assist with employee training, ensure good housekeeping in heavy equipment cabs, and assume responsibility for exposure assessments (Document ID 2262, p. 41; 3583, Tr. 2369–2370; 3583, Tr. 2345). NISA stated that a competent person could conduct qualitative objective exposure assessments or determine frequency of exposure estimates under the performance option (Document ID 2195, pp. 35–36).

CISC opposed a requirement for a competent person and stated that thorough training eliminated the need for a competent person and access control plan (Document ID 4217, pp. 25–26). In disputing the value of expanding the competent person role in the standard, CISC claimed that the ubiquitous presence of silica in construction precluded the need for a designated person who is capable of identifying existing and predictable respirable crystalline silica hazards and has authorization to take prompt corrective actions (Document ID 2319, p. 127).

Commenters also addressed the practicality of a competent person requirement. IUOE commented that an employer would not need to hire additional personnel to serve as silica competent persons because they could designate a competent person to oversee more than one construction activity or task, as long as that person is able to identify existing and predictable hazards and is authorized to take prompt corrective action (Document ID 4234, Part 3, pp. 62–63). In contrast, CISC commented that requiring a competent person at all construction sites is not realistic for small companies and pointed to testimony from Kellie Vazquez, Vice President of Holes Incorporated, as an example (Document ID 4217, pp. 26–27). Ms. Vazquez testified:

> . . . my guys are one-man crews. So I will have one operator in a truck and that truck is loaded with his equipment to go do his multiple jobs per day. He is his own operator, his own equipment operator, his own supervisor, his own foreman. He has the right to shut down any job he feels that is not safe. I don't have a second man, or a competent person, or a supervisor go with him on site to look at the job and verify if it is safe or not. That's his responsibility. That's what he is trained to do. My operators have 30-hour OSHA [training]. They are trained in trenching and excavation. They are competent people in trenching and excavation. They are scaffold builders. They get aerial lift trained (Document ID 3580, Tr. 1389).

OSHA observes that the description of Ms. Vazquez's employees is consistent with the definition of a competent person for safety issues (*i.e.,* extensive training on safety issues and the authority to close down a job site if they feel that it is not safe), and Ms. Vazquez admitted that her employees are already competent persons in trenching and excavation. It is likely that her employees already have the knowledge to fully and properly implement controls on the tools they use and recognize if they are not functioning properly. With the training required under paragraph (i) of the standard for construction and the authority to take corrective actions, those employees could be designated as competent persons for respirable crystalline silica. OSHA concludes there is no need to designate a separate competent person in that situation.

In addition, any prompt corrective measures that competent persons would take to eliminate or minimize respirable crystalline silica hazards would likely have minimal impact on work activities in most cases. Such measures might include briefly stopping work to clear a clogged water line on a tool with wet method controls or clean a filter on a tool with vacuum controls if the competent person sees signs that controls are not functioning effectively. OSHA concludes that even for small businesses, a competent person requirement will not be unduly burdensome because knowledgeable employees, who will already be on site, can be designated as competent persons.

OSHA concludes that the ubiquitous presence of respirable crystalline silica and the many variables that can affect employee exposure when performing construction tasks justify a requirement for a competent person in construction, who is not only trained to identify and correct respirable crystalline silica hazards, but also is authorized to take immediate corrective actions to eliminate or minimize them.

Exposures and hazards can vary according to environmental conditions such as wind and humidity, geological profile of soil, if work is performed indoors or outdoors, or how well exposure controls are maintained. Consequently, there is an obvious need for a competent person to frequently inspect the construction job site, identify respirable crystalline silica hazards, and verify that effective control measures are being used. Site assessment is a continuous process because of changing environmental and work conditions as a construction job is being completed. In cases where the competent person is the only person from his or her company on a job site, frequent inspections of the job site would equate to continuous assessment of variables associated with the job that the competent person is conducting (*e.g.,* signs that the controls are not functioning effectively, a change in weather condition that might require an adjustment of controls, or moving from an outdoor area to an enclosed area).

Therefore, paragraph (g)(4) of the standard for construction requires an employer to designate a competent person to make frequent and regular inspections of job sites, materials, and equipment to implement the written exposure control plan. OSHA concludes that the uniqueness and complexity of scenarios on construction sites justify the designation of a competent person.

OSHA agrees with commenters that a competent person is needed in construction because employers who use the specified exposure control methods in Table 1 are not required to conduct exposure assessments and because large numbers of small construction companies do not typically employ health and safety professionals. Another reason for including a competent person provision in the construction standard is because at multi-employer worksites, the actions of one employer may expose employees of other employers to hazards. For these reasons, OSHA agrees with ACCSH and commenters from NIOSH, labor unions, and employee health advocate groups that a requirement for a designated competent person is needed and will improve employee protections in construction.

In addition, as noted above, a requirement for a competent person is consistent with OSHA substance-specific standards for construction, such as lead (29 CFR 1926.62), asbestos (29 CFR 1926.1101), and cadmium (29 CFR 1926.1127). OSHA's general safety and health provisions for construction require the employer to initiate and maintain programs for accident prevention, as may be necessary, and such programs require frequent and regular inspections of job sites, materials, and equipment by a designated competent person (29 CFR 1926.20(b)(1) and (2)). Designating a competent person is consistent with current construction industry practices because, as the record indicates, employers in the construction industry are already using competent persons.

OSHA is requiring that the competent person implement the written exposure control plan because, as discussed above, the plan specifies what must be done to consistently identify and control respirable crystalline silica hazards on a job site. In construction, a competent person is needed to ensure that the requirements of the written exposure control plan are being met under variable conditions. The subjects that must be described in the written exposure control plan for construction—tasks involving exposure to respirable crystalline silica; engineering controls, work practices, and respiratory protection; housekeeping methods for limiting exposure; and procedures for restricting access when needed to minimize exposures or numbers of employees exposed—are consistent with the duties of a competent person suggested by representatives from NIOSH, labor unions, employee health advocates, and some industries. Therefore, having the competent person implement the written exposure control plan is consistent with many of the competent person duties recommended by commenters. It also makes the competent person requirements easy to understand.

Implementation of the written exposure control plan does not address every competent person duty that was recommended by commenters, such as training or specific duties related to abrasive blasting with sand. OSHA is not mandating that the competent person conduct training because training could, in many cases, be performed by other individuals. For example, ensuring that an employee can demonstrate knowledge and understanding of health hazards, contents of the rule, and medical surveillance, and providing the employee with any needed training, may be better addressed by an individual other than the designated competent person, or at another location before the employee reports to the job site. A competent person could use the written exposure control plan to recognize employees who are not knowledgeable about full and proper implementation of controls or work practices and take appropriate action, such as reminding them of proper practices or recommending additional training to the employer.

The standard does not specify a duty for the competent person regarding abrasive blasting with sand, but unique aspects of that operation, such as more frequent checks of controls, could be specified in the written exposure control plan. OSHA reasons that evaluating alternate media for use in abrasive blasting, as was recommended in the draft standard for SBREFA, requires specialized knowledge in toxicology or a related science, and is thus beyond the knowledge of a typical employee who would be designated a competent person and unduly burdensome to employers. Also, as discussed in the summary and explanation section of *Methods of Compliance*, OSHA recognizes that alternative media may present health risks. Other duties that commenters recommended, such as conducting exposure assessment, are usually done by professionals such as industrial hygienists. Requiring an industrial hygienist to be on worksites daily would be very burdensome, especially to small employers. In addition, OSHA expects the need for exposure assessments in construction to be limited because most employers will likely rely on Table 1 in paragraph (c) rather than do exposure assessments, based on the number of comments OSHA received about exposure assessments being impractical in construction (*see* summary and explanation of *Exposure Assessment*).

In its prehearing comments, BCTD also requested that the exposure control plan list the identity of the competent person (Document ID 2371, Attachment 1, pp. 16–17). OSHA is not requiring that the written exposure control plan include the identity of the competent person because it is both impractical and unnecessary. Construction companies could have more than one designated competent person because they need a backup competent person or they have jobs being conducted at various construction sites. Therefore the identity of the competent person could change from day to day if employees work at different job sites, or if a backup person is sent to a particular job site. However, it is important for employees to be able to identify the competent person. Therefore, OSHA is requiring that employers covered by the standard for construction notify employees about the identity of the competent person as part of the training provision under paragraph (i)(2)(i)(E). OSHA expects this could simply involve announcing the identity of the competent person at the start of each work shift.

As stated above, paragraph (b) (*Definitions*) of the standard for construction specifies that the competent person have the knowledge and ability necessary to fulfill his or her responsibilities. The proposed rule did not specify particular training requirements for competent persons. Rather, the requirement for a competent person was performance-based in that the competent person needed to be capable of effectively performing the duty assigned under the standard, which was to identify, in advance, areas where exposures were reasonably expected to exceed the PEL. In the standard for construction, the duties of the competent person have been expanded, and expanded training requirements for the competent person therefore need to be considered.

OSHA received many comments regarding knowledge and competencies for a competent person. IUOE recommended inclusion of specific training requirements for competent persons in the standard for construction

because it thought that without them, competent persons may not get the training needed to train employees in the implementation and maintenance of controls or understand and adjust to variables that affect exposures, smaller employers might not understand the scope of appropriate training, employers might avoid expenditures for appropriate training, and the standard would be more difficult to enforce (Document ID 4234, Part 2, p. 52). IUOE summarized one case concerning an occupational fatality resulting from inadequate training or knowledge and other cases supporting specific training for competent persons (Document ID 4234, Part 2, pp. 55–56). ASSE cautioned that many OSHA standards do not specify parameters for determining competency and referred to the challenges in judging competency when litigating citations (Document ID 4201, pp. 4–5).

NIOSH requested that OSHA require competency training, as it did for asbestos (29 CFR 1926.1101(o)(4)), and list requirements for silica-specific training and capabilities for competent persons in the standard or an appendix of the standard. NIOSH further stated that ''OSHA could consider allowing appropriate experience to qualify (*e.g.,* learning by apprenticing to a trained silica-competent person).'' NIOSH noted that such an approach is consistent with the ANSI A10.38 standard that defines a competent person based on specific education, training, or experience (Document ID 2177, Attachment B, p. 9).

IUOE, ASSE, LHSFNA, and BCTD endorsed the competency objectives set forth in an AIHA White Paper as a minimum body of knowledge for a silica competent person (Document ID 4201, p. 6; 4207, p. 3; 4223, pp. 113–114). BCTD requested that the White Paper be included as a non-mandatory appendix to the rule (Document ID 4223, pp. 113–114). The AIHA White Paper indicates that a silica competent person can demonstrate competency by completing a training course addressing the criteria in the White Paper or successfully demonstrating the capabilities described in the White Paper through training or direct job experience. The competency objectives listed in the AIHA White Paper include an understanding of (a) the role of a competent person; (b) what silica is and where it is found; (c) silica hazards and exposures, occupational exposure limits, and regulations; (d) how to determine if silica is present through bulk sample analyses, safety data sheets, or material checklists; (e) exposure ranges for common construction tasks in the absence of controls and under conditions that can result in higher exposures, and recognition of situations when a qualified person needs to be called in; (f) effective use of controls to reduce exposures and basic understanding of respiratory protection; (g) understanding of need for oversight and quality assurance, including review of exposure monitoring by a qualified person and communication to other employers on a multi-employer sight; (h) understanding of OSHA standard; and (i) understanding of authority, responsibilities and procedures (*e.g.,* resolving safety or health situations) (Document ID 4076, pp. 4–9).

Commenters further elaborated on training requirements and competencies for a silica competent person. ASSE requested that OSHA give clear guidance on what qualifies an individual to be designated a competent person, asserted that certification in safety or industrial hygiene should presume competency, recommended similar competency requirements as the AIHA White Paper, and suggested that OSHA include training competency requirements in a non-mandatory appendix. ASSE also noted that the asbestos standard, 29 CFR 1926.1101(o)(4), requires competent persons to complete an Environmental Protection Agency course, and although an equivalent course does not exist for crystalline silica, training to address competencies for a silica competent person could be added to a 30-hour course for construction (Document ID 4201, pp. 2–6).

As discussed in detail in the summary and explanation of *Communication of Respirable Crystalline Silica Hazards to Employees*, BCTD requested a tiered approach to training in which the competent person would receive training necessary to perform his or her duties, in addition to awareness training for all covered employees and hands-on training on engineering controls and work practices for employees performing tasks that generate silica dust (Document ID 4223, pp. 117–118). IUOE, LHSFNA, and BAC similarly advocated competent person training as part of a tiered approach and stressed that the competent person receive site-specific training on engineering controls (Document ID 2262, pp. 39–40; 4207, p. 5; 4219, p. 24). Tom Nunziata, Training Coordinator for LHSFNA, stressed that the minimum training for a competent person should be at least the training required for employees performing tasks that generate silica dust (Document ID 3589, Tr. 4221). Similar to NIOSH, Travis Parsons testified that experience can contribute to a competent person's knowledge (Document ID 3589, Tr. 4197–4198).

LHSFNA indicated that competent person training should be tailored based on needs and exposure potential (Document ID 4207, p. 5). Other commenters provided numerous examples of unique training requirements for heavy equipment operators. For example, Gary Fore, retired Vice President for Health, Safety, and Environment for NAPA, referenced best practices for inspection of controls on asphalt milling machines by competent persons and testified that those machines are very complicated and sophisticated (Document ID 3583, Tr. 2182–2183). Therefore, training is required to detect issues requiring maintenance, such as a plugged or inappropriately placed nozzle (Document ID 2181, p. 10). IUOE commented that a competent person must have the knowledge to make informed judgments about the potential for silica exposures to exceed the action level (Document ID 2262, pp. 42–43). Martin Turek, Assistant Coordinator and Safety Administrator for IUOE Local 150, and Kyle Zimmer gave several examples of variables that could affect silica exposures in earth moving tasks, such as weather (*e.g.,* wind, humidity) and soil compositions and handling (*e.g.,* clay versus rock, distance soil is dropped from a bucket) (Document ID 3583, Tr. 2351–2352, 2356–2359). Matt Gillen, Deputy Director of NIOSH's Office of Construction Safety and Health, testified that a competent person should be able to recognize variability issues and make changes to address them (Document ID 3579, Tr. 205–206).

NRECA commented that a competent person for rural electric utilities should be trained in setting up air monitoring, setting boundaries for control zones, physical characteristics of crystalline silica, and PPE such as respirators (Document ID 2365, pp. 19–20). Francisco Trujillo testified that a competent person should have knowledge of work processes and their associated hazards and possibly, some knowledge of previous sampling evaluations to know if employees might be overexposed (Document ID 3585, Tr. 2980–2981). Upstate Medical University recommended that the competent person be trained on the respirable crystalline silica standard, the hierarchy of controls, exposure determinants, and the written control plan (Document ID 2244, p. 4).

Ameren Corporation opposed specific training requirements for a competent person (Document ID 2315, p. 2). CISC stated that if OSHA does include a competent person requirement in the

standard, the agency should not require training because:

> An individual's experience, job training, and silica awareness training, in the CISC's view, will provide the capabilities envisioned by OSHA for a competent person with respect to crystalline silica. For silica in construction, the CISC respectfully believes that no specific training for a ''competent person'' is required. Furthermore, the Agency has traditionally not included specific competent person training requirements in its construction standards, instead taking a performance-oriented approach to the requirements and definition. There is nothing unique about silica that would cause the Agency to deviate from this past approach (Document ID 2319, pp. 127–128).

OSHA concludes, after consideration of all the comments, that it is not practical to specify in the rule the elements and level of training required for a competent person. The Agency does not find it appropriate to mandate a ''one size fits all'' set of training requirements to establish the competency of competent persons in every conceivable construction setting. Therefore, the training requirement for a competent person is performance-oriented. This approach is consistent with most OSHA construction standards, such as cadmium (29 CFR 1926.1127) and lead (29 CFR 1926.62), which include a performance-based approach by not specifying training or qualifications required for a competent person.

It is evident from the comments that controlling respirable crystalline silica exposures involves tailoring controls and work practices to each particular work setting. Moreover, training is addressed by the HCS and paragraph (i) of the standard for construction. The HCS and paragraph (i) require that employees be trained on subjects that overlap with competencies listed in the AIHA White Paper. For example paragraph (h)(3)(i) of the HCS (29 CFR 1910.1200) requires training of covered employees on methods to detect the release of hazardous chemicals (in this case, respirable crystalline silica). The respirable crystalline silica standard for construction requires training on health hazards, tasks that could result in exposures, engineering and work practice controls and respiratory protection, and the contents of the standard (paragraphs (i)(2)(i)(A–D)).

OSHA concludes that successful completion of training requirements in the HCS and the standard for construction impart a high level of competency to employees. The training focuses on general requirements that apply to most construction settings and should be sufficient to provide an employee with the knowledge and ability to be designated a competent person at some companies. Competent persons might require more knowledge and training in certain circumstances, but that would vary widely among construction companies. For example, competent persons at a small residential construction company might only need training on controls for power tools that they do not typically use to perform their own tasks, so that they could assist employees with questions about or problems with dust controls on those tools. In contrast, a competent person for heavy equipment tasks may require more specialized training in heavy equipment inspection or identifying various soil types to estimate exposure potential. Because companies covered under the construction standard conduct a wide range of tasks involving unique scenarios, training requirements will vary widely among different companies. It is, therefore, the employer's responsibility to identify and provide any additional training that the competent person needs to implement the employer's written exposure control plan.

Finally, a compliance officer could ascertain whether the employer is in compliance with the competent person requirement by asking questions to assess whether the competent person has adequate knowledge to perform his or her duties, such as an understanding of engineering controls and how to recognize if they are not functioning properly. As is the case with training of all employees, the employer is responsible for determining that a competent person is adequately trained and knowledgeable to perform his or her duties.

Competent Person (General Industry). As part of the proposed written access control plan, OSHA proposed that a competent person identify and maintain regulated areas in workplaces covered by the general industry and maritime standard. AFL–CIO and USW requested expanded competent person duties and training requirements for general industry and maritime because a competent person could recognize and take action to protect employees from high exposures (Document ID 4204, pp. 58–60; 4214, pp. 14–16). AFL–CIO urged OSHA to reinstate the competent person duties from the 2003 SBREFA draft standard (Document ID 4204, pp. 58–60). USW commented that a competent person could ensure that hazards are recognized, employees receive proper training, adequate controls and PPE are implemented, and an effective exposure control plan is developed (Document ID 4214, pp. 14–15). In describing how a competent person is relevant to general industry, AFL–CIO pointed to testimony by employees who were trained to evaluate the function of ventilation systems (Document ID 4204, p. 60). AFL–CIO also asserted that NIOSH and AIHA urged OSHA to include a competent person requirement for both general industry and construction (Document ID 4204, pp. 59–60). OSHA examined the AIHA and NIOSH comments referenced by AFL–CIO and identified only recommendations for a competent person regarding construction-related topics, such as Table 1 (Document ID 2169, pp. 4–5; 2177, Attachment B, pp. 8–10, 25–26).

OSHA is not requiring a competent person for the general industry and maritime standard. OSHA has determined that in most cases, general industry scenarios are not as variable as those in construction. For example, most work is performed indoors and therefore, not subject to variables such as wind shifts and moving exposure sources that could significantly affect exposures or complicate establishment of regulated areas. In general industry and maritime, controls are not usually built into tools that require action by the individual employees who use them to function effectively. The exposure assessments that employers in general industry and maritime are required to conduct will verify that controls are functioning effectively. Employers covered under the general industry and maritime standard are more likely to have health and safety professionals on staff who could assist with implementation of the standard. Finally, competent persons have not been included in other OSHA substance-specific standards for general industry. For example, a competent person requirement was included in the construction standard for cadmium because of environmental variability and the presence of multiple employers on the job site, but a competent person requirement was not included in the general industry standard for cadmium (29 CFR 1910.1027; 29 CFR 1926.1127; 57 FR 42101, 42382 (9/14/1992)). Moreover, as explained in the summary and explanation of *Regulated Areas,* establishing regulated areas is reasonable in most general industry scenarios because employers are required to conduct exposure assessment and are thus able to determine the boundaries of a regulated area. Therefore, the general industry and maritime standard requires regulated areas that are demarcated and posted with warning signs. This negates the

need for a competent person to identify and maintain regulated areas. These factors explain and support OSHA's conclusion that there is no regulatory need for including a competent person requirement in the respirable crystalline silica standard for general industry and maritime.

Comparison to ASTM Standards. The written exposure control plan is comparable to the ASTM standards in some respects and different in others. Section 4.2.6 of ASTM Standard E 1132–06 and Section 4.2.5 of ASTM standard E 2625–09 recommend written exposure control plans for areas with persistent overexposures; address engineering, work practice, and administrative controls; and call for a root cause analysis to investigate the causes of the overexposure, identify remedies, and conduct follow-up sampling to verify that exposures are below the PEL (Document ID 1466, p. 2; 1504, p. 2). The major difference between the written plans in the ASTM standards and the written plans in the respirable crystalline silica rule is that the written plans for the respirable crystalline silica rule are not limited to overexposure scenarios. The ASTM standards address work practices and administrative controls, but the written exposure control plans in the respirable crystalline silica rule further explain what those practices and controls are (*i.e.,* restricting access as needed (construction standard only), engineering controls, work practices, respiratory protection, and housekeeping methods). In addition, the written exposure control plans in the respirable crystalline silica rule are implemented by a competent person (construction standard only), are required to be reviewed and updated at least annually by the employer, and are to be made available to employees, employee representatives, OSHA, and NIOSH upon request.

The requirements of the rule for respirable crystalline silica better protect employees and, therefore, better effectuate the purposes of the OSH Act of 1970 than the ASTM standards. Because the written plans are required for all workplaces covered by the rule, they help to maintain comprehensive and consistent controls, which can prevent overexposures from occurring. The provision for annual review ensures that the plans remain effective, and the provision for making the plans available to employees helps to make employees aware of the protections they should expect. More details about how the requirements of the rule better effectuate the requirements of the OSH Act are discussed above.

Medical Surveillance

Paragraph (i) of the standard for general industry and maritime (paragraph (h) of the standard for construction) sets forth requirements for the medical surveillance provisions. The paragraph specifies which employees must be offered medical surveillance, as well as the frequency and content of medical examinations. It also sets forth the information that the physician or other licensed health care professional (PLHCP) is to provide to the employee and employer.

The purpose of medical surveillance for respirable crystalline silica is, where reasonably possible, (1) to identify respirable crystalline silica-related adverse health effects so that appropriate intervention measures can be taken; (2) to determine if an employee can be exposed to respirable crystalline silica in his or her workplace without increased risk of experiencing adverse health effects, or in other words, to determine if an employee has any condition, regardless of the cause, that might make him or her more sensitive to respirable crystalline silica exposure; and (3) to determine the employee's fitness to use respirators. The inclusion of medical surveillance in this rule is consistent with Section 6(b)(7) of the Occupational Safety and Health (OSH) Act (29 U.S.C. 655(b)(7)) which requires that, where appropriate, medical surveillance programs be included in OSHA standards to determine whether the health of employees is adversely affected by exposure to the hazard addressed by the standard. Almost all other OSHA health standards have also included medical surveillance requirements and OSHA finds that a medical surveillance requirement is appropriate for the respirable crystalline silica rule because of the health risks resulting from exposure.

General. Paragraph (i)(1)(i) of the standard for general industry and maritime requires employers to make medical surveillance available for employees who will be occupationally exposed to respirable crystalline silica at or above the 25 μg/m^3 action level for 30 or more days per year. Paragraph (h)(1)(i) of the standard for construction requires employers to make medical surveillance available to employees who will be required under this section to use a respirator for 30 or more days per year. Thus, employers are required to determine if their employees will be exposed at or above the action level of 25 μg/m^3 in general industry and maritime, or required to wear a respirator under the construction standard for 30 or more days per year (*i.e.,* the next 365 days), and then make a medical examination available to those employees who meet these criteria under two scenarios: (1) Within 30 days of initial assignment, unless the employee has had a current examination that meets the requirements of this rule within the last three years (paragraph (i)(2) of the standard for general industry and maritime, paragraph (h)(2) of the standard for construction) and (2) within three years from the last initial or periodic examination (paragraph (i)(3) of the standard for general industry and maritime, paragraph (h)(3) of the standard for construction). As in previous OSHA standards, both standards are intended to encourage participation by requiring that medical surveillance be offered at no cost to the employee and at a reasonable time and place. Under the ''at no cost to the employee'' proviso, if participation requires travel away from the worksite, the employer will be required to bear the cost of travel, and employees will have to be paid for time spent taking medical examinations, including travel time.

Some employers and industry representatives questioned the general need for medical surveillance or expressed their concerns with the medical surveillance requirement. For example, OSCO Industries, Inc. argued that medical surveillance would not identify many employees with silicosis and OSCO Industries and National Association of Home Builders (NAHB) emphasized the progress that has already been made in eliminating silicosis (Document ID 1992, p. 11; 2296, p. 43). Fann Contracting, Inc. stated that medical surveillance is not needed because employees exposed above the permissible exposure limit (PEL) are required to wear respirators and they should therefore be protected (Document ID 2116, Attachment 1, p. 43).

OSHA does not find these comments persuasive. As discussed in Section VI, Final Quantitative Risk Assessment and Significance of Risk, OSHA has found that employees exposed to respirable crystalline silica at the preceding PELs are at significant risk of material impairment of health. Although the revised PEL of 50 μg/m^3 substantially decreases risks, the risk remains significant at and below the PEL, including at the action level of 25 μg/m^3. Consequently, even employees exposed at the action level are at significant risk of developing silicosis and other respirable crystalline silica-related diseases. Based on these risk assessment findings, OSHA concludes that silicosis and other respirable

crystalline silica-related illnesses are an ongoing occupational risk. OSHA expects that those illnesses are likely to be detected as part of medical surveillance, and the detection of these illnesses will benefit employees.

Even employees required to wear respiratory protection in high exposure environments are at risk of developing disease. As OSHA notes in the summary and explanation of *Methods of Compliance,* respirators fully protect employees only if they are properly fitted and maintained correctly and replaced as necessary; they do not protect employees if they are not used consistently and properly. The committee that developed the ASTM International (ASTM) standard, ASTM E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, also concluded that medical surveillance is needed for employees who wear respirators to ensure that the respiratory protection is working (Document ID 3580, Tr. 1452). (This requirement is consistent with that in ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica.) Consequently, OSHA concludes that the requirement for respiratory protection for exposures exceeding the PEL does not obviate the need for medical surveillance.

Employers also expressed concern about responsibility for exposures occurring through other employment or non-occupational sources (*e.g.,* environmental exposures) (*e.g.,* Document ID 2116, Attachment 1, pp. 20, 36, 37, 39; 2295, p. 2; 2296, p. 31; 3531, p. 9). Construction Industry Safety Coalition (CISC) and Holes Incorporated questioned how medical surveillance would decrease exposures, and Holes Incorporated stated it would not prevent the onset of silicosis (Document ID 2319, p. 116; 2338, p. 6).

OSHA stresses that the main purposes of medical surveillance are early detection of disease related to respirable crystalline silica exposure so appropriate intervention methods can be taken, to let employees know if they have a condition that might make them more sensitive to respirable crystalline silica exposure, and to assess fitness to wear a respirator. The purpose of medical surveillance is not to identify which employer is responsible for illnesses resulting from respirable crystalline silica exposures or must offer financial compensation. OSHA agrees with the Building Construction and Trades Department, AFL–CIO (BCTD), which stated that ''[e]arly detection of silica-related medical conditions will enable employees to make informed decisions about their work, their medical care and their lifestyles'' (Document ID 4223, p. 123). For example, as the American College of Occupational and Environmental Medicine (ACOEM) and the National Institute for Occupational Safety and Health (NIOSH) stated, an early diagnosis allows an employee to consider employment choices that minimize or eliminate respirable crystalline silica exposure to decrease the risk of progression or exacerbation of disease (Document ID 1505, p. 3; 3579, Tr. 257). In another example, an early diagnosis of silicosis allowed bricklayer Dennis Cahill, representing the International Union of Bricklayers and Allied Craftworkers (BAC), to manage his health by getting flu and pneumonia shots, avoiding the public during cold season, and staying indoors during periods of high air pollution (Document ID 3585, Tr. 3089, 3104). OSHA finds that although medical surveillance does not reduce exposures, like engineering controls do, it is nonetheless an integral component of this (and most) occupational safety and health standards and important in its own right for safeguarding the health of employees exposed to respirable crystalline silica.

OSHA also agrees with the viewpoint expressed so well by Mr. Cahill, that employees who are knowledgeable about their health risks will take actions in response to information from medical surveillance. Such actions will likely benefit not only the employees but also employers because their employees are likely to be healthier. Members of the medical community, labor unions, employee health advocate groups, and industry groups emphasized the value of early detection for intervention purposes (*e.g.,* Document ID 2080, p. 9; 2178, Attachment 1, p. 2; 2351, p. 15; 3541, p. 1; 3577, Tr. 570–571; 3588, Tr. 3751; 3589, Tr. 4292; 4204, p. 79; 4219, p. 28; 4223, pp. 123–124). In addition, more than 100 commenters including construction employees, employee health advocates, medical professionals, and employers or industry representatives voiced their general support for medical examinations in the respirable crystalline silica rule (*e.g.,* Document ID 1771, p. 1; 2030; 2268; 2134, p. 10; 2403; 3294).

Some commenters representing the construction industry questioned the practicality of medical surveillance for construction employees due to a number of particular difficulties, such as the short-term nature and high turnover rate of construction jobs (*e.g.,* Document ID 2116, Attachment 1, p. 20; 2187, p. 7; 2247, p. 1; 2276, p. 10; 2289, p. 8; 2295, p. 2; 2296, pp. 42–43; 3230, p. 1; 3442, pp. 5–6; 4029, p. 3; 4217, p. 21). For example, American Subcontractors Association and Hunt Construction Group stated that the difficulty in tracking medical surveillance in a mobile work force could result in repeated, unnecessary testing for construction employees (Document ID 2187, p. 7; 3442; pp. 5–6). Kenny Jordan, Executive Director of the Association for Energy Services Companies (AESC), which represents another industry with high turnover rates, expressed similar concerns about repeated testing, although he did not oppose medical surveillance and asked for a medical record that would follow the employee (Document ID 3589, Tr. 4063). The Laborers' Health and Safety Fund of North America (LHSFNA) supported medical surveillance, but expressed concerns about repeated testing and urged OSHA to include provisions for contractor associations and union management funds to coordinate medical examinations for employees who work for several contractors in a year to avoid unnecessary medical examinations (Document ID 4207, p. 5).

After considering these comments, OSHA concludes that the necessity for medical surveillance is not negated by the practical challenges of tracking medical surveillance in a mobile work force. OSHA has included medical surveillance in other health standards where construction has been a primary industry impacted by those rules (*e.g.,* lead, asbestos, and chromium (VI)) and finds no reason why the respirable crystalline silica standard for construction should be an exception. Moreover, there are practical solutions for tracking medical surveillance to avoid duplicative, unneeded testing. One simple solution, which OSHA has included in this rule, is to have employers ensure that each employee receives a dated copy of the PLHCP's written medical opinion for the employer. The employee can then provide the opinion to his or her next employer as proof of up-to-date medical surveillance (Document ID 4207, p. 5; 4223, p. 125). Employers could also work with a third party, such as an industry association, union, or local medical facility, to coordinate, provide, or keep records of medical examinations (Document ID 4207, p. 5; 4236, pp. 3–4, Appendix 1, pp. 1–2). Such an approach has been used by LHSFNA to avoid unnecessary testing of employees who work for several contractors in a

year (Document ID 3759, Appendix 3). The respirable crystalline silica rule does not preclude such pooled employer-funded approaches, and OSHA expects such coordination to occur in response to this rule. OSHA concludes that there are practical solutions for addressing the challenge posed by employee mobility and turnover in the construction industry, and those factors should not prevent construction employees who are eligible for medical surveillance under the standard (*i.e.,* those who will be engaged in tasks requiring respirator use for 30 or more days in the upcoming year) from being offered such surveillance as part of the employer's compliance obligations.

In the proposed standards, OSHA specified that employers must ''make medical surveillance available'' to those employees who would be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days a year. The Agency received a variety of comments on this provision. First, NAHB expressed concern about employees refusing to participate in medical surveillance (Document ID 2296, p. 32). OSHA emphasizes that the mandate to offer medical surveillance to eligible employees does not include a requirement for employee participation, and no liability for non-participation arises so long as the employer does not discourage such participation.

Second, OSHA received numerous comments related to the proposed triggers for determining which employees should be provided medical surveillance. Some commenters focused on the level of exposure at which medical surveillance should be triggered. For example, Ameren Corporation agreed with the proposed PEL trigger, noting that it is consistent with the asbestos standard (Document ID 2315, p. 9). Some stakeholders from industry, the medical community, and employee health advocate groups also supported a trigger based on a PEL (*e.g.,* Document ID 1785, pp. 4–5; 2175, p. 5; 2291, p. 26; 2327, Attachment 1, p. 26; 2339, p. 5; 2379, Appendix 1, p. 71; 3577, Tr. 784–785).

Other commenters advocated that medical surveillance should be triggered on an action level. However, these stakeholders disagreed on what the action level should be. For example, some commenters, like the National Industrial Sand Association (NISA), American Petroleum Institute, and other employers and industry groups, advocated an action level trigger of 50 μg/m^3 (with a higher PEL of 100 μg/m^3) (*e.g.,* Document ID 1963, pp. 1–2; 2196, Attachment 1, pp. 1–2; 2200, pp. 1–2; 2213, p. 3; 2232, p. 1; 2233, p. 1; 2301, Attachment 1, p. 78; 2311, p. 3; 4208, pp. 7–9). NISA did not agree with OSHA that significant risk remains at 50 μg/m^3, but stated that an action level trigger is consistent with other OSHA standards; can lead to identification of individuals who might be more susceptible to silica exposures because of factors, such as genetic variability, prior work exposures, or smoking; addresses variability in workplace exposures; and provides an economic incentive for employers to maintain lower exposures (Document ID 2195, pp. 6, 30, 32).

Other stakeholders, including representatives of labor unions, the medical community, and other employee health advocate groups, stated that the proposed action level of 25 μg/m^3, or even a lower level, should trigger medical surveillance in general industry (*e.g.,* Document ID 2157, p. 7; 2178, Attachment 1, p. 2; 2240, p. 3; 2282, Attachment 3, p. 14; 2336, p. 11; 2256, Attachment 2, p. 9; 2351, pp. 13–15; 3516, p. 3; 3541, p. 4). Other members of the medical community and employee health advocate groups also voiced general support for an action level trigger of 25 μg/m^3 or lower (*e.g.,* Document ID 2080, p. 5; 2176, p. 2; 3538, Attachment 1, pp. 3–4).

American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) supported an action level trigger of 25 μg/m^3 because the union agreed with OSHA about the remaining significant risk for diseases at a PEL of 50 μg/m^3 and because an action level at half the PEL would be consistent with the majority of OSHA health standards (Document ID 4204, pp. 51, 79–80). Other representatives from the medical community, labor unions, and other employee health advocate groups, who also supported an action level trigger of 25 μg/m^3 or lower, expressed similar thoughts about significant risk or consistency with past standards (Document ID 2080, p. 5; 2157, p. 7; 2176, p. 2; 2178, Attachment 1, p. 2; 2282, Attachment 3, p. 22; 2336, p. 11; 3516, p. 3; 3535, p. 2; 3541, pp. 14–15). Some of those same commenters, including the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) and ACOEM, supported an action level trigger because of the variability of workplace exposures (Document ID 2282, Attachment 3, p. 14; 3577, Tr. 766–767); the medical society Collegium Ramazzini and United Steelworkers (USW) also noted an economic benefit for employers to maintain lower exposures (Document ID 2336, p. 11; 3541, p. 15). Lastly, AFL–CIO noted that because OSHA proposed a requirement for exposure assessment in general industry, employers will know if employees are exposed above the action level; the same is not true in construction because employers may use Table 1 instead of conducting exposure assessments (Document ID 4204, pp. 80–81).

OSHA also received comments on whether medical surveillance should be triggered by a number of days of exposure at a certain level. For example, NISA objected to the proposed 30-day exposure-duration trigger for medical surveillance and stated that it should be offered to all employees with likely exposure to respirable crystalline silica above the action level (Document ID 4208, p. 8, Fn 12). The Asphalt Roofing Manufacturers Association (ARMA) supported the 30-day exposure-duration trigger for medical surveillance because some employees are only infrequently exposed above the PEL as a result of scheduled maintenance tasks performed once or twice per year or when filling in for other employees, and the 30-day trigger would exclude employees with lower average exposures (Document ID 2291, p. 26). Other commenters representing industry or the medical community also agreed with the 30-day exposure-duration trigger (*e.g.,* Document ID 2080, p. 5; 2157, p. 7; 2175, p. 5; 2178, Attachment 1, p. 2; 2301, Attachment 1, p. 78; 2311, p. 3; 2315, p. 9; 2327, Attachment 1, p. 26; 2379, Appendix 1, p. 71; 3541, p. 14).

OSHA agrees with the majority of commenters who indicated that maintaining the 30-day exposure-duration trigger is appropriate for general industry and maritime because the health effects of respirable crystalline silica occur as a result of repeated exposures and concludes that a 30-day trigger is a reasonable benchmark for capturing cumulative effects caused by repeated exposures. Including a 30-day exposure-duration trigger also maintains consistency with other OSHA standards, such as chromium (VI) (29 CFR 1910.1026), cadmium (29 CFR 1910.1027), lead (29 CFR 1910.1025), and asbestos (29 CFR 1910.1001). OSHA also agrees with commenters who indicated that triggering medical surveillance at the action level of 25 μg/m^3 addresses residual significant risk and varying susceptibility of employees that can result in some experiencing adverse health effects at lower exposure levels. An action level trigger in the standard for general industry and maritime is also appropriate based on variability in exposure levels and the availability of exposure assessment data in general

industry and maritime. However, OSHA has concluded that a delayed implementation of the action level trigger for medical surveillance is appropriate. Therefore, as indicated in the Summary and Explanation for *Dates*, medical surveillance will be triggered by exposures exceeding the PEL for 30 or more days per year during the first two years after medical surveillance requirements commence (*i.e.,* beginning two years after the effective date). After that time (*i.e.,* four years after the effective date), medical surveillance will be triggered by exposures exceeding the action level for 30 or more days per year (paragraph (l)(4)). This approach will focus initial medical surveillance efforts on those employees at greatest risk, while giving most employers additional time to fully evaluate the engineering controls they have implemented in order to determine which employees meet the action level trigger for medical surveillance.

OSHA intends to conduct a retrospective review five years after the action level trigger is fully implemented (*i.e.,* at nine years after the effective date of the standard for general industry and maritime) to gain a better understanding of the effectiveness of the action level trigger for medical surveillance. OSHA will engage other federal agencies, such as NIOSH, and stakeholders as appropriate, and will issue a report about the findings of the evaluation.

Construction industry representatives, employee health advocates, and others also commented on OSHA's proposed use of the PEL to trigger medical surveillance in the standard for construction. The Center for Progressive Reform (CPR) and Charles Gordon, a retired occupational safety and health attorney, advocated an action level trigger for medical surveillance; Mr. Gordon also requested that conducting Table 1 activities trigger medical surveillance (Document ID 2351, p. 13; 4236, pp. 3–4). Fann Contracting supported a PEL trigger for medical surveillance (Document ID 2116, Attachment 1, p. 42). BAC and BCTD supported the PEL (as determined by monitoring) or Table 1 tasks requiring respirator use as triggers for medical surveillance in construction because employees using Table 1 would not be required to conduct exposure assessments and therefore would not know if exposures exceed the action level (Document ID 4219, p. 29; 4223, p. 124). [Note 1 for proposed Table 1 indicated that required respirator use in Table 1 presumed exposures exceeding the PEL (78 FR 56273, 56499 (9/12/13))]. In prehearing comments, LHSFNA supported a PEL trigger as a practical approach and requested that medical surveillance be triggered by tasks (Document ID 2253, p. 5). In its post-hearing comments, however, LHSFNA recommended that medical surveillance be required for employees who are required to wear a respirator since those employees would already need to undergo a medical evaluation to make sure they can safely wear a respirator (as required by the respiratory protection standard) (Document ID 4207, pp. 4–5).

After reviewing these comments, OSHA concludes that an action level trigger is not practical in the construction industry because many employers will be using Table 1, and, therefore, will not have an exposure assessment indicating if the action level is met or exceeded. OSHA acknowledges that some construction employees who are not required to use respirators for 30 or more days per year are at significant risk, but has decided that triggering medical surveillance based on respirator use is the most practical trigger for the construction standard. Triggering medical surveillance in this manner is consistent with the proposed rule, because respirator use under Table 1 is based on tasks in which exposures consistently (more often than not) exceed the revised PEL, as found in OSHA's technological feasibility analyses of the various tasks included in Table 1 (*see* Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA) and the summary and explanation for *Specified Exposure Control Methods*). OSHA expects most construction employers to be following Table 1, and therefore decided it also made the most practical sense to tie medical surveillance to required respirator use. In addition, use of the respirator trigger allows construction employers to more efficiently determine if the 30-day duration trigger is met in cases where one of their employees may be required to use respirators when doing Table 1 tasks and while doing tasks (*e.g.,* abrasive blasting) that are not on Table 1 but are determined to have exposures above the PEL based on exposures assessments conducted under paragraph (d)(2) of the standard for construction. Finally, OSHA decided not to expand the trigger for medical surveillance to Table 1 tasks that do not require respirator use because many employees engaged in those tasks will be exposed below the action level (*see* Chapter III of the FEA).

Some commenters expressed concerns about the practicality of requiring employers to offer medical surveillance for exposures exceeding a trigger level for 30 days or more in the construction industry. George Kennedy, Vice President of Safety for the National Utility Contractors Association, testified that they do not know what employees are doing in the field each day and so will have to assume that they are exposed and, therefore, offer medical surveillance to every employee (Document ID 3583, Tr. 2245). BCTD questioned the feasibility of the 30-day exposure-duration trigger because the transient nature of construction work makes it difficult to predict if an employee will be exposed for 30 days; the American Industrial Hygiene Association (AIHA), AFL–CIO, and LHSFNA expressed similar views (Document ID 2169, p. 6; 4204, p. 81; 4207, p. 4; 4223, p. 125). CISC and some of its member companies questioned how an employer would know if employees were exposed above the PEL for 30 or more days a year unless they were following Table 1 or conducting near continuous monitoring (Document ID 2269, pp. 6–7; 2289, p. 8; 2319, p. 116). CISC and AIHA questioned how OSHA could verify the number of days an employee was exposed (Document ID 2169, p. 6; 2319, p. 116). Larger employers, such as Fann Contracting, expressed the challenges of tracking employee exposures due to large numbers of employees and various ongoing projects (*e.g.*, Document ID 2116, Attachment 1, p. 11).

OSHA acknowledges that tracking exposures in construction can be challenging but observes that some employers are currently able to track employee exposures to determine which employees should be offered medical surveillance. For example, Kevin Turner, Director of Safety at Hunt Construction Group and representing CISC, testified that safety representatives on job sites keep track of exposures based on employees' schedules, and the company provides medical surveillance for employees exposed above the preceding construction PEL for 30 or more days a year (Document ID 3580, Tr. 1535–1536). Francisco Trujillo, Safety Director at Miller and Long, Inc., testified that at his company, they conduct hazard assessments based mainly on the tasks the employees will be performing, to determine which employees are likely to be exposed above the preceding PEL, and they offer those employees medical evaluations as part of the company's respiratory protection program. The company has a system that monitors participating employees' training, medical evaluations, and fit tests. The system sends email reminders to company

representatives when the participating employees are due to be re-examined or re-evaluated. However, Mr. Trujillo expressed concern that if the number of employees participating in the program greatly increases, then maintaining the company's tracking program would become a more daunting task (Document ID 3585, Tr. 3008–3010).

After reviewing the comments and testimony submitted on the proposed construction trigger, OSHA concludes that the special circumstances in construction, such as lack of exposure data for employees using Table 1 or difficulties in tracking exposures for numerous short-term assignments conducted at various sites, warrant a simpler approach for triggering medical surveillance. Therefore, OSHA revised paragraph (h)(1)(i) of the standard for construction to require that employers offer medical surveillance to employees who will be required to wear a respirator under this standard for 30 or more days a year to limit exposure to respirable crystalline silica. Under the standard for construction, employees must wear a respirator when required to do so under Table 1 (paragraph (c)) or when, pursuant to the performance option or the scheduled monitoring option set forth in paragraph (d)(2), their exposures exceed the PEL (paragraph (e)(1)(ii)). Respirator use under Table 1 is equivalent to the PEL because the tasks that require respirator use are those that, in its technological feasibility analysis of the construction industry, OSHA has determined result in exposures exceeding 50 μg/m^3 a majority of the time (*see* Chapter IV of the FEA and the summary and explanation of *Specified Exposure Control Methods*). Based on the number of commenters who indicated that exposure assessment is not practical in construction because of changing tasks and conditions (*see* summary and explanation of *Exposure Assessment*), OSHA expects most employers to use Table 1 for tasks listed on the Table (*i.e.*, most of the tasks that generate silica exposure in construction). Under any available exposure control method, however, the most convenient way for construction employers to determine eligibility for medical surveillance is by counting the number of days the employee will be required to wear a respirator. Because respirator use is tied with certain tasks in Table 1, medical surveillance based on respirator use in Table 1 is consistent with the task-based approach described by Francisco Trujillo above. It is also consistent with the task-based triggers in the cadmium construction standard (29 CFR 1926.1127) and operation-based triggers (*e.g.*, Class I work) in the asbestos construction standard (29 CFR 1926.1101).

OSHA concludes that a trigger based on respirator use will greatly simplify determining which employees covered by the construction standard must be offered medical surveillance. Consistent with the approach described by Kevin Turner above, company personnel on site, such as supervisors, could easily record or estimate when employees perform, or will perform, tasks requiring respirator use. Such information could be conveyed to a company employee who tracks it. Despite testifying that he would have a hard time tracking a greater number of employees who may require medical surveillance if the PEL or action level in effect at that time were lowered, Francisco Trujillo, from Miller and Long, a company with approximately 1,500 field employees, indicated that his company has a system that monitors and sends emails when employees are due for another medical examination (Document ID 3585, Tr. 3008–3010). OSHA sees no reason why this system could not be applied to larger numbers of employees, and this shows that it is possible for large companies to track exposures for numerous employees. Tracking exposures or days of respirator use will likely be easier for smaller companies who have fewer employees to track; OSHA estimates from existing data that approximately 93 percent of construction companies covered by the respirable crystalline silica standard have fewer than 20 employees (*see* Chapter III of the FEA). In addition, compliance officers would be able to determine if employees were exposed for 30 or more days a year but not offered medical surveillance by questioning employees about how often they engage in tasks that require respirator use for that employer.

Fann Contracting asked how a trigger for medical surveillance would apply to employees, such as heavy machine operators, who may briefly use respirators, such as when outside a cab for 30 minutes (Document ID 2116, Attachment 1, p. 3). OSHA clarifies that if an employee is required to wear a respirator at any time during a given day, whether to comply with the specified exposure control methods in paragraph (c) or to limit exposure to the PEL under the construction standard for respirable crystalline silica, that day counts toward the 30-day threshold.

Commenters also questioned the appropriateness of a 30-day exposure-duration trigger for construction. For example, American Society of Safety Engineers (ASSE) voiced concerns about the standard not addressing temporary employees who are continually exposed from job to job but may never stay with an employer for a full 30 days (Document ID 2339, p. 5). Conversely, CISC questioned why OSHA diverged from the ASTM exposure-duration trigger of 120 days, which would reduce the need to make medical surveillance available for short-term employees, and stated that OSHA needed to explain how this would improve the health of employees (Document ID 2319, p. 118; 1504, pp. 4–5). Members of the ASTM committee that developed the ASTM E 2625–09 standard testified that a 120-day exposure-duration trigger was selected so that employers did not have to provide medical surveillance to transient employees and that even a trigger of less than 90 days was considered but would have resulted in too much pressure and cost for employers because of the transient nature of construction work (Document ID 3580, Tr. 1452–1453; 3585, Tr. 2919–2920).

OSHA understands that offering medical surveillance for a transient workforce may be challenging, especially for small companies. However, the requirement to offer periodic medical examinations every three years rather than annually will reduce the cost and burden of providing such examinations considerably (*see* Chapter V of the FEA). OSHA finds both the 120-day exposure-duration trigger (in the ASTM standards) and the 90-day trigger (considered by the ASTM committee) overly exclusive and insufficiently protective. Under those longer triggers, many short-term employees (*i.e.*, those doing tasks requiring respirator use or otherwise exposed above the PEL for 30 or more days a year but nonetheless exposed for less than 90 days with the same employer) would be deprived of the health benefits of medical surveillance, such as early detection of disease, despite being at risk due to repeated exposures with different employers. As noted above, the health effects of respirable crystalline silica are most likely to occur as a result of repeated exposures. OSHA concludes that a 30-day exposure-duration trigger strikes a reasonable balance between the administrative burden of offering medical surveillance to all employees, many of whom may not be further exposed or only occasionally exposed, and the need for medical surveillance for employees who are regularly exposed and more likely to experience adverse health effects. The 30-day

trigger is also administratively convenient insofar as it is consistent with OSHA standards for construction, including asbestos (29 CFR 1926.1101), cadmium (29 CFR 1926.1127), chromium (VI) (29 CFR 1926.1126), and lead (29 CFR 1926.62).

Commenters also raised other issues regarding the 30-day exposure-duration trigger that could apply to both the general industry and maritime standard and the construction standard. One concern was that inclusion of a 30-day trigger would result in discriminatory actions by employers in order to avoid offering medical surveillance. For example, Dr. Daniel Anna, Vice President of AIHA, was concerned that employers might refuse to hire someone approaching 30 days of exposure (Document ID 3578, Tr. 1048–1049); BAC also expressed concerns about employers terminating employees approaching their 30th day of exposure (Document ID 4219, p. 29). In addition, BAC noted that employers rotating employees to maintain employee exposure below 30 days might result in more employees being exposed to silica (Document ID 2329, p. 8).

Comments indicating that an employer might refuse to hire employees approaching their 30th day of exposure are based on an interpretation that medical surveillance is triggered by a total of 30 days of exposure per year with any employer. Such an interpretation was conveyed by the Shipbuilders Council of America and ASSE who commented that employers would need to know employee exposures with past employers when determining total days of exposure above the PEL (Document ID 2255, p. 3; 3578, Tr. 1048). That is not OSHA's intent, and OSHA clarifies that exposures occurring with past employers do not count towards the 30-day-per-year exposure-duration trigger with the current employer (*i.e.,* the trigger is for employment with each particular employer). However, the 30-day-per-year exposure-duration trigger would apply when an employer hires a particular employee for more than one short-term assignment during a year, totaling 30 days or more. An advantage of not considering total exposures with all employers in triggering medical surveillance is that it avoids creating an incentive not to hire. With regard to comments about possible discriminatory practices (*e.g.,* termination before the 30th day) or rotating employees to avoid medical surveillance, OSHA rejects the reasoning that employers will base employment and placement decisions on the 30-day exposure-duration trigger because the cost of medical examinations is modest (*i.e.,* the FEA estimates the average cost of each medical examination at approximately $400 every three years).

Charles Gordon suggested that employers give each departing employee a card indicating the number of days they were exposed above the trigger point so that future employers would have a better idea if the employee was eligible for another medical examination based on 30 days of exposure (Document ID 4236, pp. 3–4). Such a record of past exposure with any prior employer is not necessary because of OSHA's decision to not consider exposures with past employers when triggering medical surveillance. Requiring employers to record exposures with past employers and to give employees a card indicating the number of days they were exposed above the trigger point increases recordkeeping and paperwork burdens for employers. It also imposes a burden on employees because it gives them an additional document that they need to maintain. To avoid these added burdens and for the reasons previously given for not counting exposures with other employers towards an employee's medical surveillance requirement, OSHA rejects Mr. Gordon's suggestion.

NIOSH and Fann Contracting questioned the 30-day-per-year exposure-duration trigger because employees who have been exposed to silica for years, but are not currently exposed 30 days per year, would be at risk of developing lung diseases (Document ID 2116, Attachment 1, p. 41; 2177, Attachment B, pp. 39–40). NIOSH recommended that medical surveillance continue after an employee is no longer exposed to respirable crystalline silica but continues to work for the same employer (Document ID 2177, Attachment B, p. 39). James Schultz, safety director at Navistar Waukesha Foundry and representing the Wisconsin Coalition for Occupational Safety and Health (WisCOSH), testified that medical surveillance should continue after employees have left ''this type of work environment'' (Document ID 3586, Tr. 3200–3201). However, NIOSH also stated that considerations for continued medical surveillance include the number of years an employee was required to be monitored and if the employee is showing signs of silica-related illness (Document ID 2177, Attachment B, p. 39).

OSHA agrees with NIOSH that silica is retained in the lungs and can cause progressive damage after exposures end. However, the lack of clear criteria in the record for determining when continued medical surveillance would be beneficial precludes OSHA from mandating continued medical surveillance after exposure ends. In addition, OSHA policy is clear that requirements are imposed on current employers. In the benzene standard, OSHA articulated that policy in deciding not to mandate continued medical surveillance for employees who are no longer exposed above the trigger, noting administrative difficulties in keeping track of employees who had moved on to other jobs (52 FR 34460, 34550 (9/11/1987)).

CISC, American Subcontractors Association, OSCO Industries, and Holes Incorporated questioned why medical surveillance is needed for younger employees when respirable crystalline silica-related diseases take years to develop (Document ID 1992, p. 11; 2187, p. 7; 2319, pp. 116–117; 3580, Tr. 1471). CISC recommended that OSHA trigger medical surveillance after a minimum duration of exposure or when a silica-related disease is diagnosed. In contrast, Andrew O'Brien, Vice President of Safety and Health at Unimin Corporation and representing NISA, emphasized the importance of establishing a baseline for future measurement (Document ID 3577, Tr. 570). When asked if age or duration of exposures should be considered in determining frequency of medical surveillance, Dr. Laura Welch, occupational physician with BCTD, responded:

> . . . we're looking at different disease outcomes. If we were only concerned about silicosis, you could probably . . . make that argument, but silica exposure also causes [chronic obstructive pulmonary disease], and that has an earlier onset and . . . it's good to have a baseline of a couple of tests before someone develops disease so you can more clearly see an early decline (Document ID 3581, Tr. 1667).

When a BAC panel was asked if 20 years after first exposure is the appropriate time to start medical surveillance, terrazzo worker Sean Barret responded:

> According to their 20-year standard, you wouldn't even find out I was sick until next year. I was sick a year ago, and it probably showed five years before that. So, I mean, that's ludicrous (Document ID 3585, Tr. 3055).

OSHA agrees that employees' baseline findings are important for future diagnoses and notes Dr. Welch's testimony that other silica-related diseases, such as chronic obstructive pulmonary disease (COPD), develop in shorter times than silicosis. Based on such evidence, OSHA concludes that it is appropriate to start medical surveillance in young or newly exposed

employees before they experience declines in health or function associated with age or respirable crystalline silica exposure.

Paragraph (i)(1)(ii) of the standard for general industry and maritime (paragraph (h)(1)(ii) of the standard for construction) requires that the medical examinations made available under the rule be performed by a PLHCP, who is defined (*see* summary and explanation of *Definitions*) as an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health services required by paragraph (i) of the standard for general industry and maritime (paragraph (h) of the standard for construction). This provision is unchanged from the proposed rule.

The American Public Health Association (APHA) requested changes to the definition of PLHCP that would require the PLHCP to be licensed for independent practice (Document ID 2178, Attachment 1, p. 5). OSHA finds that requested change to be too restrictive. To assure competency while providing for increased flexibility, OSHA continues to find it appropriate to allow any professional to perform medical examinations and procedures made available under the standard when he or she is licensed by state law to do so. In this respect, which and how a health care professional can function as a PLHCP under the rule may vary from state to state depending on each state's licensing requirements and laws governing what diagnostic examinations and procedures they are permitted to perform. In no case, however, is the authorization in this rule to use any PLHCP narrower or stricter than what is authorized in the particular state where an examination occurs.

Some commenters expressed concern about the availability of PLHCPs or other medical professionals in certain geographical locations. For example, Fann Contracting and the National Rural Electric Cooperative Association commented that PLHCPs who can offer the required examinations or occupational health resources may not be available for employers located in rural areas or near retirement communities (Document ID 2116, Attachment 1, p. 43; 2365, p. 10). Under the rule, a PLHCP, as defined, does not have to be an occupational medicine physician or even a physician to conduct the initial and periodic examinations required by the rule, but can be any health care professional who is state-licensed to provide or be delegated the responsibility to provide those services. The procedures required for initial and periodic medical examinations are commonly conducted in the general population (*i.e.,* medical history, physical examination, chest X-ray, spirometry test, and tuberculosis test) by practitioners with varying qualifications. Because medical examinations consist of procedures conducted in the general population and because OSHA is giving employers maximum flexibility in selecting a PLHCP who can offer these services, OSHA intends to assure that employers will not experience great difficulty in finding PLHCPs who are state-licensed to provide or be delegated the responsibility to provide these services. Even in the case of X-rays, OSHA finds that the availability of digital X-ray technology allows for electronic submission to a remotely located B Reader for interpretation, and thus does not expect a limited number of B readers in a certain geographic location to be an obstacle to employers covered by the rule.

Initial examination. Paragraph (i)(2) of the standard for general industry and maritime (paragraph (h)(2) of the standard for construction) specifies that an initial (baseline) medical examination must be made available within 30 days of initial assignment (*i.e.,* the day the employee starts working in a job with potential exposures above the trigger point), unless the employee received an examination that meets the requirements of this section within the past three years. This provision is unchanged from the proposed rule. The requirement for an initial examination within 30 days of assignment provides a health baseline for future reference and lets employees know of any conditions that could increase their sensitivity to respirable crystalline silica exposure. For example, Dr. Tee Guidotti, an occupational medicine physician representing the Association of Occupational and Environmental Clinics (AOEC), testified that existing COPD may make an individual more sensitive to respirable crystalline silica exposure (Document ID 3577, Tr. 797–798).

Newmont Mining Corporation, Nevada Mining Association, and Distribution Contractors Association (DCA) questioned whether recent or future exposures should be considered in triggering certain aspects of the initial examination (*e.g.,* physical examination, chest X-ray, or pulmonary function tests) and indicated that baseline examinations should only be required near the time when exposures begin (Document ID 1963, p. 2; 2107, p. 3; 2309, p. 5). The requirement is for employers to offer initial examinations to employees who ''will be'' occupationally exposed to respirable silica at or above the action level for 30 or more days a year in the standard for general industry and maritime (paragraph (i)(1)(i)) or who ''will be'' required to use a respirator under this section for 30 or more days per year in the standard for construction (paragraph (h)(1)(i)). Therefore, eligibility for medical examinations is based on expected exposure with the current employer. These triggers apply to both initial and periodic medical surveillance, and inclusion of the terms ''will be occupationally exposed'' or ''will be required'' makes it clear that requirements to offer medical surveillance are not based on past exposures. OSHA is aware that unexpected circumstances may result in employees being exposed more frequently than initially anticipated. In those cases, employers should make medical surveillance available as soon as it becomes apparent that the employee will be exposed above the appropriate trigger point for 30 or more days per year.

In the preamble of the Notice of Proposed Rulemaking (NPRM), OSHA indicated that where an examination that complies with the requirements of the standard has been provided in the past three years, an additional initial examination would not be needed (78 FR at 56468). Ameren agreed with OSHA's preliminary determination on this issue and asked the Agency to verify that examinations conducted in the last three years could be supplemented with any additional requirements of the rule, such as tuberculosis testing (Document ID 2315, p. 4). OSHA agrees that this is a reasonable approach. For example, if an employee received an examination that met all the requirements of the initial medical examination, with the exception of a tuberculosis test, within the last three years, the employer could supplement that examination by offering only the tuberculosis test. That same employer or a future employer could then offer a periodic medical examination, which does not require a tuberculosis test, three years from the last medical examination. New hires, who received medical surveillance that met the requirements of the respirable crystalline silica rule from a past employer, should have a copy of the PLHCP's written medical opinion for the employer, which the employer must ensure that the employee receives

within 30 days of the examination (paragraph (i)(6)(iii) of the standard for general industry and maritime, paragraph (h)(6)(iii) of the standard for construction), as proof of a current initial or periodic medical examination that met the requirements of this section (*see* example of the PLHCP's written medical opinion for the employer in Appendix B). If a newly hired employee eligible for medical surveillance presents proof of an examination that met the requirements of the rule, the employer's obligation is to offer the periodic examination required by paragraph (i)(3) of the standard for general industry and maritime (paragraph (h)(3) of the standard for construction) within three years of the previous examination.

Commenting on the three year period in which the result of a prior examination can substitute for a new initial (baseline) examination, APHA, Collegium Ramazzini, and the American Federation of State, County and Municipal Employees (AFSCME) opined that three years between examinations is an excessive time period because it does not provide for an adequate baseline; Collegium Ramazzini further commented that medical findings and medical or work histories can change in three years and that spirometry performed at other locations does not provide an adequate baseline (Document ID 2178, Attachment 1, p. 4; 3541, pp. 4–5; 4203, p. 6). Dr. Celeste Monforton, from George Washington University School of Public Health, agreed with APHA (Document ID 3577, Tr. 846). OSHA disagrees. The three-year interval is consistent with the frequency of periodic examinations, and the reasons for this interval, such as the typical slow progression of respirable crystalline silica-related diseases, are discussed below.

The American Foundry Society (AFS) supported the 30-day period for offering medical surveillance, stating that it addressed the turnover rates in its industry because employees who work 30 days are likely to continue their employment (Document ID 2379, Appendix 1, p. 71). AESC requested that OSHA allow medical examinations to be provided within 90 days of assignment to address the turnover rate in its industry (Document ID 2344, p. 2). The National Stone, Sand and Gravel Association (NSSGA) noted difficulties in scheduling medical examinations within 30 days in remote locations because testing vans that offer medical examinations might not be available within that time period (Document ID 3583, Tr. 2316–2317). Because a 30-day period for offering medical examinations is reasonable for AFS, which represents an industry with high turnover rates, OSHA concludes that a 30-day period should be reasonable in most general industry settings. OSHA does not agree with AESC that the period to offer medical surveillance should be extended to 90 days in the standard for general industry and maritime. That longer time period to offer medical surveillance would exclude and leave unprotected many employees who may be exposed to significant amounts of silica while working short-term assignments, for periods up to 90 days, for numerous companies within the same industry.

Representatives from the construction industry also commented on the 30-day period to offer medical surveillance. BAC and BCTD recommended that medical examinations be made available as soon as practicable, instead of within 30 days after assignment, in the construction industry because it would be difficult for employers to predict if an employee would be exposed for 30 days or more during the upcoming year, and it could encourage employers to terminate employees before the 30-day period ends (Document ID 4219, p. 29; 4223, p. 125). Fann Contracting suggested that a better trigger would be after the employee has been exposed for 30 days instead of within the first 30 days of assignment (Document ID 2116, Attachment 1, p. 43).

OSHA rejects this reasoning, and is maintaining the requirement to offer medical surveillance within 30 days of assignment for the construction standard. The requirement better assures that medical examinations will be offered within a reasonable time period than allowing the employer to offer them ''as soon as practicable.'' As noted above, employers can determine who will be eligible for medical surveillance based on required respirator use under Table 1 or similar task-based approaches. Even at the time of initial assignment, OSHA expects that employers will know the tasks that the employee will be performing, and in the case of short-term employees, the approximate duration the employee will be with the company. In addition, terminating employees to avoid offering medical surveillance would not be cost effective because the employer would incur more costs from constantly having to train new employees.

The Precast/Prestressed Concrete Institute commented that local union halls from which they hire employees and the Americans with Disability Act may prohibit pre-hire medical testing (Document ID 2276, p. 10). National Electrical Contractors Association expressed concern about economic burdens associated with pre- and post-employment medical evaluations in transient or temporary employees (Document ID 2295, p. 2). OSHA clarifies that no pre-hire or post-employment testing is required in the respirable crystalline silica rule, which requires that medical examinations related to respirable crystalline silica exposure be offered within 30 days after initial assignment to employees who will meet the trigger for medical surveillance.

Contents of initial medical examination. Paragraphs (i)(2)(i)–(vi) of the standard for general industry and maritime (paragraphs (h)(2)(i)–(vi) of the standard for construction) specify that the initial medical examination provided by the PLHCP must consist of: A medical and work history; a physical examination with special emphasis on the respiratory system; a chest X-ray; a pulmonary function test; a latent tuberculosis test; and other tests deemed appropriate by the PLHCP. Special emphasis must be placed on the portions of the medical and work history focusing on exposure to respirable crystalline silica, dust or other agents affecting the respiratory system, any history of respiratory system dysfunction (including signs and symptoms, such as shortness of breath, coughing, and wheezing), any history of tuberculosis, and current or past smoking. The only changes from the proposed rule are reflected in paragraphs (i)(2)(iii) and (iv) of the standard for general industry and maritime (paragraphs (h)(2)(iii) and (iv) of the standard for construction), and those revisions are discussed below.

OSHA received a range of comments related to the contents of the initial examination. Some stakeholders, including NIOSH and commenters representing the medical community, labor unions, and industry, supported the contents of medical surveillance that OSHA proposed, though some wanted to expand the contents, as addressed below (*e.g.,* Document ID 2175, p. 6; 2177, Attachment B, pp. 38–39; 2282, Attachment 3, p. 19; 2336, p. 12; 2371, Attachment 1, p. 43; 3589, Tr. 4205; 4204, p. 82). Further, the contents of medical surveillance in this standard are fairly consistent with the recommendations in occupational health programs, such as those by NISA and NSSGA (Document ID 2195, pp. 40–41; 2327, Attachment 1, p. 23).

However, not all stakeholders agreed that the list of proposed initial examination contents was appropriate. For example, Fann Contracting favored

limiting the contents of medical examinations to X-rays, while Dal-Tile Corporation, the 3M Company, and the Tile Council of North America indicated that requirements for medical examinations under the respiratory protection standard were sufficient (Document ID 2116, Attachment 1, p. 37; 2147, p. 3; 2313, p. 7; 2363, pp. 5–6). Similarly, Nevada Mining Association commented that the need to conduct physical examinations, X-rays, or pulmonary function testing should be left to the discretion of the PLHCP (Document ID 2107, pp. 3–4). Newmont Mining also said that one or more of these tests should be at the discretion of the PLHCP (Document ID 1963, pp. 2–3).

OSHA finds that X-rays alone are not sufficient because, as explained in more detail below, some employees may have symptoms or abnormal lung function that are not detected by X-ray but may become evident by other tests, such as spirometry. The Agency also finds that the evaluations offered under the respiratory protection standard are insufficient because the information gathered under that standard is limited and may not involve examinations, while the respirable crystalline silica rule requires examinations that include objective measures, such as physical examinations, spirometry testing and X-rays, that may detect early disease in asymptomatic employees. In addition, OSHA does not agree that all required tests should be left to the discretion of the PLHCP because the Agency has determined that employees who must be offered medical surveillance are at risk of developing respirable crystalline silica-related diseases, and the required tests are the minimum tests needed to screen for those diseases. Therefore, OSHA concludes that limiting medical surveillance to only X-rays, the evaluations performed under the respiratory protection standard, or only tests selected by the PLHCP is not sufficiently protective.

The first item required as part of the initial medical examination is a medical and work history, with emphasis on: Past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (*e.g.,* shortness of breath, cough, wheezing); history of tuberculosis; and smoking status and history (paragraph (i)(2)(i) of the standard for general industry and maritime, paragraph (h)(2)(i) of the standard for construction). OSHA is requiring medical and work histories because they are an efficient and inexpensive means for collecting information that can aid in identifying individuals who are at risk due to hazardous exposures (Document ID 1505, p. 2; 1517, p. 25). Recording of symptoms is important because, in some cases, symptoms indicating onset of disease can occur in the absence of abnormal laboratory test findings (Document ID 1517, p. 25).

Because symptoms may be the earliest sign of disease and to allow for consistent and comprehensive data collection, Collegium Ramazzini recommended that an appendix with a standardized questionnaire be included; it also recommended that the questionnaire address non-respiratory effects, such as renal disease and connective tissue disorders (Document ID 3541, pp. 3, 6). While not going as far as this recommendation, OSHA includes in the rule an appendix for medical surveillance (Appendix B), which gives PLHCPs detailed information on what is to be collected as part of the medical history. The appendix recommends collecting information on renal disease and connective tissue disorders. OSHA intends for this approach to allow PLHCPs to easily standardize their method for gathering information for work and medical histories related to respirable crystalline silica exposure.

Newmont Mining and Nevada Mining Association objected to a requirement for a medical and work history, asserting that a personal medical history is not related to silica exposure (Document ID 1963, p. 2; 2107, p. 3). Commenters, including DCA and International Brotherhood of Teamsters, objected to employees revealing medical and work history information not related to respirable crystalline silica exposure because of privacy concerns (*e.g.,* Document ID 2309, p. 5; 2318, pp. 13–14). Retired foundry employee, Allen Schultz, representing WisCOSH, expressed concern that information, such as smoking history, could be used against employees (Document ID 3586, Tr. 3255). As noted above, a purpose of medical surveillance is to inform employees if they may be at increased risk of adverse effects from respirable crystalline silica exposure. Personal habits, such as smoking, could lead to compromised lung function or increased risk of lung cancer, and exposure to respirable crystalline silica could compound those effects (*see* Section V, Health Effects). Collecting information, such as smoking habits and related medical history, allows the PLHCP to warn employees about their increased risks from exposure to respirable crystalline silica so employees can make informed health decisions.

As discussed below, OSHA is addressing employee privacy issues by reducing the information to be included in the PLHCP's written medical opinion for the employer without the employee's permission (paragraphs (i)(6)(i)(A)–(C) of the standard for general industry and maritime and paragraphs (h)(6)(i)(A)–(C) of the standard for construction); under those paragraphs, the only medically related information that is to be reported to the employer without authorization from the employee is limitations on respirator use. Personal habits, such as smoking, are not included in the medical opinion for the employer. Therefore, employees' privacy will not be compromised as a result of the information collected as part of the exposure and medical history.

The second item required as part of the initial medical examination is a physical examination that focuses on the respiratory system (paragraph (i)(2)(ii) of the standard for general industry and maritime, paragraph (h)(2)(ii) of the standard for construction), which is known to be susceptible to respirable crystalline silica toxicity. OSHA finds that aspects of the physical examination, such as visual inspection, palpation, tapping, and listening with a stethoscope, allow the PLHCP to detect abnormalities in chest shape or lung sounds that are associated with compromised lung function (Document ID 1514, p. 74; 1517, pp. 26–27). Dr. Michael Fischman, occupational and environmental physician/toxicologist and professor at the University of California, representing ACOEM, strongly endorsed a physical examination and noted that another valuable aspect is that it allows the employee to have a face-to-face interaction with the clinician to talk about symptoms or other concerns (Document ID 3577, Tr. 767). OSHA agrees and concludes that the physical examination is necessary.

The third item required as part of the initial medical examination is a chest X-ray, specifically a single posteroanterior radiographic projection or radiograph of the chest at full inspiration recorded on either film (no less than 14 x 17 inches and no more than 16 x 17 inches) or digital radiography systems, interpreted and classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader (paragraph (i)(2)(iii) of the standard for general industry and maritime, paragraph (h)(2)(iii) of the standard for construction). The proposed rule

specified only film X-rays but would have allowed for an equivalent diagnostic study, such as digital X-rays; OSHA also sought comment on whether computed tomography (CT) or high resolution computed tomography (HRCT) scans should be considered equivalent diagnostic tests (78 FR at 56469–56470). As discussed in greater detail below, OSHA received many comments on the proposed provision, and in response to those comments, the current provision differs substantially from the proposed rule in two main ways. First, the rule now specifically allows for chest X-rays to be recorded on either film or digital radiography systems. Second, the rule does not allow for an ''equivalent diagnostic study.''

Medical experts including ACOEM, the American Thoracic Society (ATS), and NIOSH recommend X-rays as part of medical examinations for employees exposed to respirable crystalline silica (*e.g.,* Document ID 1505, p. 2; 2175, p. 6; 2177, Attachment B, pp. 38–39). The initial X-ray provides baseline data against which to assess any subsequent changes. An initial chest X-ray can be useful for diagnosing silicosis and for detecting mycobacterial disease (*e.g.,* active pulmonary tuberculosis, which employees with latent tuberculosis infections and exposed to respirable crystalline silica are at greater risk of developing (Document ID 1514, pp. 75, 100). X-rays are important because the findings can lead to the initiation of employment choices that can reduce exposures to respirable crystalline silica and might decrease the risk of silicosis progression or allow for treatment of mycobacterial infections (Document ID 1505, p. 3).

As noted above, OSHA proposed that the required chest X-ray be interpreted and classified according to ILO International Classification of Radiographs of Pneumoconiosis by a NIOSH-certified B Reader. The ILO system was designed to assess X-ray and digital radiographic image quality and to describe radiographic findings of pneumoconiosis in a simple and reproducible way by comparing an employee's X-ray to a standard X-ray to score opacities according to shape, size, location, and profusion (Document ID 1475, p. 1; 1511, pp. 64–68; 1514, pp. 77–78). A NIOSH-certified B Reader is a physician who has demonstrated competency in the ILO classification system by passing proficiency and periodic recertification examinations (Document ID 1498, p. 1). The NIOSH certification procedures were designed to improve the proficiency of X-ray and digital radiographic image readers and minimize variability of readings.

In 2011, the ILO made standard digital radiographic images available and published guidelines on the interpretation and classification of digital radiographic images (Document ID 1475). The guidelines included requirements for display monitors. NIOSH also published guidelines for conducting digital radiography and displaying digital radiographic images in a manner that will allow for classification according to ILO guidelines (Document ID 1513). Based on these developments, OSHA stated in the preamble of the NPRM that digital X-rays could now be evaluated according to the same guidelines as film X-rays and could therefore be considered equivalent diagnostic tests. The Agency also noted several advantages of digital X-rays: Compared to film X-rays, digital imaging systems offer more consistent image quality, faster results, increased ability to share images with multiple readers, simplified storage of images, and reduced risk for technicians and the environment due to the elimination of chemicals for developing film (Document ID 1495, p. 2).

Commenters, such as Collegium Ramazzini, NIOSH, and the Dow Chemical Company, agreed with OSHA that digital radiographic images are equivalent to conventional X-rays; NIOSH and Dow Chemical suggested OSHA clarify that the proposed requirement for chest X-rays may be satisfied either with conventional film-based technology or with digital technology; and NIOSH and Collegium Ramazzini referred OSHA to an interim final regulation for coal miners that allows for digital technology (Document ID 2177, Attachment B, pp. 40–41; 2270, p. 13; 3541, p. 7). After reviewing the record evidence on this issue, OSHA reaffirms its preliminary conclusion that X-rays recorded on digital radiography systems are equivalent to those recorded on film. Therefore, OSHA has revised paragraph (i)(2)(iii) of the standard for general industry and maritime (paragraph (h)(2)(iii) of the standard for construction) to indicate that X-rays can be recorded on either film or digital systems, using language that is consistent with that in the interim final regulation for coal miners (42 CFR part 37.2 (10–1–13 Edition)).

NSSGA commented that good quality digital images reproduced on film should also be considered acceptable as equivalent to X-rays (Document ID 2327, Attachment 1, p. 23). OSHA disagrees. The Agency does not recommend classification using hard copies printed from digital images because a 2009 study by Franzblau *et al.* indicates that they give the appearance of more opacities compared to films or digital images (Document ID 1512). OSHA does not find hard copy printouts of digital images equivalent to conventional X-rays. Consequently, classification through the use of hard copies printed from digital images may not be used to satisfy the requirement for chest X-rays.

As indicated above, the proposed rule called for the chest X-ray to be interpreted and classified by a NIOSH-certified B reader. A number of commenters offered opinions on this requirement. For example, Dow Chemical urged OSHA to allow board certified radiologists to interpret the X-rays because it claimed that insufficient numbers of B Readers would lead to a backlog of X-ray interpretation that would make it impossible for B Readers to get their reports back to PLHCPs within the required 30 days (Document ID 2270, p. 9). Other representatives from industry, such as the Mason Contractors Association of America, ARMA, and the North American Insulation Manufacturers Association, expressed similar concerns about numbers of B Readers (*e.g.,* Document ID 2286, pp. 2–3; 2291, p. 26; 2348, Attachment 1, pp. 39–40).

The rulemaking record contains ample evidence of sufficient numbers of B Readers and the value of B Reader interpretation according to ILO methods. CISC and NIOSH estimated demands on B Readers based on OSHA's estimate in the preamble of the NPRM that 454,000 medical examinations would be required in the first year after the rule is promulgated (78 FR at 56468). Based on the 242 B Readers accounted for as of February 12, 2013 (78 FR at 56470), CISC estimated 1,876 chest X-rays for each B Reader, requiring each B Reader to interpret more than five chest X-rays per day, which CISC claimed would result in a backlog (Document ID 2319, p. 118). However, Dr. David Weissman, Director of NIOSH's Division of Respiratory Disease Studies, indicated that a B Reader can easily classify 10 images in an hour (Document ID 3579, Tr. 196, Attachment 2, p. 1). NIOSH estimated that a B Reader working 1 hour per day, 5 days per week, 50 weeks per year can classify 2,500 images and that 182 B Readers working a minimum of 1 hour per day and 50 weeks per year would be needed to classify X-rays for 454,000 employees (Document ID 4233, Attachment 1, p. 40). As of May 19, 2014, there were 221 certified B Readers in the United States, an adequate number to meet the demands for the respirable crystalline silica rule (Document ID 3998, Attachment 15, p.

2). Based on the new triggers and more recent data on turnover rates, OSHA estimates that approximately 520,000 medical examinations will be required in the first year after the rule is promulgated. Using Dr. Weissman's assumptions, OSHA estimates that 221 B Readers would need to spend less than 1 hour a day to classify X-rays for 520,000 employees.

Dr. Weissman testified that the number of B Readers is driven by supply and demand created by a free market and that many physicians choose to become B Readers based on demands for such services (Document ID 3579, Tr. 197–198, Attachment 2, p. 1). He went on to state that NIOSH provides several pathways for physicians to become B Readers, such as free self-study materials by mail or download and free B Reader examinations. In addition, courses and examinations for certification are offered for a fee every three years through the American College of Radiology. Dr. Robert Cohen, pulmonary physician and clinical professor at the University of Illinois, representing ATS, agreed that NIOSH is able to train enough B Readers to handle any potential increase in demand (Document ID 3577, Tr. 777). Moreover, even if B Readers are scarce in certain geographical locations, digital X-rays can easily be transmitted electronically to B Readers located anywhere in the U.S. (Document ID 2116, Attachment 1, p. 43; 3580, Tr. 1471–1472; 3585, Tr. 2887; 2270, p. 13; 2195, p. 44; 3577, Tr. 817–818). Based on this information, OSHA concludes that numbers of B Readers in the U.S. are adequate to interpret X-rays conducted as part of the respirable crystalline silica rule.

Some commenters questioned the value of requiring B Readers. Dow Chemical claimed that board certified radiologists are able to provide interpretations of X-rays that are consistent with those of B Readers and that such an approach is consistent with that of the OSHA Asbestos standard (29 CFR 1910.1001, Appendix E) (Document ID 2270, pp. 9–10). Dow Chemical also stated that digital radiography has improved interpretation accuracy for radiologists who are not B Readers. American Road and Transportation Builders Association (ARTBA) commented that inadequate numbers of B Readers could result in misinterpretations of X-rays. It also cited a study by Gitlin *et al.* (2004), which it interpreted as showing that B Readers can be biased by exposure information; according to ARBTA, the study reported that B Readers hired for asbestos litigation cases read 95.9 percent of X-rays as positive, while independent, blinded B readers only read 4.5 percent of those X-rays as positive (Document ID 2245, pp. 2–3).

Based on record evidence, OSHA finds that the requirement for B Readers to demonstrate proficiency in ILO methods results in more consistent X-ray interpretation. For example, guidelines by the World Health Organization (WHO) acknowledge the value of consistent, high-quality X-rays for reducing interpretation variability and note that B Reader certification may also improve consistency of X-ray interpretation (Document ID 1517, p. 21). Robert Glenn, Certified Industrial Hygienist representing the Brick Industry Association and previously in charge of the B Reader program at NIOSH, said he thought the reduced variability (*i.e.,* lower prevalence of small opacities graded 1/0 or greater in unexposed populations) in the U.S. compared to Europe in a study by Meyer *et al.* (1997) could be attributed to the success of the B Reader program (Document ID 3577, Tr. 668, 670, 682; 3419, p. 404). Dr. James Cone, occupational medicine physician at the New York City Department of Health, stated that development of ILO methods for evaluating pneumoconiosis by chest X-ray has led to greater precision and sensitivity. Dr. Cone gave the example that two B Readers who evaluated X-rays performed on foundry employees as part of a NIOSH Health Hazard Evaluation identified six cases of X-rays and occupational history consistent with silicosis that had been classified as normal by company physicians (Document ID 2157, pp. 4–5). Based on the record evidence demonstrating the value of B Reader certification, OSHA rejects the suggestion that the standard should allow X-ray interpretation by board-certified radiologists.

The evidence discussed above supports OSHA's conclusions that adequate numbers of B Readers are available locally or by electronic means to interpret chest X-rays of respirable crystalline silica-exposed employees and that B Reader certification improves the quality of X-ray interpretation. OSHA concludes that standardized procedures for the evaluation of X-ray films and digital images by certified B Readers is warranted based on the seriousness of silicosis and is therefore retaining that requirement in the rule.

OSHA noted in the preamble for the NPRM that CT or HRCT scans could be considered ''equivalent diagnostic studies.'' CT and HRCT scans are superior to chest X-ray in the early detection of silicosis and the identification of progressive massive fibrosis. However, CT and HRCT scans have risks and disadvantages that include higher radiation doses and current unavailability of standardized methods for interpreting and reporting the results (78 FR at 56470). Because of these concerns, OSHA specifically sought comment on whether CT and HRCT scans should be considered equivalent diagnostic studies under the rule, and a number of stakeholders provided comments on this issue.

In its prehearing comments, ATS stated that despite the lack of standardized interpretation and reporting methods, CT or HRCT are reasonable ''equivalent diagnostic studies'' to standard chest X-rays because they are more sensitive than X-rays for early detection of diseases, such as silicosis and lung cancer; however, the group's representative, Dr. Robert Cohen, later testified that HRCT is not ready as a screening technique but is a useful diagnostic tool (Document ID 2175, p. 6; 3577, Tr. 825). USW noted that interpretation methods are being developed for the evaluation of pneumoconiosis by CT scan and suggested approaches for the use of low dose CT (LDCT) scans to evaluate silicosis and lung cancer in some employees (Document ID 4214, pp. 9–12).

Physicians, such as those representing ACOEM, Collegium Ramazzini, and NIOSH, did not consider CT or HRCT to be equivalent diagnostic studies because of the lack of a widely-accepted standardized system of interpretation, such as the ILO method (*e.g.,* Document ID 2080, pp. 7–8; 2177, Attachment B, p. 40; 3541, p. 7). In addition, NIOSH, APHA, Edison Electric Institute (EEI), Collegium Ramazzini, and ACOEM indicated the higher radiation doses received from CT and HRCT scans make it inappropriate to consider these methods equivalent to X-rays (Document ID 2177, Attachment B, p. 40; 2178, Attachment 1, p. 6; 2357, pp. 34–35; 3541, p.7; 3577, Tr. 768).

NIOSH and Collegium Ramazzini also commented on the increased sensitivity of CT scans in detecting abnormalities that require follow-up, which they cited as another reason why CT scans should not be considered equivalent to X-rays (Document ID 2177, Attachment B, p. 40; 3541, p. 7). NIOSH said the abnormalities can suggest lung cancer, but most are found to be ''false positives'' (Document ID 2177, Attachment B, p. 40). Detection of abnormalities that might suggest cancer can lead to anxiety in patients; it can also lead to follow-up with more imaging tests that increase radiation exposures or invasive biopsy procedures

that have a risk of complications (Document ID 2177, Attachment B, p. 40; 3978, pp. 2423, 2427). Commenters also noted that CT scans cost more than X-rays (Document ID 2177, Attachment B, p. 40; 2178, Attachment 1, p. 6; 3541, p. 7). In addition, Collegium Ramazzini stated that chest X-rays are readily accessible in most cases, but availability of CT scanning is more limited, especially in rural areas (Document ID 3541, p. 7).

ACOEM, NIOSH, APHA, NSSGA, EEI, and AFL–CIO stated that CT scans are appropriate in some cases, such as a part of follow-up examinations or if recommended by the PLHCP (Document ID 2080, p. 8; 2177, Attachment B, pp. 40–41; 2178, Attachment 1, p. 6; 2327, Attachment 1, p. 26; 2357, pp. 34–35; 4204, p. 82). Dr. David Weissman and Dr. Rosemary Sokas, occupational physician from Georgetown University, representing APHA, indicated that if an employee happens to have had a CT scan that was conducted as part of a clinical workup or diagnosis, it should be accepted in place of X-rays (Document ID 3577, Tr. 792; 3579, Tr. 256).

After reviewing the record on this issue, OSHA has determined that CT or HRCT scans should not be considered ''equivalent diagnostic studies'' to conventional film or digital chest X-rays for screening of silicosis because of higher radiation exposures, lack of a standardized classification system for pneumoconiosis, increased false positive findings, higher costs, and limited availability in some areas. OSHA also agrees with commenters that CT scans may be useful for follow-up purposes, as determined on a case-by-case basis by the PLHCP. For example, the PLHCP could request a CT scan to diagnose possible abnormalities detected by X-ray or other testing done as part of surveillance, and the rule gives the PLHCP this option (paragraph (i)(2)(vi) of the standard for general industry and maritime, paragraph (h)(2)(vi) of the standard for construction). However OSHA does not agree that a CT scan conducted within the past three years can meet the requirement for an X-ray because the CT scan cannot be evaluated according to ILO methods.

OSHA also received comments on the use of CT scans to screen for lung cancer, and those comments are discussed below, as part of the Agency's discussion of additional tests that commenters proposed for inclusion in medical examinations.

In sum, unlike the proposed rule, paragraph (i)(2)(iii) of the standard for general industry and maritime (paragraph (h)(2)(iii) of the standard for construction) specifically allows for digital X-rays, but does not allow for an equivalent diagnostic study. The rule was revised to allow for digital radiography because OSHA determined that digital X-rays are equivalent to film X-rays. The rule was also revised to remove the allowance for equivalent diagnostic studies because OSHA determined that CT scans are not equivalent to X-rays for screening purposes and no other imaging tests are equivalent to film or digital X-rays interpreted by ILO methods at this time. The provision for X-rays does not contain any other substantive changes compared to the proposed provision.

The fourth item required as part of the initial medical examination is a pulmonary function test, including forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and FEV_1/FVC ratio, administered by a spirometry technician with a current certificate from a NIOSH-approved spirometry course (paragraph (i)(2)(iv) of the standard for general industry and maritime, paragraph (h)(2)(iv) of the standard for construction). FVC is the total volume of air exhaled after a full inspiration, FEV_1 is the volume of air exhaled in the first second, and the FEV_1/FVC ratio is the speed of expired air (Document ID 3630, p. 2). OSHA proposed the inclusion of pulmonary function testing (*i.e.,* spirometry, as required by this rule) because it is useful for obtaining information about the employee's lung capacity and expiratory flow rate and for determining baseline lung function status against which to assess any subsequent lung function changes.

Some industry representatives, such as Fann Contracting and CISC, opposed the requirement for spirometry testing because reduced pulmonary function can be related to smoking or exposures other than respirable crystalline silica (Document ID 2116, Attachment 1, Page 39; 2319, pp. 118–119). CISC further commented that OSHA did not address statements in the ASTM standard about the non-specificity of lung function changes to respirable crystalline silica exposure, and a lack of evidence that routine spirometry is useful for detecting respirable crystalline silica-related diseases in early stages.

In contrast, commenters, such as Collegium Ramazzini and NIOSH, noted that spirometry is useful for detecting lung function changes associated with COPD, a disease outcome related to respirable crystalline silica exposure (Document ID 3541, p. 8; 3579, Tr. 255). ACOEM and Collegium Ramazzini explained that respirable crystalline silica exposures can result in lung function changes in the absence of radiological abnormalities, and spirometry is important for detecting those changes in the early stages of disease; ACOEM further commented that early detection of abnormal lung function is important to fully assess employees' health and apply protective intervention methods (Document ID 2080, p. 8; 3541, p. 8).

ASSE and some industry representatives, including Newmont Mining, NISA and AFS, also supported spirometry testing (*e.g.,* Document ID 1963, pp. 2–3; 2339, p. 9; 2379, Appendix 1, p. 70; 4208, p. 22). NISA includes spirometry testing as part of its occupational health program for respirable crystalline silica-exposed employees; it emphasized that spirometry testing: (1) Allows for early detection and measurement of severity of lung function loss, the most direct symptom of silicosis or other nonmalignant respiratory disease, and (2) is useful for determining an employee's ability to safely wear a negative pressure respirator (Document ID 4208, p. 22).

After reviewing the comments submitted, OSHA reaffirms that spirometry testing should be included in the rule. OSHA concludes that even though declines in lung function may not always be related to respirable crystalline silica exposure, the test results are nonetheless useful for detecting lung function abnormalities that can worsen with further exposure to respirable crystalline silica, providing a baseline of lung function status against which to assess any subsequent changes, and assessing the health of employees who wear respirators. The requirement for lung function testing is also consistent with other OSHA standards, such as asbestos (29 CFR 1910.1001) and cadmium (29 CFR 1910.1027). Thus, OSHA decided to retain the proposed requirement for a pulmonary function test in the rule.

OSHA proposed that spirometry be administered by a spirometry technician with current certification from a NIOSH-approved spirometry course. NIOSH recommended changing ''current certification'' to ''a current certificate'' to clarify that NIOSH does not certify individual technicians (Document ID 2177, Attachment B, p. 43). OSHA agrees with NIOSH that the change provides clarity, without modifying the original meaning of the provision, and thus made the change to the proposed provision.

Some stakeholders questioned whether a certificate from a NIOSH-approved course should be required. For

example, Dow Chemical recommended that OSHA follow the asbestos standard and allow for spirometry testing to be conducted by a person who has completed ''a training course in spirometry sponsored by an appropriate academic or professional institution'' (29 CFR 1910.1001(l)(1)(ii)(B)) (Document ID 2270, pp. 11–12). However, other stakeholders, including NIOSH and commenters from the medical community and labor unions, agreed that the standard should require a current certificate from a NIOSH-approved course (Document ID 2157, p. 6; 2177, Attachment B, pp. 38–39, 43; 3541, p. 10; 3577, Tr. 777; 4223, pp. 129–130). Dr. Robert Cohen stated:

> . . . spirometry performed by certified NIOSH technicians would be very important. We don't want garbage spirometry that we see out in the industry all the time. We want real, not what I call cosmetic or ceremonial spirometry (Document ID 3577, Tr. 777).

Dr. James Cone noted an example in which a NIOSH Health Hazard Evaluation at a foundry found that the company had recorded abnormal pulmonary function test results for 43 employees; however, spirometry testing later conducted by NIOSH found that only 9 of those same employees had abnormal pulmonary function results. Dr. Cone thought that the difference in findings most likely resulted from differences in equipment and test procedures used to motivate and elicit cooperation of employees during testing (Document ID 2157, pp. 4–5). He concluded:

> The difference does suggest that proper equipment, certification and training of pulmonary technicians, and standardized reading of pulmonary function tests are important to maintain uniformity and comparability of such tests (Document ID 2157, p. 5).

Some commenters, including Collegium Ramazzini, suggested other ways that the rule for respirable crystalline silica could improve quality of spirometry results. It recommended that the rule specify spirometry conducted according to ATS/European Respiratory Society (ERS) or similar guidelines, that spirometers meet ATS/ERS recommendations, and that the third National Health and Nutrition Examination Survey (NHANES III) reference values be used for interpretation of results (Document ID 3541, pp. 8–10). Collegium Ramazzini emphasized that quality spirometry results depend on standardized equipment, test performance, and interpretation of results, including criteria, such as acceptability and reproducibility of results (Document ID 3541, p. 8). Labor unions, such as LHSFNA and BCTD, also supported more stringent spirometry requirements (Document ID 3589, Tr. 4205; 4223, pp. 129–130). ACOEM, NIOSH, and BCTD recommended that reference values or other spirometry guidelines be added to the appendix on medical surveillance (Document ID 2080, p. 9; 2177, Attachment B, pp. 45–46; 4223, pp. 128–129).

After considering the record to determine what the rule must include to improve spirometry quality, OSHA concludes that requiring technicians to have a current certificate from a NIOSH-approved spirometry course is essential for maintaining and improving spirometry quality. The purpose of requiring spirometry technicians to have a current certificate from a NIOSH-approved spirometry course is to improve their proficiency in generating quality results that are interpreted in a standardized way. OSHA included the certification requirement in the proposed rule because spirometry must be conducted according to strict standards for quality control and results must be consistently interpreted. The NIOSH-approved spirometry training is based upon procedures and interpretation standards developed by the ATS/ERS and addresses factors, such as instrument calibration, testing performance, data quality, and interpretation of results (Document ID 3625, pp. 2–3).

NIOSH approves a spirometry training course if it meets the minimum OSHA/NIOSH criteria for performance of spirometry testing in the cotton textile industry. Since these course criteria are based on recommendations from ATS/ERS, they are applicable to spirometry testing in all industries. The curriculum of NIOSH-approved courses encompasses ATS/ERS recommendations on instrument accuracy (*e.g.,* calibration checks); test performance (*e.g.,* coaching, recognizing improperly performed maneuvers), and data quality with emphasis on repeatability and interpretation of results. Students taking the course use actual equipment, while supervised, and are evaluated on their spirometry testing skills (Document ID 3625, pp. 2–3). NIOSH periodically audits spirometry course sponsors who provide the courses (see *http://www.cdc.gov/niosh/topics/spirometry/sponsor-renewal-dates.html*). Therefore, based on the evidence in the record for this rulemaking, OSHA concludes that completing a NIOSH-certified course will make spirometry technicians knowledgeable about various issues that commenters raised regarding spirometry quality, and has determined that the best way to ensure that spirometry technicians receive the level of quality training approved by NIOSH is to require a certificate from a NIOSH-approved course.

In considering the alternative suggestions, OSHA concludes that requiring a current certificate from a NIOSH-approved course is a better approach than mandating requirements for equipment, testing procedures, reference values, and interpretation of results, which could become outdated. OSHA fully expects that the NIOSH-approved initial and periodic refresher courses required to maintain a current certificate under this rule will ensure that technicians keep up-to-date on the most recent ATS/ERS recommendations on spirometry equipment and procedures as technology and methods evolve over time.

In addition, OSHA agrees with commenters that the NHANES III reference values should be used to interpret spirometry results because they are the most widely endorsed for use in the U.S. (Document ID 3630, p. 28–29). In cross-sectional testing to evaluate lung function at a single point in time, spirometry results are compared to reference values (*i.e.,* spirometry values for individuals of the same gender, age, height, and ethnicity as the employee being tested). Although agreeing with commenters on the value of spirometry testing and use of the NHANES III data set for cross-sectional testing, OSHA disagrees with commenters that procedures for conducting spirometry and NHANES III reference values should be included as part of an appendix. As stated above, OSHA's approach to improving spirometry quality is to require technicians to have a current certificate from a NIOSH-approved course. Describing procedures in an appendix is not necessary because spirometry guidance documents, including a comprehensive guidance document from OSHA, are widely available. The OSHA spirometry guidance is available from the OSHA Web site and lists the NHANES III values in an appendix. OSHA encourages individuals who conduct or interpret spirometry to review the OSHA guidance on spirometry, which is based on recommendations by ATS/ERS, ACOEM, and NIOSH (Document ID 3630; 3624; 3629; 3631; 3633; 3634).

OSHA received one comment regarding the practicality of requiring a current certificate from a NIOSH-approved course. Dow Chemical claimed that availability of NIOSH-approved courses may be limited

outside of metropolitan areas (Document ID 2270, p. 11). However, NIOSH's Web site indicates that course sponsors are located throughout the U.S. and that some sponsors will travel to a requested site to teach a course (Document ID 3625, p. 3). Moreover, Dow Chemical also reported that it and another local company had teamed up to bring in an instructor to teach a NIOSH-approved course in their geographical area (Document ID 2270, p. 11). OSHA expects that this is a cost-effective means of providing NIOSH-approved training in places where none currently exists and can be replicated by other spirometry providers that provide services to companies covered by this rule. Maintaining a certificate from a NIOSH-approved course currently requires initial training and then refresher training every five years (Document ID 3625, p. 1). Because courses appear to be widely available throughout the U.S. and the required training is infrequent, OSHA concludes that the requirement for a technician to maintain a certificate from a NIOSH-approved course will not impose substantial burdens on providers of spirometry testing.

The fifth item required as part of the initial medical examination is a test for latent tuberculosis infection (paragraph (i)(2)(v) of the standard for general industry and maritime, paragraph (h)(2)(v) of the standard for construction). This provision is unchanged from the proposed rule. ''Latent'' refers to a stage of infection that does not result in symptoms or possible transmission of the disease to others. OSHA proposed the inclusion of a test for latent tuberculosis infection because exposure to respirable crystalline silica increases the risk of a latent tuberculosis infection becoming active (*i.e.,* the infected person shows signs and symptoms and is contagious), even in employees who do not have silicosis (*see* Section VI, Final Quantitative Risk Assessment and Significance of Risk) (Document ID 0360; 0465; 0992, p.1461–1462). This places not only the employee, but also his or her coworkers, at increased risk of acquiring this potentially fatal disease.

OSHA sought comment on its preliminary determination that all employees receiving an initial medical examination should be tested for latent tuberculosis infection. A number of stakeholders, including Dr. James Cone, ATS, NIOSH, APHA, NISA, NSSGA, ASSE, BCTD, and ACOEM agreed with OSHA's preliminary conclusion that testing for latent tuberculosis infection should be part of the initial examination (*e.g.,* Document ID 2157, p. 6; 2175, p. 6; 2177, Attachment B, pp. 38–39; 2178, Attachment 1, p. 5; 2195, p. 41; 2327, Attachment 1, p. 23; 2339, p. 9; 2371, Attachment 1, p. 43). However, other stakeholders, such as Newmont Mining, Nevada Mining Association, and EEI, recommended that testing for latent tuberculosis infection be limited to employees who have silicosis (*e.g.,* Document ID 1963, p. 2; 2107, p. 3; 2357, p. 34). EEI specifically opposed testing for latent tuberculosis infection in the absence of radiological evidence of silicosis, arguing that there are no good methods for quantifying the benefits of that testing.

After reviewing the comments on this issue, OSHA affirms its conclusion that testing for latent tuberculosis infections is a necessary and important part of the initial examination. As noted above, evidence demonstrates that exposure to respirable crystalline silica increases the risk for developing active pulmonary tuberculosis infection in individuals with latent tuberculosis infection, independent of the presence of silicosis (Document ID 0360; 0465; 0992, pp. 1461–1462). Active tuberculosis cases are prevented by identifying and treating those with latent tuberculosis infections. Therefore, OSHA concludes it is appropriate to test for latent tuberculosis infection in all employees who will be exposed to respirable crystalline silica and are eligible for medical surveillance, for their protection and to prevent transmission of an active, potentially fatal infection to their coworkers. Any concerns about a lack of good methods for calculating benefits associated with latent tuberculosis infection testing do not negate the scientific evidence demonstrating that exposure to respirable crystalline silica increases the risk of a latent infection becoming active.

Newmont Mining, Nevada Mining Association, and Fann Contracting did not support testing for latent tuberculosis infection because employees with the infection may not have contracted it in an occupational setting (Document ID 1963, p. 2; 2107, p. 3; 2116, Attachment 1, p. 38). While that may be true, testing for latent tuberculosis infection provides another example and support for two of the main objectives of medical surveillance: (1) To identify conditions that might make employees more sensitive to respirable crystalline silica exposure; and (2) to allow for intervention methods to prevent development of serious disease. Employees with latent tuberculosis infections are at greater risk of developing active disease with exposure to respirable crystalline silica, and informing them that they have a latent infection allows for intervention in the form of treatment to eliminate the infection. Treating latent tuberculosis disease before it becomes active and can be transmitted to coworkers (and others) is in the best interest of both the employer and the affected employee.

Dr. James Cone and APHA have stated that a positive boosted or initial test for tuberculosis infection warrants medical referral for further evaluation (Document ID 2157, p. 6; 2178, Attachment 1, p. 5). Ameren commented that a positive tuberculosis test warrants medical removal (Document ID 2315, p. 9). OSHA agrees that employees who test positive for active tuberculosis should be referred to their local public health departments as required by state public health law (Document ID 2177, Attachment B, p. 50). Those employees will need treatment and, if necessary, to be quarantined until they are no longer contagious. That is the appropriate action for employees with active tuberculosis to prevent infection of coworkers and others, according to procedures established by state public health laws. In the case of latent tuberculosis, the PLHCP may refer the employee to the local public health department, where the employee may get recommendations or prescriptions for treatment. Removal is not necessary for latent tuberculosis infections because employees with latent tuberculosis infections are not contagious. More information about testing for latent tuberculosis infections is included in Appendix B.

The sixth and final item required as part of the initial medical examination is any other test deemed appropriate by the PLHCP (paragraph (i)(2)(vi) of the standard for general industry and maritime, paragraph (h)(2)(vi) of the standard for construction). This provision, which is unchanged from the proposed rule, gives the examining PLHCP the flexibility to determine additional tests deemed to be appropriate. While the tests conducted under this section are for screening purposes, diagnostic tests may be necessary to address a specific medical complaint or finding related to respirable crystalline silica exposure (Document ID 1511, p. 61). For example, the PLHCP may decide that additional tests are needed to address abnormal findings in a pulmonary function test. OSHA considers the PLHCP to be in the best position to decide if any additional medical tests are necessary for each individual examined. Under this provision, if a PLHCP decides another

test related to respirable crystalline silica exposure is medically indicated, the employer must make it available. EEI commented that OSHA should clarify that additional tests must be related to occupational exposure to respirable crystalline silica (Document ID 2357, p. 35). OSHA agrees and intends the phrase ''deemed appropriate'' to mean that additional tests requested by the PLHCP must be both related to respirable crystalline silica exposure and medically necessary, based on the findings of the medical examination.

Finally, some stakeholders suggested additional tests to be included as part of medical examinations. OSHA did not propose a requirement for the initial examination to include a CT scan to screen for lung cancer, but a number of commenters thought the rule should contain such a requirement. UAW requested that OSHA consider LDCT scanning for lung cancer, with guidance from NIOSH and other medical experts (Document ID 2282, Attachment 3, pp. 19–20). Charles Gordon asked Dr. David Weissman if OSHA should consider CT scans for lung cancer screening of silica-exposed employees, as has been recently recommended by the U.S. Preventive Service Task Force (USPSTF) for persons at high risk of lung cancer. Dr. Weissman responded:

> Well, the recommendation that you're referring to related to very heavy cigarette smokers, people who are age 55 to 80, had a history of smoking I believe at least 30 pack-years and had smoked as recently as 15 years ago. That group has a very, very high risk of lung cancer, and as of this time, there are no recommendations that parallel that for occupational carcinogens (Document ID 3579, Tr. 159–160, Attachment 2, p. 2).

Collegium Ramazzini and USW asked OSHA to consider various scenarios for LDCT lung cancer screening of employees exposed to respirable crystalline silica; the different scenarios considered age (as a proxy for latency), smoking history, and other risk factors, such as non-malignant respiratory disease (Document ID 4196, pp. 5–6; 4214, pp. 10–12). Both groups recommended screening in non-smokers, and Collegium Ramazzini also recommended screening in employees less than 50 years of age; both groups cited National Comprehensive Cancer Network (NCCN) guidelines as a basis for one or more recommendations, and Collegium Ramazzini also cited the American Association for Thoracic Surgery (AATS) guidelines. The Communication Workers of America (CWA) requested LDCT scans every three years for silica-exposed employees over 50 years of age (Document ID 2240, p. 3). Consistent with one scenario presented by USW, AFL–CIO requested that OSHA require LDCT scans if recommended by the PLHCP or specialist, and AFL–CIO also requested that OSHA include a provision (for employees exposed to respirable crystalline silica) to allow for regular LDCT scans if recommended by an authoritative group (Document ID 4204, p. 82). Dr. Rosemary Sokas and Dr. James Melius, occupational physician/epidemiologist for LHSFNA, requested that OSHA reserve the right to allow for adoption of LDCT scans (Document ID 3577, Tr. 793; 3589, Tr. 4205–4206). Dr. Sokas went on to say that OSHA should start convening agencies and organizations to look at levels of risk that warrant LDCT (Document ID 3577, Tr. 793).

In addition to the issues that Dr. Weissman testified about regarding the USPSTF recommendations, OSHA notes that the USPSTF recommendations are based on modeling studies to determine optimum ages and frequency for screening and the scenarios in which benefits of LDCT screening (*e.g.,* increased survival) would outweigh harms (*e.g.,* cancer risk from radiation exposure). The screening scenario recommended by USPSTF (55- to 80-year-olds with a 30-pack-year smoking history who have not quit more than 15 years ago) is estimated to result in a 14 percent decrease in lung cancer deaths, with a less than 1 percent risk for radiation-related lung cancer (Document ID 3965, p. 337). USPSTF stresses that LDCT screening should be limited to high-risk persons because persons at lower risk are expected to experience fewer benefits and more harm; they cautioned that starting LDCT screening before age 50 might result in increased rates of radiation-related lung cancer deaths (Document ID 3965, p. 336). USPSTF also warns about the high rate of false positive findings with LDCT, which often lead to more radiation exposure through additional imaging tests and can result in invasive procedures, which have their own risks, to rule out cancer. It cautions that lower rates of lung cancer mortality from LDCT screening are most likely to be found at institutions demonstrating accurate diagnoses, appropriate follow-up procedures for abnormal findings, and clear standards for performing invasive procedures (Document ID 3965, pp. 333, 336).

Both NCCN and AATS guidelines recommend screening scenarios that are similar to the USPSTF guideline (*e.g.,* 55 or more years of age and at least a 30-pack-year history) (Document ID as cited in 3965, p. 338; 3976, p. 33). NCCN and AATS guidelines also recommend screening for 50-year-olds or older, who have a 20-pack-year or more smoking history and an additional risk factor. AATS specifies that the additional risk factor should result in a cumulative lung cancer risk of at least 5 percent in the next 5 years, and they identify additional risk factors, such as COPD, with an FEV_1 of 70 percent or less of predicted value, and environmental or occupational exposures, including silica (Document ID 3976, pp. 33, 35–37). Neither the NCCN nor AATS guideline recommend screening for individuals younger than 50 years of age or nonsmokers, and neither NCCN nor AATS indicates that its guidelines are based on risk-benefit analyses.

OSHA agrees that employees exposed to respirable crystalline silica are at increased risk of developing lung cancer, as addressed in Section V, Health Effects. However, OSHA has two major concerns that preclude the Agency from requiring LDCT screening for lung cancer under the respirable crystalline silica rule. The first concern is that availability of LDCT is likely to be limited. Few institutions that offer LDCT have the specialization to effectively conduct screening for lung cancer. The second major concern is the lack of a risk-benefit analysis. There is no evidence in the rulemaking record showing that the benefits of lung cancer screening using LDCT in respirable crystalline silica-exposed employees outweigh the risks of lung cancer from radiation exposure. OSHA has also not identified authoritative recommendations based on risk-benefit analyses for LDCT scanning for lung cancer in persons who do not smoke or are less than 50 years of age. OSHA concludes that without authoritative risk-benefit analyses, the record does not support mandating LDCT screening for respirable crystalline silica-exposed employees.

Periodic examinations. In paragraph (i)(3) of the standard for general industry and maritime (paragraph (h)(3) of the standard for construction), OSHA requires periodic examinations that include all of the items required by the initial examination, except for testing for latent tuberculosis infection, *i.e.*, a medical and work history, a physical examination emphasizing the respiratory system, chest X-rays, pulmonary function tests, and other tests deemed to be appropriate by the PLHCP. Employers must offer these examinations every three years, or more frequently if recommended by the PLHCP. The frequency of periodic

examinations and their requirements is unchanged from the proposed rule.

Some commenters disagreed with the proposed three-year interval for periodic medical examinations. WisCOSH and Charles Gordon thought that medical examinations should be offered more often than every three years (Document ID 3586, Tr. 3200–3201; 2163, Attachment 1, p. 14). Other commenters, including AFSCME and some employee health advocates and labor unions, requested that one or more components of medical examinations be offered annually (Document ID 1960; 2208; 2240, p. 3; 2351, p. 15; 4203, p. 6). Collegium Ramazzini recommended annual medical surveillance consisting of medical and work history and spirometry testing to better characterize symptoms, changes in health and work history that could be forgotten, and lung function changes (Document ID 3541, p. 12). CISC stated that OSHA did not explain why it found an examination every three years necessary and appropriate (Document ID 2319, p. 119).

ATS, NIOSH, USW, and AFS supported the three-year frequency requirement for medical surveillance (Document ID 2175, p. 6; 2177, Attachment B, pp. 38–39; 2336, p. 11; 2379, Appendix 1, p. 70). NSSGA, however, recommended examinations every three to five years (Document ID 2327, Attachment 1, p. 24). Although WHO guidelines recommend an annual history and spirometry test, the guidelines state that if that is not possible, those examinations can be conducted at the same frequency they recommend for X-rays (every 2-to-5 years) (Document ID 1517, p. 32). In support of triennial medical examinations, ATS commented that an examination provided every three years is appropriate to address a lung disease that typically has a long latency period (Document ID 2175, p. 6).

ACOEM agreed with a frequency of every three years for a medical examination, provided that a second baseline examination (excluding X-rays) is conducted at 18 months following the initial baseline examination; this approach was recommended to detect possible symptoms of acute silicosis and to more effectively establish a spirometry baseline since rapid declines in lung function can occur in dusty work environments (Document ID 2080, pp. 5–6). Dr. Celeste Monforton agreed with a follow-up examination at 18 months (Document ID 3577, Tr. 846).

APHA, AFL–CIO, BAC, and BCTD also agreed with ACOEM's suggestion for a follow-up examination within 18-months, adding that a three-year interval between examinations is acceptable if medical examinations are offered to employees experiencing signs and symptoms related to respirable crystalline silica exposure (Document ID 2178, Attachment 1, pp. 4–5; 4204, pp. 81–82; 4219, pp. 30–31; 4223, pp. 127–128). BlueGreen Alliance, UAW, Center for Effective Government (CEG), CPR, WisCOSH, and AFSCME also requested that medical surveillance be offered for employees experiencing symptoms (Document ID 2176, p. 2; 2282, Attachment 3, pp. 22–23; 2341, pp. 2–3; 2351, p. 15, Fn 29; 3586, Tr. 3200–3201; 4203, p. 6). The AFL–CIO and UAW stated that a symptom trigger is appropriate based on the high level of risk remaining at OSHA's proposed action level and PEL (Document ID 2282, Attachment 3, p. 22; 4204, p. 81). APHA, CEG, and BCTD also argued that employees should be allowed to see a PLHCP if they are concerned about excessive exposure levels or their ability to use a respirator (Document ID 2178, p. 5: 2341, pp. 2–3; 4223, pp. 127–128).

After considering all comments on this issue, OSHA concludes that the record supports requiring periodic examinations to be offered to employees at least every three years after the initial (baseline) or most recent periodic medical examination for employees who are eligible for initial and continued medical surveillance under the rule. Accordingly, paragraph (i)(3) of the standard for general industry and maritime (paragraph (h)(3) of the standard for construction) requires periodic examinations at least every three years, or more frequently if recommended by the PLHCP. One of the main goals of periodic medical surveillance for employees exposed to respirable crystalline silica is to detect adverse health effects, such as silicosis and other non-malignant lung diseases, at an early stage so that medical and other appropriate interventions can be taken to improve health. Consistent with the NIOSH and ATS comments, OSHA finds that medical examinations offered at a frequency of at least every three years is appropriate for most employees exposed to respirable crystalline silica in light of the slow progression of most silica-related diseases. This decision is also consistent with ASTM standards E 1132–06 and E 2625–09 (Section 4.6.5), which recommend that medical surveillance be conducted no less than every three years (Document ID 1466, p. 5; 1504, p. 5).

OSHA declines to adopt ACOEM's recommendation for a second baseline examination at 18 months. As noted above, this request was based upon detection of possible acute silicosis symptoms. Considering that acute silicosis and the rapid declines in lung function associated with it, as a result of extremely high exposures, are rare, OSHA determines that this extra examination would not benefit the vast majority of employees exposed to respirable crystalline silica. However, as noted above, paragraph (i)(3) of the standard for general industry and maritime (paragraph (h)(3) of the standard for construction) authorizes the PLHCP to recommend, and requires the employer to make available, increased frequency of medical surveillance. OSHA agrees with Dr. James Melius that more frequent medical examinations are appropriate if requested by the PLHCP based on abnormal findings or signs of possible illness, and the Agency agrees with ACOEM that the PLHCP may recommend more frequent medical surveillance based on an exposure history indicating unknown or high exposure to respirable crystalline silica (Document ID 2080, p. 6; 3589, Tr. 4203). OSHA concludes that allowing the PLHCP to determine when increased frequency of medical examinations is needed is a better approach than requiring all employees to receive annual medical examinations or a second baseline examination at 18 months.

OSHA did not include a symptom trigger because symptoms of silica-related lung diseases (*e.g.,* cough, shortness of breath, and wheeze) are very common and non-specific, unlike symptoms resulting from exposures to some other chemicals OSHA has regulated. In addition, based on the employee health privacy concerns expressed in this rulemaking (discussed below), OSHA does not expect many employees to ask their employer for a medical examination when they experience symptoms. Furthermore, employees who are the most likely to develop symptoms are those exposed above the PEL. Those employees, who would be required to wear respirators, and also construction employees required to wear respirators under Table 1, are entitled to an additional medical evaluation under the respiratory protection standard if they report signs or symptoms that are related to ability to use a respirator (29 CFR 1910.134(e)(7)(i)). Therefore, employees at the highest risk of developing symptoms will be able to take advantage of that provision in the respiratory protection standard.

AIHA recommended that OSHA consider decreased frequency of testing in employees with less than 10 to 15 years of experience because of the small chance of finding disease, and it noted

that this was done in the asbestos standard (29 CFR 1910.1001, 1926.1101) (Document ID 2169, p. 6). Medical surveillance guidelines from ACOEM, Industrial Minerals Association (IMA)/ Mine Safety and Health Administration (MSHA) and NISA recommend periodic medical examinations at intervals from two to four years (with the exception of a follow-up examination in some cases), depending on age, years since first exposure, exposure levels, or symptoms (Document ID 1505, pp. 3–4; 1511, pp. 78–79; 1514, pp. 109–110). As noted by the IMA/MSHA guidelines, a compromise schedule that is easier to administer is acceptable if it is difficult to offer surveillance based on multiple considerations (Document ID 1511, pp. 78–79). OSHA agrees with the IMA/ MSHA approach of choosing a schedule that is easy to administer. The Agency concludes that surveillance every three years is an administratively convenient frequency that strikes a reasonable balance between the resources required to provide surveillance and the need to diagnose health effects at an early stage to allow for interventions.

In addition to the above general comments as to the appropriate frequency of periodic examinations, some stakeholders offered comments on particular components of periodic examinations, in particular chest X-rays and pulmonary function tests. As noted above, chest X-rays are included in the periodic, as well as initial (baseline), medical examinations. Periodic chest X-rays are appropriate tools for detecting and monitoring the progression of silicosis and possible complications, such as mycobacterial disease, including tuberculosis infection (Document ID 1505, p. 3; 1511, pp. 63, 79). Safety professional Albert Condello III stated that X-rays should be offered annually (Document ID 1960). OSHA concludes that every three years is an appropriate interval for X-ray examinations. The frequency is within ranges recommended by ACOEM, IMA/ MSHA, NISA, and WHO (Document ID 1505, pp. 3–4; 1511 pp. 78–79; 1514, pp. 109–110; 1517, p. 32). Commenters representing NIOSH, the medical community, and industry agreed that a frequency of every three years is appropriate for X-rays (Document ID 2157, p. 6; 2177, Attachment B, pp. 38–39; 2315, p. 9; 2327, Attachment 1, p. 25; 2379, Appendix 1, p. 70; 3541, p. 5).

OSHA also received comments on the inclusion of pulmonary function (*i.e.*, spirometry) tests in periodic examinations and the appropriate frequency for such tests. As noted under the discussion of tests included as part of the initial medical evaluation, some commenters questioned whether spirometry in general should be required for employees exposed to respirable crystalline silica. For the same reason that OSHA decided to include spirometry as a required element in the initial medical examination, it concludes that requiring spirometry as part of the periodic examination is appropriate; that reason is that a spirometry test is a valuable tool for detecting possible lung function abnormalities associated with respirable crystalline silica-related disease and for monitoring the health of exposed employees. Spirometry tests that adhere to strict quality standards and that are administered by a technician who has a current certificate showing successful completion of a NIOSH-approved spirometry course, are useful for monitoring progressive lung function changes in individual employees and in groups of employees.

The proposed interval of three years for spirometry testing was an issue in the rulemaking. OSHA proposed this interval because exposure to respirable crystalline silica does not usually cause severe declines in lung function over short time periods. Spirometry testing conducted every three years is within ranges of recommended frequencies, based on factors such as age and exposure duration or intensity, in guidelines by ACOEM and BCTD, although ACOEM and BCTD recommend an evaluation at 18 months following the baseline test (Document ID 1505, p. 3; 1509, p. 15; 2080, pp. 5–6; 4223, p. 128). Guidelines from WHO recommend yearly spirometry tests, but indicate that if that is not possible, spirometry can be conducted at the same frequency as X-rays (every 2-to-5 years) (Document ID 1517, p. 32).

OSHA specifically requested comment on the appropriate frequency of lung function testing, which it proposed at intervals of every three years. ASSE agreed that spirometry testing every three years is consistent with most credible occupational health programs for respirable crystalline silica exposure (Document ID 2339, p. 9). Industry stakeholders, such as Ameren, NSSGA, and AFS, also supported conducting spirometry testing every three years (Document ID 2315, p. 9; 2327, Attachment 1, pp. 24–25; 2379, Appendix 1, p. 70).

Collegium Ramazzini stated that spirometry testing should be conducted annually rather than triennially (Document ID 3541, pp. 12–13). In support of its statement, Collegium Ramazzini interpreted data from a Wang and Petsonk (2004) study to mean that an FEV_1 loss of 990 milliliters (mL) or higher could occur before detection of lung function loss with testing every three years (Document ID 3541, pp. 12–13; 3636).

The Wang and Petsonk 2004 study was designed to measure lung function changes in coal miners over 6- to 12-month intervals. The study authors reported that in the group of coal miners studied, a year-to-year decline in lung function (*i.e.,* FEV_1) of 8 percent or 330 mL or more, based on the 5th percentile, should not be considered normal (*i.e.,* the results did not likely occur by chance in healthy males). To understand the implications of this finding, OSHA consulted 2014 ATS guidelines. Those guidelines urge caution in interpreting early lung function changes in miners because early, rapid declines in lung function are often temporary and might occur because of inflammation. They further indicate that estimates of lung function decline are more precise as the length of follow-up increases and that real declines in lung function become easier to distinguish from background variability. In addition, ATS cautions that short-term losses in lung function can be difficult to evaluate because of variability (Document ID 3632, pp. 988–989).

OSHA notes that, in fact, Figure 1 of the Wang and Petsonk study shows that lung function loss measured over a 5-year period in that cohort of miners is much less variable than changes measured over 6- to 12-month intervals. OSHA therefore finds that this study indicates that long-term measurements in lung function are more reliable for assessing the level of lung function decline over time. Based on Table 1 of the Wang and Petsonk study, mean annual FEV_1 loss, when evaluated over a 5-year period, was 36 and 56 mL/year in stable and healthy miners, respectively. Even among rapid decliners evaluated over five years, mean decline in FEV_1 was 122 mL/year. Unlike Collegium Ramazzini, OSHA does not interpret the Wang and Petsonk study to mean that an FEV_1 loss of 990 mL or higher could occur before detection of lung function loss with testing every three years The study authors themselves conclude:

> However, even among workers in our study who met this >8% or >330 mL criterion, many did not show accelerated declines over the entire 5 years of follow up (data not shown), emphasizing that a finding of an increased year-to-year decline in an individual requires further assessment and confirmation (Document ID 3636, p. 595).

In sum, OSHA finds that the Wang and Petsonk study is not a basis for concluding that triennial spirometry

testing is inadequate for assessing lung function loss in most employees exposed to respirable crystalline silica.

Collegium Ramazzini also cited a 2012 Hnizdo study that demonstrated greater stability and predictability for excessive loss of lung function with more frequent testing. In that study, spirometry data were useful for predicting decline only after the fourth or fifth year of follow-up; Collegium Ramazzini stated that only two spirometry tests would be available in six years if employees are tested every three years (Document ID 3541, p. 13; 3627, p. 1506). OSHA notes that three spirometry reports would be available following six years of triennial testing (the initial examination, the three-year examination, and the six-year examination). In addition, Hnizdo concluded that annual spirometry was best, but even in employees tested every three years, useful clinical data were generated with five to six years of follow-up (Document ID 3627, p. 1511).

The ATS committee also reviewed the Hnizdo study and concluded that precision in determining rate of FEV_1 decline improves with greater frequency of measurement and duration of follow-up. Because chronic diseases, such as COPD and pneumoconiosis, typically develop over a span of years, the ATS committee concluded that spirometry performed every two-to-three years should be sufficient to monitor the development of such diseases (Document ID 3632, p. 988). NIOSH Division of Respiratory Disease Studies Director, Dr. David Weissman, who was on the ATS committee, also agreed that spirometry testing every three years is appropriate for respirable crystalline silica-exposed employees (Document ID 3632, p. 1; 3579, Tr. 255).

After consideration of the rulemaking evidence on this issue, OSHA concludes that spirometry testing every three years is appropriate to monitor employees' lung function and that the frequency is well supported in the record. Therefore, consistent with its proposed rule, OSHA is including a frequency of at least every three years for spirometry testing.

As discussed above in connection with the initial testing requirement, spirometry usually involves cross-sectional testing for assessing lung function at a single time point. Longitudinal spirometry testing that compares employees' lung function to their baseline levels is also useful for detecting excessive declines in lung function that could lead to severe impairment over time. OSHA did not propose a requirement to assess longitudinal changes in lung function. Commenters including Collegium Ramazzini, LHSFNA, and BCTD requested that the standard include requirements or instructions for longitudinal testing to compare an employee's current lung function value to his or her baseline value (Document ID 3541, p. 10; 3589, Tr. 4205; 4223, p. 129). As noted by Dr. L. Christine Oliver, associate clinical professor of medicine at Harvard Medical School, representing Collegium Ramazzini:

> Excessive loss of lung function may indicate early development of silica-related disease, even in the absence of an abnormal test result. So spirometry at one point in time may be normal, but compared to the baseline of that individual, there may have been a decline. So even though the test result itself is normal, it doesn't mean that there is not something going on with regard to that individual's lung function (Document ID 3588; Tr. 3855).

Both Collegium Ramazzini and BCTD requested that the standard require referral to a specialist for excessive losses of pulmonary function. Collegium Ramazzini recommended specialist referral for a year-to-year decline in FEV_1 of greater than 8 percent or 330 mL based on the study by Wang and Petsonk discussed above (Document ID 3541, pp. 3, 9–10; 3636). BCTD recommended specialist referral for a year-to-year decline in FEV_1 of greater than 10 percent based on ACOEM guidance (Document ID 4223, p. 129; 3634, pp. 579–580).

OSHA endorses in principle the value of longitudinal spirometry analyses to compare employees' lung function to their baseline values, but is not adopting the specific recommendation to incorporate it into the rule. Based on a review of the available evidence, OSHA is concerned about several challenges in determining an employee's change from baseline values, which preclude the Agency from requiring longitudinal analyses with an across-the-board trigger of 8-to-10 percent loss of baseline lung function for specialist referral. First, a lung function loss of 8-to-10 percent is more stringent than general recommendations from ACOEM and ATS. OSHA notes that the complete ACOEM recommendation for evaluating longitudinal changes in lung function states:

> When high-quality spirometry testing is in place, ACOEM continues to recommend medical referral for workers whose FEV_1 losses exceed 15%, after allowing for the expected loss due to aging. Smaller declines of 10% to 15%, after allowing for the expected loss due to aging, may be important when the relationship between longitudinal results and the endpoint disease is clear. These smaller declines must first be confirmed, and then, if the technical quality of the pulmonary function measurement is adequate, acted upon (Document ID 3634, p. 580).

The ACOEM recommendation is based on ATS guidelines indicating that year-to-year changes in lung function exceeding 15 percent are probably unusual in healthy individuals. A recent ATS committee restated that position:

> ATS recommends that a decline of 15% or more over a year in otherwise healthy individuals be called ''significant,'' beyond what would be expected from typical variability (Document ID 3632, p. 989).

As ATS indicated, actual lung function losses must be distinguished from measurement variability. Variability in spirometry findings can occur as a result of technical factors (*e.g.*, testing procedures, technician competence, and variations in equipment) and biological factors related to employees being tested (*e.g.,* circadian rhythms, illness, or recovery from surgery) (Document ID 3630, p. 32). The requirement for testing by a technician with a current certificate from a NIOSH-approved course improves spirometry quality and reduces variability related to testing technique and technician competence. However, OSHA is aware that even with high quality spirometry programs, variability in results can still occur from factors such as changes in equipment and/or testing protocol.

Collegium Ramazzini noted that spirometry performed at a location other than that of the first employer may not provide an adequate baseline to evaluate lung function changes in the absence of quality control and standardized equipment, methodology, and interpretation (Document ID 3541, p. 5). OSHA is concerned about the ability to differentiate lung function changes from variability, even with standardization and quality control. ACOEM has concluded that frequent changing of spirometry providers may prevent a meaningful evaluation of longitudinal testing results (Document ID 3633, p. 1309). OSHA recognizes that changes in spirometry providers could preclude evaluating changes in lung function from baseline values and that employees in high-turnover industries, *e.g.*, construction, could be particularly affected if they undergo spirometry testing on different types of spirometers used by different providers contracted by the different employers for whom they work.

In addressing the issue of construction employees frequently changing employers, Dr. L. Christine Oliver recommended storing spirometry results in a central database or providing them to employees to allow

comparison of current results with past results (Document ID 3588, Tr. 3873–3875). As indicated above, technical quality of past spirometry should be evaluated before examining longitudinal change in lung function. Full spirometry reports should be examined for indicators of test quality (*e.g.*, acceptability and repeatability of spirometry maneuvers). OSHA encourages PLHCPs to give employees copies of their full medical records, including spirometry reports with numerical values and graphical illustrations of expiratory curves. Employees (including former employees) also have a right to access their medical records under OSHA's access to medical and exposure records rule (29 CFR 1910.1020). Presenting past spirometry records to a new PLHCP might allow for the interpretation of lung function compared to baseline values, but the PLHCP would have to determine if this evaluation is possible based on spirometry technical quality.

In sum, OSHA recognizes the value of longitudinal analyses that compare an individual's lung function to their baseline values. Recent studies have shown that excessive decline in lung function can be an early warning sign for risk of COPD development (Document ID 1516). Therefore, identifying employees who are at risk of developing severe decrements in lung function can allow for interventions to possibly prevent or slow progression of disease and thus justifies periodic spirometry. But because of the complexities and challenges described above, OSHA is not mandating testing to compare employees' lung function values to baseline values or specifying a lung function loss trigger for referral to a specialist. OSHA concludes that spirometry conducted every three years is appropriate to detect the possible development of lung function impairment. However, the PLHCP is in the best position to determine how spirometry results should be evaluated. Under paragraph (i)(5)(iv) of the standard for general industry and maritime (paragraph (h)(5)(iv) of the standard for construction), PLHCPs have the authority to recommend referral to a specialist if ''otherwise deemed appropriate,'' and an informed judgment or suspicion that excessive lung function loss or an actual lung function abnormality has occurred would be an appropriate reason for referral to a specialist with the necessary skills and capability to make that evaluation.

Information provided to the PLHCP. Paragraph (i)(4)(i)–(iv) of the standard for general industry and maritime (paragraph (h)(4)(i)–(iv) of the standard for construction) requires the employer to ensure that the examining PLHCP has a copy of the standard, and to provide the following information to the PLHCP: A description of the employee's former, current, and anticipated duties as they relate to respirable crystalline silica exposure; the employee's former, current, and anticipated exposure levels; a description of any personal protective equipment (PPE) used, or to be used, by the employee, including when and for how long the employee has used or will use that equipment; and information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer. OSHA determined that the PLHCP needs this information to evaluate the employee's health in relation to assigned duties and fitness to use PPE.

Some of these provisions reflect minor edits from the proposed rule. In paragraphs (i)(4)(i) and (iv) of the standard for general industry and maritime (paragraphs (h)(4)(i) and (iv) of the standard for construction), OSHA changed ''affected employee'' to ''employee.'' OSHA removed the word ''affected'' because it is clear that the provisions refer to employees who will be undergoing medical examinations. In paragraph (i)(4)(iii) of the standard for general industry and maritime (paragraph (h)(4)(iii) of the standard for construction), OSHA changed ''has used the equipment'' to ''has used or will use the equipment'' to make it consistent with the earlier part of the provision that states ''personal protective equipment used or to be used.'' These non-substantive changes simply remove superfluous language or clarify OSHA's intent, which has not changed from the proposed rule.

OSHA received few comments regarding information to be supplied to the PLHCP. NAHB was concerned about obtaining or verifying information, such as PPE use, exposure information, and medical information, from past employers to give to the PLHCP (Document ID 2296, p. 31). Paragraph (i)(4)(iv) of the standard for general industry and maritime (paragraph (h)(4)(iv) of the standard for construction) is explicit, however, that employers must only provide the information within their control. Employers are not expected to provide information to PLHCPs on exposures experienced by employees while the employees were working for prior employers. Similarly, OSHA intends that where the employer does not have information on the employee's past or current exposure level, such as when a construction employer uses Table 1 in lieu of exposure monitoring, providing the PLHCP with an indication of the exposure associated with the task (*e.g.,* likely to be above the PEL) fulfills the requirement.

OSHA identifies the information that the employer must provide to the PLHCP, along with information collected as part of the exposure and work history, as relevant to the purposes of medical surveillance under the rule because it can assist the PLHCP in determining if symptoms or a health finding may be related to respirable crystalline silica exposure or if the employee might be particularly sensitive to such exposure. For example, a finding of abnormal lung function caused by asthma might indicate increased sensitivity to a workplace exposure. The information will also aid the PLHCP's evaluation of the employee's health in relation to recommended limitations on the employee's use of respirators or exposure to respirable crystalline silica. For these reasons, OSHA is retaining the proposed provisions detailing information to be provided to the PLHCP in the rule.

Written medical reports and opinions. The proposed rule provided for the PLHCP to give a written medical opinion to the employer, but relied on the employer to give the employee a copy of that opinion; thus, there was no difference between information the employer and employee received. The rule differentiates the types of information the employer and employee receive by including two separate paragraphs within the medical surveillance section that require a written medical report to go to the employee, and a more limited written medical opinion to go to the employer. The former requirement is in paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction); the latter requirement is in paragraph (i)(6) of the standard for general industry and maritime (paragraph (h)(6) of the standard for construction). This summary and explanation for those paragraphs first discusses the proposed requirements and general comments received in response to the proposed requirements. OSHA then explains in this subsection of the preamble its decision in response to these comments to change from the proposed requirement for a single opinion to go to both the employee and employer and replace it with two separate and distinct requirements: (1) A full report of medical findings, recommended limitations on respirator use or exposure

to respirable crystalline silica, and any referral for specialist examination directly to the employee; and (2) an opinion focused primarily on any recommended limitations on respirator use, and with the employee's consent, recommended limitations on the employee's exposure to respirable crystalline silica and referral to a specialist. The ensuing two subsections will then discuss the specific requirements and the record comments and testimony relating to those specific requirements.

OSHA proposed that the employer obtain from the PLHCP a written medical opinion containing: (1) A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including any conditions that would put the employee at increased risk of material impairment of health from further exposure to respirable crystalline silica; (2) recommended limitations on the employee's exposure to respirable crystalline silica or use of PPE, such as respirators; (3) a statement that the employee should be examined by a pulmonary disease specialist if the X-ray is classified as 1/0 or higher by the B reader, or if referral to a pulmonary disease specialist is otherwise deemed appropriate by the PLHCP; and (4) a statement that the PLHCP explained to the employee the medical examination results, including conditions related to respirable crystalline silica exposure that require further evaluation or treatment and any recommendations related to use of protective clothing or equipment. The proposed rule would also have required the employer to ensure that the PLHCP did not include findings unrelated to respirable crystalline silica exposure in the written medical opinion provided to the employer or otherwise reveal such findings to the employer. OSHA raised the contents of the PLHCP's written medical opinion, including privacy concerns, as an issue in the preamble of the NPRM in Question 71 in the ''Issues'' section (78 FR at 56290).

OSHA received a number of comments on these provisions. The majority of these comments related to the proposed contents of the PLHCP's written medical opinion and its transmission to the employer. For example, Dr. Laura Welch expressed concern that the provision that would have required the PLHCP to disclose ''a medical condition that puts him or her at risk of material impairment to health from exposure to silica'' could be read to require disclosure of the employee's medical diagnosis (Document ID 3581, Tr. 1580). Dr. Steven Markowitz, physician and director of the Center for Biology of Natural Systems at Queens College, representing USW, explained:

> So, for example, if I were the examining healthcare provider and I saw an employee, and he had what I identified as idiopathic pulmonary fibrosis, which is diffuse scarring of the lungs with an unknown cause, in this case, not silica, is that information that I would need to turn over to the employer because further exposure to silica might impair that person's health or not? Or what if the worker has emphysema, which is a silica-related condition, and the provider believes that that emphysema is not due to silica exposure but to the employee's long-time smoking history. Is that information that the healthcare provider is supposed to turn over to the employer? It isn't at all clear (Document ID 3584, Tr. 2518–2519).

Some commenters offered suggestions to address privacy concerns regarding the content of the proposed PLHCP's written medical opinion for the employer and the proposed requirement that the opinion be given to the employer instead of the employee. One suggestion advocated by UAW, LHSFNA, AFSCME, AFL–CIO, and BCTD was for OSHA to use a model based on the black lung rule for coal miners (Document ID 2282, Attachment 3, pp. 20–21; 3589, Tr. 4207; 4203, p. 6; 4204, p. 88; 4223, p. 134). Under the coal miner regulations, miners receive the medical information and employers are prohibited from requiring that information from miners (30 CFR 90.3). Commenters including BlueGreen Alliance, CWA, USW, and Collegium Ramazzini also urged OSHA to require that findings from medical surveillance only be given to employers upon authorization by the employee (Document ID 2176, p. 2; 2240, pp. 3–4; 2336, p. 12; 3541, p. 13). UAW, AFL–CIO, and BCTD referred OSHA to ACOEM's recommendations for workplace confidentiality of medical information (Document ID 2282, Attachment 3, p. 20; 3578, Tr. 929; 3581, Tr. 1579–1580). The ACOEM guidelines state:

> Physicians should disclose their professional opinion to both the employer and the employee when the employee has undergone a medical assessment for fitness to perform a specific job. However, the physician should not provide the employer with specific medical details or diagnoses unless the employee has given his or her permission (Document ID 3622, p. 2).

Exceptions to this recommendation listed under the ACOEM guidelines include health and safety concerns. Collegium Ramazzini, BCTD, USW, and BAC argued that providing an employer with information about an employee's health status violates an employee's privacy and is not consistent with societal views reflected in laws, such as the Health Insurance Portability and Accountability Act (HIPAA) (Document ID 3541, p. 13; 3581, Tr. 1578–1579; 3584, Tr. 2519; 4219, p. 31).

Although HIPAA regulations allow medical providers to provide medical information to employers for the purpose of complying with OSHA standards (Document ID 4214, p. 7), OSHA has accounted for stakeholder privacy concerns in devising the medical disclosure requirements in the rule. OSHA understands that the need to inform employers about a PLHCP's recommendations on work limitations associated with an employee's exposure to respirable crystalline silica must be balanced against the employee's privacy interests. As discussed in further detail below, OSHA finds it appropriate to distinguish between the PLHCP's recommendations and the underlying medical reasons for those recommendations. In doing so, OSHA intends for the PLHCP to limit disclosure to the employer to what the employer needs to know to protect the employee, which does not include an employee's diagnosis. Contrary to some of the comments, it was not OSHA's intent, either in the proposed rule or in earlier standards that require information on an employee's medical or health condition, to transmit diagnostic information to the employer; OSHA intended for the PLHCP merely to convey whether or not the employee is at increased risk from exposure to respirable crystalline silica (or other workplace hazards in other standards) based on any medical condition, whether caused by such exposure or not. In re-evaluating how to express this intent, however, OSHA concludes that the employer primarily needs to know about any recommended limitations without conveying the medical reasons for the limitations. Thus, in response to the weight of opinion in this rulemaking record and to evolving notions about where the balance between preventive health policy and patient privacy is properly struck, OSHA is taking a more privacy- and consent-based approach regarding the contents of the PLHCP's written medical opinion for the employer compared to the proposed requirements and earlier OSHA standards. These changes, which are reflected in paragraph (i)(6) of the standard for general industry and maritime (paragraph (h)(6) of the standard for construction), and the comments that led to these changes, are more fully discussed below.

Reinforcing the privacy concerns, various stakeholders, including labor unions, physicians, and employees,

were also concerned that employees' current or future employment might be jeopardized if medical information is reported to employers (*e.g.,* Document ID 2282, Attachment 3, p. 20; 3581, Tr. 1582; 3583, Tr. 2470–2471; 3585, Tr. 3053–3054; 3586, Tr. 3245; 3589, Tr. 4227–4228, 4294–4295; 4203, pp. 6–7; 4214, pp. 7–8). The same concerns were expressed by Sarah Coyne, a painter and Health and Safety Director from the International Union of Painters and Allied Trades, who testified that many of her fellow union members who have silicosis refused to testify at the silica hearings because they feared they would lose their jobs if their employers found out they were ill (Document ID 3581, Tr. 1613–14). Dr. L. Christine Oliver testified that her patients do not want medical information reported to employers, and Dr. James Melius stated that LHSFNA members are leery of medical surveillance because they fear losing their jobs (Document ID 3588, Tr. 3881–3882; 3589, Tr. 4228). Deven Johnson, cement mason, described employees hiding injuries from supervisors on jobsites for fear of being blacklisted, and said that:

> The same is true with occupational illnesses, that the last thing that a worker wants is to have any information that he's somehow compromised because, even though we want to think the best of the employer, that somebody wouldn't take action against that individual, we know for a fact that it happens. It's happened to our membership (Document ID 3581, Tr. 1656).

Industry representatives indirectly confirmed that discrimination based on medical results was possible. For example, CISC noted that some employers might refuse to hire an employee with silicosis because they might have to offer workers' compensation or be held liable if the disease progresses (Document ID 4217, pp. 22–23).

Evidence in the record demonstrates that a likely outcome of employees' reluctance to let employers know about their health status is refusal to participate in medical surveillance. For example, Dr. Rosemary Sokas stated that employees who lack job security would likely avoid medical surveillance if the employer receives the results (Document ID 3577, Tr. 819–820). In discussing the Coal Workers' Health Surveillance Program, Dr. David Weissman stated that maintaining confidentiality is critical because:

> One of the biggest reasons in focus groups that miners have given for not participating in surveillance is fear of their medical information being shared without their permission (Document ID 3579, Tr. 169).

When asked if employees would participate in medical surveillance that lacked both employee confidentiality and anti-retaliation and discrimination protection, employees Sarah Coyne, Deven Johnson, and Dale McNabb stated that they would not (Document ID 3581, Tr. 1657; 3585, Tr. 3053–3054). BAC and BCTD emphasized that employees must choose to participate in medical surveillance in order for it to be successful (Document ID 4219, p. 31; 4223, p. 131).

Industry groups, such as OSCO Industries and NAHB, commented that they or employers from their member companies are reluctant to handle or maintain confidential medical information (Document ID 1992, p. 12; 2296, p. 32). NAHB indicated:

> Members have expressed strong concerns that much of [the medical information], if not all, would be covered by privacy laws and should be between a doctor and patient. . . . Moreover, the PLHCP should provide a copy of the written medical opinion to the employee directly, not the employer, once it is written (Document ID 2296, pp. 31–32).

However, other industry groups asserted that employers should receive detailed information from medical surveillance. In particular, NISA argued that reporting medical surveillance findings to employers would facilitate epidemiological studies to better understand hazards and the effectiveness of a new standard (Document ID 4208, p. 14).

OSHA agrees that epidemiology studies are important; indeed its health effects and significant risk findings in this rule are overwhelmingly based on epidemiological studies. However, as noted above, it was never OSHA's intent for the PLHCP's written medical opinion on respirable crystalline silica to contain specific diagnoses or detailed findings that might be useful for an epidemiology study. As noted in the summary and explanation of *Recordkeeping,* OSHA's access to employee exposure and medical records standard (29 CFR 1910.1020) requires employers to ensure that most employee medical records are retained for the duration of employment plus 30 years for employees employed more than one year. Such records obtained through appropriate legal means, and with personal identifying information omitted or masked, would be a possible avenue for conducting epidemiology studies.

CISC also noted that in past standards, the purpose of medical surveillance was to improve health practices by allowing employers to understand effects of hazards and, therefore, make changes to the worksite, such as implementing controls or removing employees from exposure (Document ID 4217, p. 24). Attorney Brad Hammock, representing CISC at the public hearing, stated that if OSHA expects employers to make placement decisions based on health outcomes and exposure, then there would be some value in an employer receiving the PLHCP's opinion. However, Mr. Hammock further explained that if the purpose of surveillance is simply to educate employees about their health situation, then there would be arguably little value in the employer receiving the opinion (Document ID 3580, Tr. 1466–1467). Other commenters, including ACOEM, AOEC, and NISA, also noted the importance of medical surveillance for identifying adverse health effects among employees in order to make workplace changes or evaluate the effectiveness of regulations or workplace programs (Document ID 2080, pp. 9–10; 3577, Tr. 784; 4208, pp. 13, 16–17). Andrew O'Brien testified that if employers are not allowed to see medical findings, the first time they are made aware of a problem is when they receive a letter from the compensation system. Mr. O'Brien stated:

> Without access to that data, you can't . . . potentially see disease beginning and take preventative action to prevent it from actually having a negative health effect (Document ID 3577, Tr. 614).

In contrast to those views, USW questioned the value in providing employers with the PHLCP's medical opinion. It stated:

> Exactly what corrections in the workplace will the employer make based on newfound knowledge that one of his workers has a silica-related condition? Silicosis occurs 15 or more years following onset of exposure, so that today's silicosis is due to exposure that likely occurred decades ago. (Exceptions are acute and accelerated silicosis, which are rare and are not expected to occur at the recommended PEL.) What inference is the employer supposed to make about the magnitude or effect of current exposures under these circumstances? Indeed, to make sense of the issue, the employer would have to know about the worker's prior silica exposures, quite often at different workplaces. But the employer and, quite likely, even the worker are unlikely to have high quality data on exposures to silica that occurred decades ago. In the absence of such information, it is unclear how an employer can properly interpret current exposures as causing silicosis. By contrast, the best information on current exposures derives from current exposure monitoring, and the notion that documenting silicosis can somehow provide useful information about current exposures above and beyond what proper exposure monitoring is ill-conceived (Document ID 4214, p. 8).

Similarly, Peg Seminario, Director of Safety and Health with AFL–CIO, testified that employers should be basing their decisions on exposure levels and how well controls are working (Document ID 3578, Tr. 1008). NAHB and CISC questioned how an employer should respond if an employee has signs of lung disease and the employer has already implemented engineering controls and respirator use (Document ID 2296, p. 31; 2319, p. 117).

OSHA agrees that because of the long latency period of most respirable crystalline silica-related diseases, a diagnosis of such an illness in an employee will not provide useful information about current controls or exposure conditions. Employers should be basing their actions on exposure assessments and ensuring properly functioning controls, such as those listed and required for employers using Table 1. In the case where an employee may have disease related to respirable crystalline silica and the employer has properly implemented engineering controls, the only further action by the employer would be to follow PLHCP recommendations to protect the worker who may be especially sensitive to continuing exposure and need special accommodations. Such recommendations could include limitations on respirator use; they might also include specialist referral or limitations on respirable crystalline silica exposure (if the employee gives authorization for the employer to receive this information) (paragraph (i)(6)(i)(C) or (ii)(A) and (B) of the standard for general industry and maritime and paragraph (h)(6)(i)(C) or (ii)(A) and (B) of the standard for construction).

In taking a more consent-based approach than in the proposed rule regarding the PLHCP's written medical opinion for the employer, OSHA considered the countervailing factor that employers will not be able to report occupational illnesses to OSHA if they are not given medical surveillance information. USW refuted the utility of employer reporting of workplace illnesses, stating:

> However, this loss is minor, because few believe that such employer-generated reporting of chronic occupational conditions does, or even could, under the best of circumstances, provide proper counts of occupational illnesses (Document ID 4214, p. 8).

On a similar note, Fann Contracting and ASSE requested clarification on what information would be reportable or recordable (Document ID 2116, Attachment 1, p. 20; 2339, p. 9).

This rule does not change OSHA reporting or recording requirements, and employers who need more information on recording or reporting of occupational illnesses should refer to OSHA's standard on recording and reporting occupational injuries and illnesses (29 CFR 1904). OSHA finds that if employees do not participate in medical surveillance because of discrimination or retaliation fears, illnesses associated with respirable crystalline silica would generally not be identified. Although not disclosing medical information to employers appears inconsistent with the objective of recording illnesses, the net effect of that decision is improving employee protections due to more employees participating in medical surveillance. Also, as noted above, OSHA never intended for employers to get specific information, such as diagnoses, and this would further limit employers' ability to report disease. Although state surveillance systems are likely to underestimate silicosis cases (see Section V, Health Effects), they are still likely to be a better way to get information on trends of silicosis cases than employer reports. Reporting of silicosis cases by health care providers is required by 25 states (*see http://www.cste2.org/izenda/ReportViewer.aspx?rn=Condition+All&p1value=2010&p2value=Silicosis*). PLHCPs are more likely to have the information needed to report silicosis cases to state health authorities than employers. Thus, OSHA concludes that exclusion of health-related information from the PLHCP's written medical opinion for the employer will not have a significant impact on silicosis surveillance efforts.

An additional consideration relating to what information, if any, goes to the employer is that withholding information, such as conditions that might place an employee at risk of health impairment with further exposure, may leave employers with no medical basis to aid in the placement of employees. Although NSSGA did not want to receive confidential medical records, it stressed the importance of continuing to receive information concerning how the workplace could affect an employee's condition and on recommended respirator restrictions (Document ID 3583, Tr. 2315–2316; 4026, p. 5). NISA stated that employers should receive the results of medical surveillance because employers might be held liable if employees choose to keep working in settings that might aggravate their illnesses (Document ID 4208, p. 14). However, labor unions, such as USW, BAC, and BCTD, strongly opposed employers making job placement decisions based on employees' medical findings (Document ID 4214, pp. 7–8; 4219, pp. 31–32; 4223, p. 133). USW and BCTD noted that as long as employees are capable of performing their work duties, decisions to continue working should be theirs; BCTD further noted that the employee should make such decisions with guidance from the PLHCP, and USW noted that the employee should decide because of the significance of job loss or modifications (Document ID 2371, Attachment 1, pp. 45–46; 4214, pp. 7–8). Sarah Coyne agreed that employees should make decisions about placement. Ms. Coyne stated, ''I might have silicosis. I might have asbestosis. I know if I can work or not. Let me decide'' (Document ID 3581, Tr. 1656).

OSHA agrees that employees have the most at stake in terms of their health and employability, and they should not have to choose between continued employment and the health benefits offered by medical surveillance, which they are entitled to under the OSH Act. OSHA agrees that employees should make employment decisions, following discussions with the PLHCP that include the risks of continued exposure. Before that can happen, however, employees need to have confidence that participation in medical surveillance will not threaten their livelihoods. After considering the various viewpoints expressed during the rulemaking on these issues, OSHA concludes that the best way to maximize employee participation in medical surveillance, therefore promoting the protective and preventative purposes of this rule, is by limiting required disclosures of information to the employer to only the bare minimum of what the employer needs to know to protect employee health—recommended restrictions on respirator use and, only with consent of the employee, the PLHCP's recommended limitations on exposure to respirable crystalline silica and specialist referrals. Thus, OSHA views this consent-based approach to reporting of medical surveillance findings critical to the ultimate success of this provision, which will be measured not just in the participation rate, but in the benefits to participating employees—early detection of silica-related disease so that employees can make employment, lifestyle, and medical decisions to mitigate adverse health effects and to possibly retard progression of the disease.

Expressing a different view, CISC stated that OSHA lacks the legal

authority to require employers to pay for ongoing medical surveillance with no nexus to the workplace (Document ID 4217, p. 24). However, the medical surveillance requirement in this rule, and every OSHA rule, does have a nexus to the workplace. In the case of the respirable crystalline silica rule, the nexus to the workplace is that exposure in the workplace can result in or exacerbate disease and that medical surveillance information will allow employees to make health and lifestyle decisions that will benefit both them and the employer. In addition, medical surveillance provides the employer with information on fitness to wear a respirator, which is vitally important because of risks to employees who wear a respirator when they should not do so because of medical reasons.

NISA supported providing the proposed medical opinion to employers, partly because some employers might have a better understanding of medical surveillance results than employees, who might not have the training or understanding to make health-protective decisions based on those results (Document ID 4208, pp. 13–14). OSHA recognizes that larger companies that employ health, safety, and medical personnel may have in-house expertise to answer employee questions and stress the importance of protective measures, such as work practices or proper use of respirators. However, it is not likely that owners or management of small companies would have a better understanding than their employees or would be able to provide them any additional guidance. Consequently, OSHA does not find the fact some employers might have a better understanding of medical surveillance results than employees to be a compelling argument against limiting the information that is to be reported to the employer in the absence of employee consent. In addition, OSHA expects that the training required under the rule will give employees knowledge to understand protective measures recommended by the PLHCP.

In sum, OSHA concludes that the record offers compelling evidence for modifying the proposed content of the PLHCP's written medical opinion for the employer. The evidence includes privacy concerns expressed by both employees and employers, as well as evidence on the limited utility for giving medical surveillance findings to employers. OSHA is particularly concerned that the proposed requirements would have led to many employees not participating in medical surveillance and therefore not receiving its benefits. OSHA therefore has limited the information to be given to the employer under this rule, but is requiring that the employee receive a separate written medical report with more detailed medical information.

The requirements for the type of information provided to the employer are different from requirements of other OSHA standards, which remain in effect for those other standards. The requirements for this rule are based on the evidence obtained during this rulemaking for respirable crystalline silica, in particular that many employees would not take advantage of medical surveillance without privacy protections and because the findings of medical examinations would not likely reflect current workplace conditions in most cases. The action taken in this rulemaking does not preclude OSHA from adopting its traditional approach, or any other approach for reporting of medical findings to employers, in the future when it concludes, based on health effects information, that such an approach would contribute information that is relevant to current workplace conditions and would allow for design or implementation of controls to protect other employees.

PLHCP's written medical report for the employee. OSHA did not propose a separate report given directly by the PLHCP to the employee, but as discussed in detail above, several commenters requested that a report containing medical information only be given to the employee. OSHA agrees and in response to those comments, paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction) requires the employer to ensure that the PLHCP explains the results of the medical examination and provides the employee with a written medical report within 30 days.

The contents of the PLHCP's written medical report for the employee are set forth in paragraphs (i)(5)(i)–(iv) of the standard for general industry and maritime (paragraphs (h)(5)(i)–(iv) of the standard for construction). They include: The results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment of health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment; any recommended limitations on the employee's use of respirators; any recommended limitations on respirable crystalline silica exposure; and a statement that the employee should be examined by a specialist if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B reader, or if referral to a specialist is deemed appropriate by the PLHCP. Appendix B contains an example of a PLHCP's written medical report for the employee.

The health-related information in the PLHCP's written medical report for the employee is generally consistent with the proposed PLHCP's written medical opinion for the employer, with two notable exceptions. Because only the employee will be receiving the PLHCP's written medical report, the written medical report may include diagnoses and specific information on health conditions, including those not related to respirable crystalline silica, and medical conditions that require further evaluation or follow-up are not limited to those related to respirable crystalline silica exposure. Although the focus of the examination is on silica-related conditions, the PLHCP may happen to detect health conditions that are not related to respirable crystalline silica exposure during the examination, and could include information about such conditions in the written medical report for the employee. The employer, however, is not responsible for further evaluation of conditions not related to respirable crystalline silica exposure. A minor difference from the proposed written medical opinion for the employer and the written medical report for the employee in the rule is that it specifies limitations on respirator use rather than PPE because respirators are the only type of PPE required by the rule. The requirements for the PLHCP's written medical report for the employee are consistent with the overall goals of medical surveillance: To identify respirable crystalline silica-related adverse health effects so that the employee can consider appropriate steps to manage his or her health; to let the employee know if he or she can be exposed to respirable crystalline silica in his or her workplace without increased risk of experiencing adverse health effects; and to determine the employee's fitness to use respirators. By providing the PLHCP's written medical report to employees, those who might be at increased risk of health impairment from respirable crystalline silica exposure will be able to consider interventions (*i.e.,* health management strategies) with guidance from the PLHCP. Dr. Laura Welch testified that her recommendations to a patient diagnosed with silicosis would include employment choices to limit exposures, using a respirator for additional protection, quitting smoking, and

getting influenza and pneumonia vaccines (Document ID 3581, p. 1663).

The requirement for a verbal explanation in paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction) allows the employee to confidentially ask questions or discuss concerns with the PLHCP. The requirement for a written medical report ensures that the employee receives a record of all findings. As noted by BCTD, giving the employee the written report will ensure the employee understands medical conditions that require follow-up and could affect decisions of where and how to work; BCTD also noted that employees would be able to provide the PLHCP's written medical report to future health care providers (Document ID 2371, Attachment 1, p. 48); this would include PLHCPs conducting subsequent periodic examinations under the rule.

PLHCP's written medical opinion for the employer. As discussed in detail above, many commenters objected to OSHA's proposed content for the PLHCP's written medical opinion for the employer based on employee privacy concerns. OSHA agrees with these privacy concerns and is thus revising the contents of the written medical opinion. In developing the contents of the PLHCP's written medical opinion for the employer, OSHA considered what type of information needs to be included to provide employers with information to protect employee health, while at the same time protecting employee privacy. Commenters representing labor unions and the medical community stated that the only information that employers need to know is limitations on respirator use (Document ID 2178, Attachment 1, p. 5; 2240, pp. 3–4; 2282, Attachment 3, p. 21; 2336, p. 12; 3589, Tr. 4207; 4196, p. 6; 4203, p. 6; 4204, p. 89; 4219, pp. 31–32; 4223, p. 133). Dr. Laura Welch stated that giving the employer information on an employee's ability to use a respirator, but not specific medical information, strikes the appropriate balance between the employee's privacy and the employer's right to know; she noted that employees who are not fit to wear a respirator and then do can be at risk of sudden incapacitation or death (Document ID 3581, Tr. 1582, 1662).

BCTD further noted that the medical surveillance model it is recommending for respirable crystalline silica presents a different circumstance than what it advocated for regarding asbestos in *Industrial Union Department, AFL–CIO* v. *Hodgson.* There, the union was not granted its request for results of medical examinations to be given to the employer only with the employees' consent under the asbestos standard. The court ruled that employers needed the medical results because the asbestos standard requires employers to reassign employees without loss of pay or seniority if the employee was found unable to safely wear a respirator. For respirable crystalline silica, BCTD has concluded that providing employers with information regarding limitations on respirator use and nothing else that is medically related is reasonable if the employee is not requesting accommodations or additional examinations from the employer (Document ID 4223, pp. 134–135).

Based on record evidence, OSHA has determined that for the respirable crystalline silica rule, the PLHCP's written medical opinion for the employer must contain only the date of the examination, a statement that the examination has met the requirements of this section, and any recommended limitations on the employee's use of respirators. These requirements are laid out in paragraphs (i)(6)(i)(A)–(C) of the standard for general industry and maritime (paragraphs (h)(6)(i)(A)–(C) of the standard for construction). OSHA is persuaded by arguments to include limitations on respirator use, and no other medically-related information, in the PLHCP's written medical opinion for the employer. The Agency notes that the limitation on respirator use is consistent with information provided to the employer under the respiratory protection standard (29 CFR 1910.134). OSHA concludes that only providing information on respirator limitations in the PLHCP's written medical opinion for the employer is consistent with the ACOEM confidentiality guidelines that recommend reporting of health and safety concerns to the employer (Document ID 3622, p. 2). The date and statement about the examination meeting the requirements of this section are to provide both the employer and employee with evidence that requirements for medical surveillance are current. Employees would be able to show this opinion to future employers to demonstrate that they have received the medical examination, as was recommended by LHSFNA and BCTD (Document ID 4207, p. 5; 4223, p. 125).

Paragraphs (i)(6)(ii)(A)–(B) of the standard for general industry and maritime (paragraphs (h)(6)(ii)(A)–(B) of the standard for construction) state that if the employee provides written authorization, the written medical opinion for the employer must also contain either or both of the following: (1) Any recommended limitations on exposure to respirable crystalline silica; (2) a statement that the employee should be examined by a specialist if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B reader, or if referral to a specialist is otherwise deemed appropriate by the PLHCP. OSHA intends for this provision to allow the employee to give authorization for the PLHCP's written medical opinion for the employer to contain only the recommendation on exposure limitations, only the recommendation for specialist referral, or both recommendations. The Agency expects that the written authorization could easily be accomplished through the use of a form that allows the employee to check, initial, or otherwise indicate which (if any) of these items the employee wishes to be included in the PLHCP's written medical opinion for the employer. An example of an authorization form is included in Appendix B.

OSHA is convinced that routinely including recommended limitations on respirable crystalline silica exposure and specialist referrals in the PLHCP's written medical opinion for the employer could adversely affect employees' willingness to participate in medical surveillance. The requirements for this paragraph are consistent with recommendations from labor unions. For example, UAW, BAC, and BCTD suggested letting the employee decide to forward the recommendation for an examination by a specialist if the employee wanted the employer to cover the costs of that examination (Document ID 3582, Tr. 1909; 4219, p. 32; 4223, pp. 133–134). BAC and BCTD also stated the employee should decide whether recommended accommodations (*i.e.,* recommended limitations on exposure) should be reported to the employer. As both BAC and BCTD emphasized, information given to the employer should only indicate that a referral is recommended and the nature of the limitation on exposure, not an underlying diagnosis. OSHA considers this reasonable. Appendix B contains an example of a PLHCP's written medical opinion for the employer.

OSHA finds that this new format for the PLHCP's medical opinion for respirable crystalline silica will better address concerns of NAHB and Dow Chemical, who feared they would be in violation if the PLHCP's written medical opinion for the employer included information that OSHA proposed the PLHCP not report to the employer, such as an unrelated diagnosis (Document ID 2270, p. 4; 2296, pp. 31–32). OSHA finds that removing the prohibition on

unrelated diagnoses and instead specifying the only information that is to be included in the PLHCP's written medical opinion for the employer remedies this concern because it makes the contents of the opinion easier to understand and less subject to misinterpretation. The new format also addresses NAHB's request that PLHCPs' opinions be standardized so that employers could understand the results (Document ID 2296, pp. 31–32).

OSHA recognizes that some employees might be exposed to multiple OSHA-regulated substances at levels that trigger medical surveillance and requirements for written opinions. The PLHCP can opt to prepare one written medical opinion for the employer for each employee that addresses the requirements of all relevant standards, as noted in preambles for past rulemakings, such as chromium (VI) (71 FR 10100, 10365 (2/28/06)). However, the combined written medical opinion for the employer must include the information required under each relevant OSHA standard. For example, if the PLHCP opts to combine written medical opinions for an employee exposed to both chromium (VI) and respirable crystalline silica in a workplace covered by construction standards, then the combined opinion to the employer must contain the information required by paragraphs (i)(5)(A)–(C) of the chromium (VI) standard for construction (29 CFR 1926.1126) and the information required by paragraphs (h)(6)(i)(A)–(C) (and paragraphs (h)(6)(ii)(A)–(B), with written authorization from the employee) of the respirable crystalline silica standard for construction.

Other commenter recommendations for information to be included in the PLHCP's written medical opinion for the employer were not adopted by OSHA. Collegium Ramazzini and BCTD requested that the PLHCP's written medical opinion for the employer contain a statement that the employee was informed that respirable crystalline silica increases the risk of lung cancer, and Collegium Ramazzini also requested that the opinion indicate that the employee was told that smoking can compound the risk of developing lung cancer with exposure to respirable crystalline silica (Document ID 3541, p. 14; 4223, p. 137). On a similar note, Collegium Ramazzini also requested that employers establish smoking cessation programs (Document ID 3541, p. 4). OSHA notes that training provisions in paragraph (j)(3)(i)(A) of the standard for general industry and maritime (paragraph (i)(2)(i)(A) of the standard for construction) already require employers to ensure that each employee can demonstrate knowledge of the health hazards associated with exposure to respirable crystalline silica, which include lung cancer. OSHA concludes that the training required under the respirable crystalline silica rule is sufficient to inform employees about lung cancer risk.

Labor unions including UAW, CWA, USW, AFL–CIO, and BCTD requested that the rule prohibit employers from asking employees or the PLHCP for medical information (Document ID 2282, Attachment 3, p. 21; 2240, pp. 3–4; 2336, p. 12; 4204, p. 90; 4223, p. 134); as most of these commenters noted, a similar prohibition is included in the black lung rule for coal miners (30 CFR 90.3). OSHA is not including such a prohibition in the rule because employers may have legitimate reasons for requesting medical information, such as X-ray findings, to conduct epidemiology studies, and if employees are not concerned about discrimination or retaliation, they could authorize the employer to receive such information.

The proposed written medical opinion for the employer called for a statement that the PLHCP had explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment. As noted above, OSHA has retained the requirement that the employer ensure that the PLHCP explains the results to the employee in paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction), but no longer requires the PLHCP to include a statement of this fact in the written medical opinion for the employer. OSHA is not mandating how the employer ensures that the employee gets the required information because there are various ways this could be done, such as in a contractual agreement between the employer and PLHCP. PLHCPs could still include the verification in the PLHCP's written medical opinion for the employer if that is a convenient method for them to do so.

Paragraph (i)(6)(iii) of the standard for general industry and maritime (paragraph (h)(6)(iii) of the standard for construction) requires the employer to ensure that employees receive a copy of the PLHCP's written medical opinion for the employer within 30 days of each medical examination performed. OSHA is requiring that employees receive a copy of the PLHCP's written medical opinion for the employer because they can present it as proof of a current medical examination to future employers. This is especially important in industries with high turnover because employees may work for more than one employer during a three-year period and this ensures that tests, such as X-rays, are not performed more frequently than required.

As indicated above, the rule requires that employers ensure that employees get a copy of the PLHCP's written medical report and opinion and that they get a copy of the PLHCP's opinion within 30 days of each medical examination (paragraphs (i)(5), (6)(i), and (6)(iii) of the standard for general industry and maritime, paragraphs (h)(5), (6)(i), and (6)(iii) of the standard for construction). By contrast, the proposed rule would have required that the employer obtain the PLHCP's written medical opinion within 30 days of the medical examination and then provide a copy to the employee within 2 weeks after receiving it. Dow Chemical expressed concern about compliance if a PLHCP took more than 30 days to deliver the PLHCP's written medical opinion, which is a situation that is out of the employer's control (Document ID 2270, p. 4). Ameren and EEI requested 30 days for the employer to give the employee a copy of the PLHCP's written medical opinion (Document ID 2315, p. 4; 2357, p. 35).

The purpose of these requirements is to ensure that the employee and employer are informed in a timely manner. To ensure timely delivery and demonstrate a good faith effort in meeting the requirements of the standard, the employer could inform PLHCPs about the time requirements and follow-up with PLHCPs if there is concern about timely delivery of these documents. Similar 30-day requirements are included in other OSHA standards, such as chromium (VI) (1910.1026) and methylene chloride (1910.1052). Because the PLHCP will be providing the employee with a copy of the PLHCP's written medical report, he or she could give the employee a copy of the written medical opinion at the same time. This would eliminate the need for the employer to give the employee a copy of the PLHCP's written medical opinion for the employer, but the employer would still need to ensure timely delivery.

Additional examinations with a specialist. Paragraph (i)(7)(i) of the standard for general industry and maritime (paragraph (h)(7)(i) of the standard for construction) requires that the employer make available a medical examination by a specialist within 30

days of receiving the written medical opinion in which the PLHCP recommends that the employee be examined by a specialist. As is the case with the PLHCP's examination, the employer is responsible for providing the employee with a medical examination by a specialist, at no cost, and at a reasonable time and place, if the employer receives a PLHCP's referral recommendation.

OSHA proposed referral to a specialist under two circumstances: (1) Where a B reader classifies an employee's chest X-ray as 1/0 or higher and (2) where the PLHCP determines referral is otherwise appropriate. The first trigger point for specialist referral relates to the interpretation and classification of the chest X-ray employees receive as part of their initial or periodic medical examination. The second trigger point empowers the PLHCP to refer the employee to a specialist for any other appropriate reason. After considering the comments on the proposed rule (discussed below), OSHA retained the triggers for referral in Paragraphs (i)(5)(iv) and (i)(6)(ii)(B) of the standard for general industry and maritime (paragraphs (h)(5)(iv) and (h)(6)(ii)(B) of the standard for construction).

As discussed above, paragraph (i)(2)(iii) of the standard for general industry and maritime (paragraph (h)(2)(iii) of the standard for construction) requires that X-rays be interpreted according to the ILO classification system. The ILO's system is a standardized manner of classifying opacities seen in chest radiographs. It describes the presence and severity of pneumoconiosis on the basis of size, shape, and profusion (concentration) of small opacities, which together indicate the severity and extent of lung involvement (Document ID 1475). The profusion of opacities seen on chest radiographs is compared to standard X-rays and classified on a 4-point category scale (0, 1, 2, or 3), with each category representing increasing profusion of small opacities. Each category is divided into two subcategories, giving a 12-subcategory scale between 0/− and 3/+. The first subcategory value represents the B Reader's first choice for profusion rating and the second subcategory value represents the B Reader's second choice for profusion rating. CDC/NIOSH considers a category 1/0 X-ray to be consistent with silicosis (Document ID 1711, p. 41).

The respirable crystalline silica rule's 1/0 category trigger point for referral is lower than in the ASTM standards, which recommend that employees with profusion opacities greater than 1/1 be evaluated at a frequency determined by a physician qualified in pulmonary disease (Section 4.7.1 of E 1132–06 and E 2625–09) and receive annual counseling by a physician or other person knowledgeable in occupational safety and health (Section 4.7.2 of E 1132–06 and E 2625–09) (Document ID 1466, p. 5; 1504, p. 5). CISC questioned what medical evidence OSHA had that a specialist is necessary at this stage and stated that OSHA did not explain why it deviated from the ASTM standard (Document ID 2319, p. 120). However, ACOEM agreed with a cut-off point of 1/0 for abnormality, and ATS agreed with specialist referral at a category of 1/0 (Document ID 2080, p. 7; 2175, p. 6).

Other evidence in the record also weighs in favor of referral where an employee's X-ray is classified as 1/0 or higher. For example, a study by Hnizdo et al. (1993) compared X-rays read by B Readers to autopsy findings and demonstrated that a classification of 1/0 is highly specific for radiological silicosis, with 89 percent of 1/0 readings of radiological silicosis found to be true positives (Document ID 1050, pp. 427, 440). Based on the high level of specificity for 1/0 readings, *i.e.,* the low probability of a false positive reading, OSHA concludes it is appropriate to address silicosis at that stage to allow for earlier intervention to possibly slow disease progression and improve health. Therefore, based on the evidence in the record, OSHA decided to retain the 1/0 or higher trigger point for referral to a specialist.

OSHA also decided to retain the second referral trigger point contained in the proposed rule: Referral to a specialist if otherwise deemed appropriate by the PLHCP. Such referrals based on a PLHCP's written medical opinion for the employer allow potential findings of concern to be investigated further. Together, the two triggers for specialist referral in this rule are intended to ensure that employees with abnormal findings can be given the opportunity to be seen by an American Board Certified Specialist with expertise in pulmonary disease or occupational medicine, who can provide not only expert medical judgment, but also counseling regarding work practices and personal habits that could affect these individuals' respiratory health.

As indicated above, the employee must provide written authorization before the PLHCP's written medical opinion for the employer may include a recommendation for specialist examination (paragraph (i)(6)(ii)(B) of the standard for general industry and maritime, paragraph (h)(6)(ii)(B) of the standard for construction). If the employer's opinion contains a recommendation for specialist referral, then paragraph (i)(7)(i) of the standard for general industry and maritime (paragraph (h)(7)(i) of the standard for construction) requires the employer to make available a medical examination by a specialist within 30 days after receiving the PLHCP's written medical opinion. If the employer does not receive the PLHCP's referral because the employee did not authorize the employer to receive it, then the employer is not responsible for offering additional examinations and covering their costs.

Although the criteria for referral, *i.e.,* X-ray classification or PLHCP's opinion that a referral is appropriate, have not changed since the proposed rule, the professional to whom the employee would be referred has changed. Specifically, the proposed rule would have required the employer to provide the referred employee with a medical examination with a pulmonary disease specialist. As discussed further in the summary and explanation of *Definitions,* OSHA agreed with a number of commenters that an occupational medicine specialist is qualified to examine employees referred for a possible respirable crystalline silica-related disease (Document ID 2215, p. 9; 2291, p. 26; 2348, Attachment 1, p. 40; 3577, Tr. 778; 4223, p. 129). Therefore, the Agency has added the term ''specialist'' to the definitions in paragraph (b) of the rule and defined the term to mean an American Board Certified Specialist in Pulmonary Disease or an American Board Certified Specialist in Occupational Medicine. Paragraphs (i)(5)(iv) and (i)(6)(ii)(B) of the standard for general industry and maritime (paragraphs (h)(5)(iv) and (h)(6)(ii)(B) of the standard for construction) were also revised to specify referral to a ''specialist.''

Paragraph (i)(7)(i) of the standard for general industry and maritime (paragraph (h)(7)(i) of the standard for construction) sets time limits for additional examinations to be made available. Specifically, it requires that the employer make available a medical examination by a specialist within 30 days of receiving a written medical opinion in which the PLHCP recommends that the employee be examined by a specialist. This requirement is unchanged from the proposed rule. Some commenters, including Dow Chemical, Ameren, and EEI, commented that it might take more than 30 days to get an appointment with a specialist (*e.g.*, Document ID 2270, p. 5; 2315, p. 4; 2357, p. 36). OSHA does

not expect this will be the case based on the numbers of available specialists in the U.S. As of March 10, 2015, the American Board of Internal Medicine (ABIM) reported that 13,715 physicians in the U.S. had valid certificates in pulmonary disease (*see http://www.abim.org/pdf/data-candidates-certified/all-candidates.pdf*). ABIM does not report how many of these physicians are practicing. However, ABIM does report that more than 400 new certificates in pulmonary disease were issued per year from 2011 to 2014 and a total of 4,378 new certificates in pulmonary disease were issued in the period from 2001 to 2010 (*see http://www.abim.org/pdf/data-candidates-certified/Number-Certified-Annually.pdf*). Because physicians are likely to practice for some time after receiving their certification, the numbers indicate that a substantial number of pulmonary disease specialists are available in the U.S. The American Board of Preventative Medicine reports that between 2001 and 2010, 863 physicians passed their examinations for board certification in occupational medicine (*see https://www.theabpm.org/pass_rates.cfm*). In a comparison with total numbers of physicians who were board certified in pulmonary disease during 2001 to 2010, the addition of board certified occupational medicine physicians will likely increase specialist numbers by approximately 20 percent. The expansion of the specialist definition to board certified occupational medicine physicians will mean that more physicians will be available for referrals, making appointments easier to get. Consequently, OSHA considers the 30-day period to be reasonable, and expects that this deadline will ensure that employees receive timely examinations.

Under paragraph (i)(7)(ii) of the standard for general industry and maritime (paragraph (h)(7)(ii) of the standard for construction), the employer must provide the specialist with the same information that is provided to the PLHCP (*i.e.*, a copy of the standard; a description of the employee's former, current, and anticipated duties as they relate to respirable crystalline silica exposure; the employee's former, current, and anticipated exposure level; a description of any PPE used, or to be used, by the employee, including when and for how long the employee has used or will use that equipment; and information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer). The information the employer is required to give the specialist is largely unchanged from the proposed rule. The few changes and the reasons why the specialist should receive this information are the same as those for the PLHCP and are addressed above.

Under paragraph (i)(7)(iii) of the standard for general industry and maritime (paragraph (h)(7)(iii) of the standard for construction), the employer must ensure that the specialist explains medical findings to the employee and gives the employee a written medical report containing results of the examination, including conditions that might increase the employee's risk from exposure to respirable crystalline silica, conditions requiring further follow-up, recommended limitations on respirator use, and recommended limitations on respirable crystalline silica exposure. The reasons why the specialist is to give the employee this information and the changes from the proposed rule are discussed above, under the requirements for the PLHCP's written medical report for the employee. For the same reasons as addressed above, paragraph (i)(7)(iv) of the standard for general industry and maritime (paragraph (h)(7)(iv) of the standard for construction) requires the specialist to provide the employer with a written medical opinion indicating the date of the examination, any recommended limitations on the employee's use of respirators, and with the written authorization of the employee, any recommended limitations on the employee's exposure to respirable crystalline silica.

The rule does not address further communication between the specialist and the referring PHLCP. OSHA expects that because the PLHCP has the primary relationship with the employer and employee, the specialist may want to communicate his or her findings to the PLHCP and have the PLHCP simply update the original written medical report for the employee and written medical opinion for the employer and employee. This is permitted under the rule, so long as all requirements and time deadlines are met.

Medical removal protection. Some OSHA standards contain provisions for medical removal protection (MRP) that typically require the employer to temporarily remove an employee from exposure when such an action is recommended in a written medical opinion. During the time of removal, the employer is required to maintain the employee's total normal earnings, as well as all other employee rights and benefits. MRP provisions vary among health standards, depending on the hazard, the adverse health effects, medical surveillance requirements, and the evidence presented during the particular rulemaking. Although virtually every previous OSHA substance-specific health standard includes provisions for medical surveillance, OSHA has found MRP necessary for only six of those standards. They are lead (1910.1025), cadmium (1910.1027), benzene (1910.1028), formaldehyde (1910.1048), methylenedianiline (1910.1050), and methylene chloride (1910.1052).

OSHA did not include a provision for MRP in the proposed rule because the Agency preliminarily concluded that there would be few instances where temporary removal and MRP would be useful. However, OSHA asked for comment on whether the rule should include an MRP provision, which medical conditions or findings should trigger temporary removal, and what should be the maximum period for receiving benefits (78 FR at 56291).

Labor groups, industry representatives, the medical community, and other employee health advocates offered comments on this issue. NIOSH, ASSE, and some employers and industry groups agreed with OSHA's preliminary findings that MRP or temporary removal from exposure is not appropriate for the respirable crystalline silica rule (*e.g.*, Document ID 2116, Attachment 1, pp. 44–45; 2177, Attachment B, p. 39; 2195, p. 44; 2319, p. 129; 2327, Attachment 1, p. 27; 2339, p. 10; 2357, p. 35; 2379, Appendix 1, p. 72). Among the reasons noted were an inability to relocate employees to different positions, interference with workers' compensation systems, or the permanent nature of silica-related health effects.

CWA, UAW, USW, and AFL–CIO advocated for the inclusion of MRP (in the general industry and maritime standard) with provisions for multiple physician review, similar to MRP in cadmium (Document ID 2240, p. 4; 2282, Attachment 3, pp. 23–24; 3584, Tr. 2541–2546; 4204, pp. 91–98). None of the labor groups requested an MRP provision for the construction standard. According to Collegium Ramazzini and AFL–CIO, benefits of MRP include: Encouraging employees to participate in medical surveillance and allowing for transfer when an employee is unable to wear a respirator (*e.g.*, cadmium, asbestos, cotton dust); they further indicated that MRP is appropriate for the respirable crystalline silica rule because it can be applied when employees are referred to a specialist (*e.g.*, benzene) and it is not limited to

permanent conditions in other OSHA standards. AFL–CIO further commented that MRP gives employers time to find other positions involving lower exposures for at-risk workers, and indicated that it is widely supported by physicians (Document ID 3541, pp. 16–17; 4204, pp. 94–97). Physicians representing employee health advocate or public health groups testified or commented that removal from exposure can prevent or slow progression of silicosis or benefit employees during short-term periods of COPD exacerbation, which can be further exacerbated with continued exposure to respirable crystalline silica (Document ID 2244, p. 4; 3577, Tr. 830–832; 3541, p. 16).

OSHA did not propose MRP for respirable crystalline silica because the adverse health effects associated with respirable crystalline silica exposure (*e.g.*, silicosis) are chronic conditions that are not remedied by temporary removal from exposure. In contrast, removal under the cadmium standard (29 CFR 1910.1027) could allow for biological monitoring results to return to acceptable levels or for improvement in the employee's health. The evidence submitted during the rulemaking has led OSHA to conclude that its preliminary reasoning was correct and that for the reasons discussed below, there will be few instances where temporary removal from respirable crystalline silica exposures would improve employee health.

OSHA has declined to adopt MRP provisions in other health standards under similar circumstances. For example, in its chromium (VI) standard, OSHA did not include an MRP provision because chromium (VI)-related health effects are either chronic conditions that will not be improved by temporary removal from exposure (*e.g.*, lung cancer, respiratory or dermal sensitization), or they are conditions that can be addressed through proper application of control measures (*e.g.*, irritant dermatitis) (71 FR at 10366). OSHA did not include MRP provisions in the ethylene oxide (EtO) standard, concluding that,

> . . . the effects of exposure to EtO are not highly reversible, as evidenced by the persistence of chromosomal aberrations after the cessation of exposure, and the record contains insufficient evidence to indicate that temporary removal would provide long-term employee health benefits (49 FR 29734, 25788 (6/22/1984)).

Similarly, the 1,3-butadiene standard, which primarily addresses irreversible effects, such as cancer, does not include MRP provisions (61 FR 56746 (11/4/96)).

OSHA recognizes that some employees might benefit from removal from respirable crystalline silica exposure to possibly prevent further progression of disease. However, the health effects evidence suggests that crystalline silica-related diseases are permanent (Document ID 2177, Attachment B, p. 39). Thus, to be beneficial, any such removals would have to be permanent, not temporary. Even in cases where employees might benefit from temporary removal, such as to alleviate exacerbation of COPD symptoms, COPD itself is not reversible. In response to commenters indicating that temporary removal might alleviate COPD symptoms, OSHA anticipates that periods of exacerbation will continue to recur absent permanent removal from respirable crystalline silica exposure. OSHA views MRP as a tool for dealing with temporary removals only, as reflected in the Agency's decisions not to adopt MRP in the chromium (VI), ethylene oxide, and 1,3-butadiene standards. Workers' compensation is the appropriate remedy when permanent removal from exposure is required.

When the D.C. Circuit Court reviewed OSHA's initial decision not to include MRP in its formaldehyde standard, it remanded the case for OSHA to consider the appropriateness of MRP for permanently removed employees (*see UAW v. Pendergrass*, 878 F.2d 389, 400 (D.C. Cir. 1989)). OSHA ultimately decided to adopt an MRP provision for formaldehyde. However, as discussed below, the Agency did not rely on a need to protect employees permanently unable to return to their jobs. Indeed, OSHA expressly rejected that rationale for MRP, noting that ''[t]he MRP provisions [were] not designed to cover employees . . . determined to be permanently sensitized to formaldehyde'' (57 FR 22290, 22295 (5/27/92)). An important objective of MRP is to prevent permanent health effects from developing by facilitating employee removal from exposure at a point when the effects are reversible, and that objective cannot be met where the effects are already permanent.

Given that MRP benefits apply only to a temporary period, it is logical that eligibility be limited to employees with a temporary need for removal, as has been done in a number of standards, such as cadmium (1910.1027(l)(12)), benzene (1910.1028(i)(9)) and methylene chloride (1910.1052(j)(12)). Temporary wage and benefit protections may address the concerns of employees who fear temporary removal, but employees who fear permanent removal are unlikely to be persuaded by a few months of protection. The evidence in the record does not demonstrate that affected employees are unlikely to participate in medical surveillance absent wage and benefit protection. In contrast, extensive evidence in the record demonstrates that lack of confidentiality regarding medical findings would more likely lead to employees refusing medical examinations (*e.g.*, Document ID 3577, Tr. 819–820; 3579, Tr. 169; 3581, Tr. 1657; 3585, Tr. 3053–3054); OSHA has remedied that situation by strengthening confidentially requirements for medical examinations.

A major reason for inclusion of MRP in the formaldehyde standard is that medical surveillance depends on employee actions. The formaldehyde standard does not have a medical examination trigger, such as an action level, but instead relies on annual medical questionnaires and employee reports of signs and symptoms. Thus, the approach is completely dependent on employee cooperation (57 FR at 22293). Unlike the formaldehyde standard, respirable crystalline silica medical surveillance programs for the general industry/maritime and construction standards are not entirely dependent on employee reports of signs and symptoms. The respirable crystalline silica standard for general industry and maritime requires that regular medical examinations be offered to employees exposed at or above the action level for 30 or more days per year, and the construction standard requires that medical examinations be offered to employees required to wear a respirator for 30 or more days a year. Both standards mandate that those examinations include a physical examination, chest X-ray, and spirometry testing. Independent of any subjective symptoms that may or may not be reported by the employee, PLHCPs conducting these examinations can make necessary medical findings based on objective findings from the physical examination, X-ray, and spirometry tests.

Lead is another example of a standard in which medical surveillance findings may be influenced by employee actions. In the lead standard, OSHA adopted an MRP provision in part due to evidence that employees were using chelating agents to achieve a rapid, short-term reduction in blood lead levels because they were desperate to avoid economic loss, despite the possible hazard to their health from the use of chelating agents. In the case of the lead standard, successful periodic monitoring of blood lead levels depends on employees not attempting to alter their blood lead levels (43 FR 54354, 54446 (11/21/78)).

Unlike the lead standard, in which blood lead levels are reported to employers, the respirable crystalline silica rule has privacy protections that do not allow information other than limitations on respirator use to be communicated to the employer, in the absence of employee authorization. With the privacy protections, it is unlikely that employees will try and take actions to sabotage medical findings.

Other reasons OSHA has cited for needing to include MRP in its health standards are similarly inapplicable to respirable crystalline silica. In lead, for example, OSHA explained that the new blood lead level removal criteria for the lead standard were much more stringent than criteria being used by industry at that time. Therefore, many more temporary removals would be expected under the new standard, thereby increasing the utility of MRP (43 FR at 54445–54446). There are no criteria in this new rule that are likely to increase the number of medical removals that may be occurring.

OSHA adopted MRP in the lead standard because it ''. . . anticipate[d] that MRP w[ould] hasten the pace by which employers compl[ied] with the new lead standard'' (43 FR at 54450). OSHA reasoned that the greater the degree of noncompliance, the more employees would suffer health effects necessitating temporary medical removal and the more MRP costs the employer would be forced to incur. OSHA thought that MRP would serve as an economic stimulus for employers to protect employees by complying with the standard. With respect to respirable crystalline silica, its disease outcomes (*e.g.*, silicosis, COPD, lung cancer) generally take years to develop. Because of the latency period of most respirable crystalline silica-related diseases, the costs of MRP would not serve as a financial incentive for employers to comply with the requirements of the respirable crystalline silica rule. For example, most current high exposures would not result in adverse health effects until years later and most health effects requiring medical removal likely resulted from exposures that occurred years earlier, and in some cases, before the eligible employee worked for the current employer.

In addition, although OSHA required medical removal in the benzene standard after referral to a specialist (1910.1028(i)(8)(i)), the circumstances there are also distinguishable from respirable crystalline silica. MRP was required in the benzene standard because some benzene-related blood abnormalities could rapidly progress to serious and potentially life threatening disease, and continued benzene exposure could affect progression (52 FR at 34555). With the exception of acute silicosis, which is rare, silica-related diseases progress slowly over a span of years. Thus, in most cases, there is no urgent need for removal from respirable crystalline silica exposure while awaiting a specialist determination.

OSHA also notes that there are three health standards that provide limited MRP under their requirements for respiratory protection. They are asbestos, (1910.1001(g)(2)(iii)), cotton dust (1910.1043(f)(2)(ii)), and cadmium (29 CFR 1910.1027(l)(ii)). These standards require MRP when a medical determination is made that an employee who is required to wear a respirator is not medically able to wear the respirator and must be transferred to a position with exposures below the PEL, where respiratory protection is not required. OSHA has determined that such a provision is unnecessary for the respirable crystalline silica rule because OSHA has since revised its respiratory protection standard to specifically deal with the problem of employees who are medically unable to wear negative pressure respirators by requiring the employer to provide a powered air-purifying respirator (29 CFR 1910.134(e)(6)). Such an approach has been used by employers who are unable to move employees to jobs with lower exposure (Document ID 3577, p. 610). In this rule, OSHA requires employers to comply with 29 CFR 1910.134, including medical evaluations mandated under that standard.

In summary, OSHA finds MRP to be neither reasonably necessary nor appropriate for the respirable crystalline silica rule. In other health standards, OSHA has stated that the purpose of MRP is to encourage employees to participate in medical surveillance by assuring them that they will not suffer wage or benefit loss if they are temporarily removed from further exposure as a result of findings made in the course of medical surveillance. OSHA's primary reason for not including MRP in the respirable crystalline silica rule is that the Agency does not expect a significant number of employees to benefit from temporary removal from their jobs as a result of medical surveillance findings. In addition, the medical surveillance program in the respirable crystalline silica rule is less dependent on employee action that could influence medical surveillance findings than the programs in some other health standards that include MRP, such as lead and formaldehyde. Other considerations that have led OSHA to use MRP in the past are also not applicable in the context of respirable crystalline silica. OSHA expects that respirable crystalline silica-related health effects would result in very few temporary medical removals, and the evidence demonstrates that any removals that would occur would likely need to be permanent. OSHA concludes that the evidence in the record, relevant court decisions, and the criteria OSHA has previously applied to determine necessity for MRP do not support a finding that MRP is reasonably necessary or appropriate for the respirable crystalline silica rule.

Requests for anti-discrimination/retaliation clause. Labor groups and other employee health advocates requested that OSHA add a clause to prohibit employers from retaliating or discriminating against employees for participating in medical surveillance or because of the findings of medical surveillance (*e.g.*, Document ID 2176, p. 2; 2282, Attachment 3, p. 21; 2336, p. 12; 3577, Tr. 879; 3589, Tr. 4207; 4204, p. 90; 4219, pp. 33–36; 4223, p. 139). USW, BAC, and BCTD also requested that the anti-retaliation or anti-discrimination provisions address OSHA activities beyond medical surveillance (*e.g.*, reporting unsafe working conditions), and in addition, BAC requested formal procedures for filing a complaint (Document ID 3584, Tr. 2548; 4219, pp. 33–38; 4223, p. 139). Employees, unions, and employee health advocates reported instances where employees were afraid to ask for protections or file complaints; some reported employer threats or retribution in response to such actions (*e.g.*, Document ID 2124; 2173, p. 3; 3571, Attachment 3, p. 2, Attachment 4, p. 3; 3577, Tr. 816–817; 3581, Tr. 1787, 1796; 3583, Tr. 2464; 3584, Tr. 2567–2568; 3585, Tr. 3101; 3586, Tr. 3168).

To address the possibility that some employees may decline to participate in medical surveillance because of fear of retaliation or discrimination, NISA suggested that OSHA require employee participation in medical surveillance, as well as include a prohibition on discrimination in the rule or clarify that Section 11(c) of the OSH Act applies to discrimination based on medical surveillance findings. NISA requested that OSHA at least confirm that employers are free to require medical surveillance as a condition of employment (Document ID 4208, pp. 15–18).

As indicated in the NISA comments, Section 11(c) of the OSH Act prohibits discharge or discrimination against any

employee for exercising any right afforded by the Act (29 U.S.C. (660(c)(1)). OSHA observes that these rights include filing an OSHA complaint, participating in an inspection or talking to an inspector, seeking access to employer exposure and injury records, reporting an injury, and raising a safety or health complaint with the employer. Medical surveillance and the other requirements provided under the respirable crystalline silica rule are also rights afforded under the Act. Therefore, an employer may not discharge or otherwise discriminate against any employee because the employee participates in medical surveillance offered under the rule. This includes discharge or discrimination based on medical findings for an employee who is able to perform the essential functions of the job.

Although acknowledging that the 11(c) protections are important because they establish that employees cannot be discriminated against for exercising their rights under the Act, Peg Seminario, on behalf of the AFL–CIO, stated that the enforcement mechanisms are very weak. Ms. Seminario pointed to the lack of an administrative process through the Review Commission, such as exists for compliance violations under standards, and she also stated that very few 11(c) cases are moved forward. In addition, Ms. Seminario testified that 11(c) deals with individual cases but does not address broad practices (Document ID 3578, Tr. 981–982). BCTD pointed to testimony given by Professor Emily Spieler before a Senate Subcommittee on Employment and Workplace Safety that described weaknesses of 11(c) and gave recommendations for improving it (Document ID 4072, Attachment 27; 4223, p. 138). BCTD concluded that an anti-discrimination/retaliation provision might provide employees with ''an alternative, and potentially quicker, mechanism for gaining the Act's protections'' (Document ID 4223, p. 139).

OSHA recognizes that Section 11(c) of the Act has been an imperfect avenue for preventing retaliation and addressing employee complaints of discharge or discrimination for exercising rights afforded by the Act. For this reason, separate from this rulemaking, OSHA has made considerable efforts in recent years to enhance the effectiveness of its Section 11(c) program to protect employees from retaliation for exercising their rights under the OSH Act and other anti-retaliation statutes enforced by OSHA. These efforts include administrative restructuring to create a separate Directorate of Whistleblower Protection Programs as one of eight Directorates in OSHA; adding additional investigators; and providing additional training for investigators and Labor Department solicitors who work on whistleblower cases. The Agency's Whistleblower Investigations Manual updated procedures and provided further guidance to help ensure consistency and quality of investigations (*see https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-03-005.pdf*), and OSHA's memo to whistleblower enforcement staff on Employer Safety Incentive and Disincentive Policies and Practices, clarified that employer policies that discourage reporting of injuries and illnesses constitute violations of section 11(c) (*see https://www.osha.gov/as/opa/whistleblowermemo.html*). In addition, the Department of Labor has established a Whistleblower Protection Advisory Committee to advise, consult with, and make recommendations to the Secretary of Labor and the Assistant Secretary of Labor for Occupational Safety and Health on ways to improve the fairness, efficiency, effectiveness, and transparency of OSHA's administration of whistleblower protections (77 FR 29368 (5/17/12)). OSHA concludes that the Agency's limited resources will be best utilized by continuing to focus on strengthening enforcement of Section 11(c), rather than creating, on an ad hoc basis, a separate and alternative enforcement mechanism in the respirable crystalline silica rule. OSHA emphasizes that, in response to commenters' concerns about privacy and the possibility for retaliation based on employers' knowledge of employee medical information, it has made changes to the medical surveillance disclosure requirements of the rule, discussed above, in order to both encourage participation in medical surveillance and discourage discriminatory or retaliatory actions. Retaliation based on other activities, such as reporting injuries and illnesses or noting the failure of engineering controls, is not unique to the silica rule and thus does not, in OSHA's judgment, warrant a silica-specific response.

In response to the suggestion that OSHA prohibit employees from opting out of medical surveillance, OSHA observes that Section (6)(c)(7) of the OSH Act specifies that medical examinations or other tests ''be made available,'' not that they be required. OSHA considers the medical surveillance offered under the rule to offer important protections for employees, and the Agency encourages all eligible employees to take advantage of these protections. However, the Agency recognizes that employees may choose not to take advantage of medical surveillance for a variety of reasons. OSHA does not find it appropriate to require all eligible employees to receive medical surveillance simply to preclude the possibility that an employer might discriminate against those who receive medical surveillance. The Agency also notes that Section 20(a)(5) of the OSH Act generally precludes OSHA from requiring medical surveillance for those who object on religious grounds. At the same time, nothing in the rule precludes an employer from requiring participation in medical surveillance programs as appropriate under applicable laws and/or labor-management contracts.

ASTM standards. Most medical surveillance requirements in the respirable crystalline silica rule are generally consistent with ASTM standards for addressing control of occupational exposure to respirable crystalline silica (Section 4.6 and 4.7 in both E 1132–06 and E 2625–09) (Document ID 1466, p. 5; 1504, p. 5). Commenters noted differences between the ASTM standards and the respirable crystalline silica rule (*i.e.,* 120- versus 30-day exposure duration trigger, optional versus mandatory spirometry testing, and referrals based on a 1/1 versus 1/0 category X-ray). As explained above, the requirements of the rule better protect employees and therefore better effectuate the purposes of the OSH Act than the ASTM standards. There are additional differences between the ASTM standards and the rule, which are discussed briefly below.

The ASTM standards require that medical surveillance be triggered by the PEL or other occupational exposure limit, but for the general industry and maritime standard, OSHA is triggering medical surveillance at the action level because of remaining significant risk, exposure variability, and increased sensitivity of some employees. The ASTM standards recommend medical examinations before placement but OSHA allows the examinations to be conducted within 30 days to offer more flexibility.

The ASTM standards recommend tuberculosis testing for employees with radiographic evidence of silicosis, but the rule requires tuberculosis testing in the initial examination for all employees who qualify for medical surveillance. OSHA's requirement is based on evidence that exposure to respirable crystalline silica increases the risk for a latent tuberculosis infection becoming active, even in the absence of silicosis. The ASTM standards do not specifically

mention a specialist, but the requirement for specialist referral in the respirable crystalline silica rule is conceptually consistent with the provision in the ASTM standards for counseling (by a physician or other person qualified in occupational safety and health) regarding work practices and personal habits that could affect employees' respiratory health.

Lastly, the E 1132–06 standard allows the health provider to report information to the employer, such as if the employee has a condition that might put him or her at risk for health impairment or if limitations on respirator use are related to medical or emotional reasons. Under the rule for respirable crystalline silica, medical findings are withheld from the employer and only reported to the employee because of privacy concerns and discrimination/retaliation fears that might prevent participation in medical surveillance. Both ASTM standards require the employer to follow the physician's placement or job assignment recommendations; the OSHA rule differs from the ASTM standards in this respect by allowing employees to make their own placement decisions if they are able to do the work.

Communication of Respirable Crystalline Silica Hazards to Employees

Paragraph (j) of the standard for general industry and maritime (paragraph (i) of the standard for construction) sets forth requirements intended to ensure that the dangers of respirable crystalline silica exposure are communicated to employees. Employees need to know about the hazards to which they are exposed, along with associated protective measures, in order to understand how they can minimize potential health hazards. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and in safety data sheets (SDSs). These written forms of communication will be effective and relevant only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects. Numerous commenters, including industry stakeholders and dozens of construction employees and concerned individuals, generally supported inclusion of a hazard communication requirement in the rule (*e.g.*, Document ID 2039; 2113; 2116, Attachment 1, p. 45; 2302, p. 1; 2315, p. 4; 2345, p. 3; 3302, p. 1; 3295; 4217, p. 25).

Paragraph (j)(1) of the standard for general industry and maritime (paragraph (i)(1) of the standard for construction) requires the employer to (1) include respirable crystalline silica in the program established to comply with the hazard communication standard (HCS) (29 CFR 1910.1200); (2) ensure that each employee has access to labels on containers of crystalline silica and SDSs, and is trained in accordance with the provisions of the HCS and the provisions on employee information and training (contained in paragraph (j)(3) of the standard for general industry and maritime, paragraph (i)(2) of the standard for construction), and (3) ensure that at least the following hazards are addressed: Cancer, lung effects, immune system effects, and kidney effects. These requirements remain unchanged from the proposed rule, after OSHA considered comments addressing these requirements (discussed below).

The approach in paragraph (j)(1) of the standard for general industry and maritime (paragraph (i)(1) of the standard for construction) is consistent with other OSHA substance-specific health standards, which were revised as part of the 2012 update of the HCS to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The 2012 update of the substance-specific standards involved revising the hazard communication requirements to refer to the HCS requirements for labels, SDSs, and training, and to identify the hazards that need to be addressed in the employer's hazard communication program for each substance-specific standard. In applying the approach described in paragraph (j)(1) of the standard for general industry and maritime (paragraph (i)(1) of the standard for construction), OSHA intends for the hazard communication requirements in the respirable crystalline silica rule to be substantively as consistent as possible with the HCS, while including additional specific requirements needed to protect employees exposed to respirable crystalline silica. A goal of this approach is to avoid a duplicative administrative burden on employers who must comply with both the HCS and this rule.

Some stakeholders agreed with OSHA that additional hazard communication provisions are needed in this rule. For example, the National Industrial Sand Association (NISA) generally agreed with OSHA's approach for communication of hazards to employees and indicated that the generic training elements of the HCS alone are insufficient (Document ID 2195, p. 45). In addition, labor unions such as the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), International Union of Operating Engineers (IUOE), American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), International Union of Bricklayers and Allied Craftworkers (BAC), and Building and Construction Trades Department, AFL–CIO (BCTD) generally agreed that employees exposed to respirable crystalline silica need additional information and training (Document ID 2282, Attachment 3, p. 24; 3583, Tr. 2367; 4204, p. 98; 4219, p. 22; 4223, p. 114).

However, other stakeholders expressed the view that OSHA's existing HCS requirements are sufficient, and that hazard communication provisions in this rule are not warranted. For example, the National Stone, Sand, and Gravel Association (NSSGA) asserted that requiring information and training under the respirable crystalline silica rule would be duplicative and unnecessary because OSHA's existing HCS adequately addresses communication of hazards and training of employees (Document ID 2327, Attachment 1, p. 11). The Portland Cement Association and National Association of Home Builders (NAHB) expressed similar views (Document ID 2284, p. 6; 2296, p. 44).

OSHA understands that the HCS already addresses communication of hazards but, after reviewing rulemaking record comments, reaffirms that employees exposed to respirable crystalline silica need additional training and information. Therefore, OSHA has decided to include in the rule the approach set forth in the proposed rule. The rule thus requires compliance with the HCS and the additional requirements that address aspects of employee protection that are not specified in the HCS but are relevant to these standards; examples of these provisions include health hazards specific to respirable crystalline silica, signs at entrances to regulated areas, training on medical surveillance, and training on engineering controls. Specific comments on these requirements and OSHA's rationale for their inclusion in the rule are discussed below. OSHA expects this approach will reduce the administrative burden on employers who must comply with both the HCS and this rule, while providing employees with adequate information and effective training on respirable crystalline silica hazards.

Which hazards should be addressed in employers' HCS programs was a

matter of debate among commenters. For example, the American Coatings Association (ACA) asserted that OSHA's listing of health effects associated with crystalline silica was contrary to the revised HCS, which ACA argued allows qualified health professionals to established hazard classifications based on actual data (Document ID 2239, p. 2). Associated Builders and Contractors, Inc. and the Construction Industry Safety Coalition (CISC) did not support the inclusion of cancer, immune system effects, and kidney effects on the list of hazards to be addressed, asserting that OSHA did not meet its burden of showing a link between these diseases and exposure to crystalline silica (Document ID 2289, p. 8; 2319, p. 120).

OSHA does not find these arguments persuasive. As discussed in Section V, Health Effects, OSHA evaluated the best available published, peer-reviewed literature on respirable crystalline silica and considered comments from stakeholders to determine that exposure to respirable crystalline silica is associated with silicosis and other non-malignant respiratory disease, lung cancer, immune system effects, and kidney effects. Inclusion of a minimum list of health effects to address as part of hazard communication, based primarily on information from OSHA's rulemakings, is consistent with the 2012 revision of all substance-specific standards (77 FR 17574, 17749–17751, 17778–17785 (3/26/2012)). Therefore, the Agency concludes that including a list of hazards to be addressed, and the specific hazards listed, are appropriate.

Commenters such as the United Steelworkers (USW) and the American Federation of State, County, and Municipal Employees (AFSCME) requested that the rule require training on tuberculosis (Document ID 2336, pp. 14–15; 4203, p. 7). OSHA did not specifically list tuberculosis as a health hazard to be addressed because initial tuberculosis infection is not related to respirable crystalline silica exposure. In addition, the HCS describes health hazards in terms of target organs affected, such as lungs, or specific endpoints, such as carcinogenicity. Tuberculosis is not an endpoint listed in the HCS; thus, listing it in this rule would be inconsistent with the HCS. Consequently, OSHA has decided not to add tuberculosis to the list of hazards that must be addressed. However, because respirable crystalline silica exposure increases the risk of a latent tuberculosis infection becoming active, OSHA encourages employers to address tuberculosis as part of their hazard communication program.

Paragraph (j)(2) of the standard for general industry and maritime requires employers to post signs at all entrances to regulated areas. Although OSHA proposed a requirement for demarcating regulated areas, the Agency did not propose a requirement for warning signs at entrances to regulated areas, and instead noted that the areas could be effectively demarcated by signs, barricades, lines, or textured flooring (78 FR at 56273, 56450 (9/12/13)). The AFL–CIO argued that warning signs are an important method of making employees aware of potential hazards and noted that warning signs are required at entrances to regulated areas by many OSHA standards (Document ID 4204, pp. 100–101). A number of commenters, including the Communication Workers of America (CWA), Upstate Medical University, the American Public Health Association (APHA), UAW, and HalenHardy, agreed that warning signs must be required at regulated areas (*e.g.*, Document ID 2240, p. 4; 2244, p. 4; 2178, Attachment 1, p. 2; 2282, Attachment 3, p. 25; 4030, Exhibit A, pp. 5–6). Similarly, USW commented on the need for warning signs in areas with potential respirable crystalline silica exposure (Document ID 2336, p. 14). Charles Gordon, a retired occupational safety and health attorney, argued that the absence of a requirement for warning signs was inconsistent with Section 6(b)(7) of the Occupational Safety and Health (OSH) Act, which requires labels or other warnings to inform employees of hazards (Document ID 3588, Tr. 3797). Evidence in the rulemaking record indicates that inclusion of warning signs is also consistent with general industry practices. For example, a plan developed by the National Service, Transmission, Exploration, and Production Safety Network (STEPS Network) for the hydraulic fracturing industry recommends signs to warn of potential silica exposure and the requirement for respirator use near exposure zones (Document ID 4024, Attachment 2, p. 1).

OSHA finds these arguments persuasive and agrees that it is appropriate to require signs at entrances to regulated areas, which are required only in the general industry and maritime standard (*see* summary and explanation for *Regulated Areas*). Employees must recognize when they are entering a regulated area and understand the hazards associated with the area, as well as the need for respiratory protection. Signs are an effective means of accomplishing these objectives. Therefore, paragraph (j)(2) of the standard for general industry and maritime requires that regulated areas be posted with signs that bear the exact cautionary wording specified in the standard. The required legend, which begins with the word ''Danger'', warns that respirable crystalline silica is present and may cause cancer, states that it causes damage to lungs, states that respiratory protection is required, and indicates authorized personnel only are permitted to enter. The purpose of these signs is to minimize the number of employees in a regulated area by alerting them that they must be authorized by their employer to enter, and to ensure that employees take appropriate protective measures when entering. The signs will warn employees who may not know they are entering a regulated area or may not know of the hazards present in the area. They will supplement the training that employees are to receive under other provisions of paragraph (j) of the standard for general industry and maritime because even trained employees need to be reminded of the locations of regulated areas and of the necessary precautions they must take before entering these dangerous areas.

The required language for the signs is consistent with labeling requirements in Appendix C of the HCS, which specifies standardized language to communicate information to employees. The revised HCS requires the use of one of two signal words—''Danger'' or ''Warning''—on labels of hazardous chemicals. The word ''Danger'' is used for more severe hazard categories, such as carcinogens. OSHA is requiring the word ''Danger'' based on the evidence of lung toxicity and carcinogenicity of respirable crystalline silica. ''Danger'' is used to alert employees that they are in an area where the permissible exposure limit (PEL) is or can reasonably be expected to be exceeded and to emphasize the importance of the message that follows.

Charles Gordon requested that warning signs also warn about kidney hazards (Document ID 4236, p. 6). The hazard statements about cancer and lung damage required on signs are the minimum requirements and focus on the most prominent adverse health effects associated with respirable crystalline silica exposure. OSHA concludes that it is unnecessary to list every relevant hazard warning on signs at entrances to regulated areas because other sources of information, such as SDSs and training, will provide more comprehensive information to employees. In addition, addressing cancer and lung damage is conceptually consistent with specific wording

suggestions from APHA, National Consumers League, BCTD, HalenHardy, and AFL–CIO (Document ID 2178, Attachment 1, pp. 2–3; 2373, p. 2; 2371, Attachment 1, pp. 36–37; 4030, Exhibit D; 4204, p. 101). Including an abbreviated list of health hazards on signs is also consistent with other OSHA standards such as lead (29 CFR 1910.1025), benzene (29 CFR 1910.1028), and vinyl chloride (29 CFR 1910.1017). Therefore, OSHA has decided not to add a requirement to include warnings about kidney hazards on warning signs. Employers may choose to include a warning about kidney hazards on the signs required under this standard, provided that the additional information included is not confusing or misleading and does not detract from warnings required by the standard.

The warning sign must include notice about the need for respiratory protection in regulated areas required under the general industry and maritime standards. As explained in the summary and explanation of *Regulated Areas*, employers covered by the standard for general industry and maritime are required to provide each employee and his or her designated representative entering a regulated area with an appropriate respirator and require the employee and designated representative to use the respirator while in the regulated area. APHA, National Consumers League, and Charles Gordon requested that warning signs also indicate that protective clothing is required (Document ID 2178, Attachment 1, p. 3; 2373, p. 2; 4236, p. 6). As discussed in the summary and explanation of *Regulated Areas*, protective clothing is not required in this rule, and therefore no corresponding notice is required on signs.

Some labor unions that represent construction employees, such as BCTD, IUOE, and BAC, asked OSHA to include requirements for warning signs in the construction standard to warn employees about health hazards or requirements for control measures (*e.g.*, Document ID 2371, Attachment 1, pp. 36–37; 4025, Attachment 1, pp. 24–25; 4219, p. 27). Some employers, like construction company Miller and Long, Inc., opposed requiring barricades and signs at construction sites (*e.g.*, Document ID 3585, Tr. 2967).

As discussed in the summary and explanation of *Regulated Areas*, OSHA is not requiring regulated areas in the standard for construction because of the impracticality of establishing regulated areas in many construction settings. Employers using specified exposure control methods in Table 1 of paragraph (c) of the standard for construction are not required to conduct exposure assessments and therefore will not have the information necessary to establish the boundaries for the regulated area (*i.e.*, the point at which exposures would no longer exceed the PEL). Even though regulated areas with warning signs are not required for the construction standard, the employer may choose to include procedures for posting warning signs in its written exposure control plan as a method to restrict access to work areas, when necessary, to limit the numbers of employees exposed to respirable crystalline silica and the levels to which they are exposed, including exposures generated by other employers or sole proprietors (paragraph (g)(1)(iv) of the standard for construction). Because of the unique and often-changing work areas at construction sites, OSHA concludes that a universal requirement for regulated areas with signs is unwarranted, and the construction employer is in the best position to determine when warning signs should be posted.

IUOE requested a requirement to affix warning labels listing the health hazards of respirable crystalline silica on enclosed cabs to remind operators not to work with windows open (Document ID 2262, pp. 34–35). Where enclosed cabs are used to limit exposures to respirable crystalline silica, the employer must ensure that these controls are properly implemented (paragraph (c)(1) of the standard for construction) and that employees can demonstrate knowledge of the controls (paragraph (i)(2)(i)(C) of the standard for construction). Therefore, OSHA concludes that a general requirement to affix warning labels to cabs is unwarranted and construction employers are in the best position to determine if there is a need for warning labels in their workplaces as a reminder to properly implement controls. As a result, OSHA has not included such a requirement in the standard.

Proposed paragraph (i)(2)(i) included the requirements related to employee information and training. The proposed rule called for the employer to ensure that each ''affected employee'' can demonstrate knowledge of the specified training elements discussed below. OSHA defined ''affected employee'' as any employee who may be exposed to respirable crystalline silica under normal conditions of use or in a foreseeable emergency. OSHA received several comments related to a trigger for training requirements. For example, the American Iron and Steel Institute (AISI) commented that the terms ''each employee'' and ''each affected employee'' were used interchangeably in the proposed rule and that OSHA needed to clarify which employees needed to receive training; both Newport News Shipbuilding and AISI commented that training should be limited to those employees who could foreseeably be exposed above the PEL (Document ID 2144, p. 2; 3492, p. 3). Southern Company was concerned that training would be required for all employees potentially exposed to silica, and although disagreeing with an action level of 25 micrograms per cubic meter of air ($\mu g/m^3$), requested an action level-based trigger for training (Document ID 2185, p. 5). In contrast, CISC supported training for all employees potentially exposed to respirable crystalline at a construction site (Document ID 4217, p. 25). A number of other employers and industry representatives expressed views on exposure levels that should trigger training, such as action levels or PELs (*e.g.,* Document ID 2196, Attachment 1, p. 11; 2279, p. 9; 2301, Attachment 1, p. 4; 2357, pp. 31–32; 2379, Appendix 1, p. 54). BCTD requested that, in addition to employees performing work covered by this section, OSHA require training for supervisors and on-site managers who are responsible for, or who supervise, employees who perform work covered by the standard (Document ID 4223, p. 117).

OSHA has clarified the trigger for training requirements in the rule by aligning these requirements with the scope of the rule. Paragraph (j)(3)(i) of the standard for general industry and maritime (paragraph (i)(2)(i) of the standard for construction) requires training for each employee covered by the rule. Consistent with the scope provision in paragraph (a)(2) of the standard for general industry and maritime, training is required for each employee, unless the employer has objective data demonstrating that exposures will remain below 25 $\mu g/m^3$ as an 8-hour time-weighted average under any foreseeable conditions. Consistent with the scope provision in paragraph (a) of the standard for construction, training is required for all employees who are or could foreseeably be exposed to respirable crystalline silica at or above the action level of 25 $\mu g/m^3$ as an 8-hour time-weighted average. Therefore, actual or foreseeable exposure at or above the action level is used to determine which employees are covered by the rule, and covered employers are required to provide training for any employee covered by

the rule. OSHA concludes that it is appropriate to train employees covered by the rule because they will benefit from receiving information such as the role of controls in reducing exposures and illnesses associated with respirable crystalline silica.

Stakeholders also offered comments on the proposed requirement that employers ensure that affected employees can ''demonstrate knowledge'' of the training subjects in proposed paragraphs (i)(2)(i)(A)–(D). The proposed rule did not specify precisely how training should be accomplished. Instead, it defined the hazard communication requirements in terms of objectives meant to ensure that employees are made aware of the hazards associated with respirable crystalline silica in their workplace and how they can help to protect themselves. The proposed rule's performance-oriented approach was consistent with the HCS and many of OSHA's substance-specific standards.

Some stakeholders commented on OSHA's performance-based approach to training. For example, Diane Matthew Brown, Health and Safety Specialist from AFSCME, testified that training should be as interactive as possible to allow for different learning styles (Document ID 3585, Tr. 3115). CISC supported the performance-oriented approach to training but also stated it would support a requirement that employees be able to ask questions during training (Document ID 4217). IUOE recommended interactive training so that employees could have their questions answered during the training (Document ID 3583, Tr. 2369). Although agreeing with the importance of a knowledgeable person to answer trainee questions, Ameren Corporation considered it burdensome to have someone immediately available to answer questions (Document ID 2315, p. 4). The Laborers' Health and Safety Fund of North America (LHSFNA) indicated that hands-on training is the best approach to training an employee who performs tasks that generate dust in the proper operation of a tool and associated engineering controls (Document ID 3589, Tr. 4220–4221).

After considering the comments on this issue, OSHA has decided that the training requirements under the respirable crystalline silica rule, like those in the HCS, are best accomplished when they are performance-oriented. OSHA concludes that the employer is in the best position to determine how the training can most effectively be accomplished. Hands-on training, videotapes, slide presentations, classroom instruction, informal discussions during safety meetings, written materials, or any combination of these methods may be appropriate. However, to ensure that employees comprehend the material presented during training, it is critical that trainees have the opportunity to ask questions and receive answers if they do not fully understand the material that is presented to them. OSHA reiterates that when videotape presentations or computer-based programs are used, this requirement may be met by having a qualified trainer available to address questions after the presentation, or providing a telephone hotline so that trainees will have direct access to a qualified trainer. Although it is important that employees be able to ask questions, OSHA finds that the employer is in the best position to determine whether an instructor must be available for questions during training or if a trainer can answer questions after the training session. Such performance-oriented requirements are intended to encourage employers to tailor training to the needs of their workplaces, thereby resulting in the most effective training program for each workplace.

In addition to asking about how training should be accomplished, stakeholders posed questions about how employers can determine that they have fulfilled the training requirements. For example, the American Foundry Society stated that the term ''demonstrate knowledge'' is vague and requested that the rule include language to specify when a training requirement is met (Document ID 2379, Appendix 1, p. 72). OSHA concludes that employers can determine whether employees have the requisite knowledge through methods such as discussion of the required training subjects, written tests, or oral quizzes. Retired industrial hygienist Bill Kojola, testifying on behalf of the National Council for Occupational Safety and Health (NCOSH), suggested that compliance officers could question employees to determine if they know about medical surveillance and work practices or engineering controls to reduce exposures (Document ID 3586, Tr. 3259). Similarly, UAW coordinator, Andrew Comai, and a private citizen, Cara Ivens, opined that compliance officers could ask employees if they are aware that they are working with hazardous chemicals or know about the health effects of respirable crystalline silica (Document ID 1801, p. 4; 3582, Tr. 1869). OSHA concludes that employers can similarly assess their employees' knowledge and understanding of training topics.

The proposed rule did not include a provision that required training to be conducted in a language and manner that the employee understands. A number of labor unions and employee advocate groups requested that the rule include a requirement for training to be conducted in a language and manner that employees understand (*e.g.*, Document ID 2240, p. 4; 2282, Attachment 3, p. 25; 3585, Tr. 3115; 3955, Attachment 2, p. 2; 3583, Tr. 2451; 4204, p. 99; 4025, Attachment 1, p. 2; 4219, p. 24).

OSHA agrees. Paragraph (j)(3)(i) of the standard for general industry and maritime (paragraph (i)(2)(i) of the standard for construction) requires the employer to ensure that each employee covered by the standard demonstrates knowledge and understanding of the required training subjects. The requirement for employers to ensure that the employee demonstrates knowledge in the training subjects obligates the employer to provide training in a language and manner that the employee understands. The employee must understand training in order to demonstrate knowledge of the specified training elements. To clarify this requirement, OSHA has revised the proposed text to require the employer to ensure that employees demonstrate understanding, in addition to knowledge. This requirement is consistent with Assistant Secretary David Michaels' memorandum to OSHA Regional Administrators (Document ID 1499). The memorandum explains that because employees have varying educational levels, literacy, and language skills, training must be presented in a language, or languages, and at a level of understanding that accounts for these differences in order to ensure that employees understand the training. As stated by Assistant Secretary Michaels:

> . . . an employer must instruct its employees using both a language and vocabulary that the employees can understand. For example, if an employee does not speak or comprehend English, instruction must be provided in a language that the employee can understand. Similarly, if the employee's vocabulary is limited, the training must account for that limitation. By the same token, if employees are not literate, telling them to read training materials will not satisfy the employer's training obligation (Document ID 1499, p. 2).

This may mean, for example, providing materials, instruction, or assistance in Spanish rather than English if the employees being trained are Spanish-speaking and do not understand English. However, the employer is not required to provide

training in the employee's preferred language if the employee understands the language used for training.

Proposed paragraphs (i)(2)(i)(A)–(D) specified the contents of training for affected employees. The proposed list included training on operations that could result in exposures and methods for protecting employees from exposure, the contents of the respirable crystalline silica rule, and the purpose and a description of the employer's medical surveillance program. The proposed rule did not contain a provision requiring training on health effects. However, under the HCS, employers would have to train employees on the health hazards associated with chemicals in the work area (29 CFR 1910.1200(h)(3)(ii)). In addition, the preamble to the proposed rule mentioned that training on medical surveillance under proposed paragraph (i)(2)(i)(D) should cover the signs and symptoms of respirable crystalline silica-related health effects (78 FR at 56474).

OSHA asked for comments on the scope and depth of the proposed training requirements and whether additional training provisions needed to be added (78 FR at 56291). Stakeholders offered a number of comments on these proposed provisions. For example, concerned individuals, a medical school, and labor unions requested that training address the health effects associated with respirable crystalline silica exposure (*e.g.*, Document ID 1771, p. 1; 2188; 3479, p. 1; 4025, Attachment 1, p. 2; 4203, p. 7). Training on health hazards of respirable crystalline silica is consistent with stakeholder practices. For example, health hazards are addressed in training plans or modules by the National Precast Concrete Association, IUOE, and the STEPS Network (*e.g.*, Document ID 2067, pp. 2–3; 3583, Tr. 2414; 4024, Attachment 2, p. 1).

Several commenters stated that employees would not ask for or use appropriate protection without knowledge of health hazards (*e.g.,* Document ID 2166, p. 3; 3571, Attachment 1, pp. 2–3, 3585, Tr. 2976). For example, in discussing her experience with overhead drilling of concrete, Sandra Darling-Roberts commented:

> I had a dust mask and a pair of safety glasses for my protection. . . . We were not offered better personal protection gear and did not request any as we were not made aware of the risks of silica exposure (Document ID 1758).

Operating engineer Keith Murphy, representing IUOE, testified that employees will wear respirators if informed that they are exposed to dangerous concentrations of respirable crystalline silica (Document ID 3583, Tr. 2375–2376). In testifying about her experiences in training construction employees, Marién Casillas Pabellón, Director of New Labor, stated:

> [Seventy percent] of these workers were not able to say what silica was or if they were . . . exposed to it. When they learned about the long term effects to their health many were alarmed. Training has been key in getting workers to demand . . . the right equipment and tools to complete their task safely. Always after trainings we follow up with the participants to measure the impact of the trainings. [Fifty-five percent] of the workers that received training around these issues expressed that they have demanded personal protective equipment and other tools to do their work safely after the training (Document ID 3571, Attachment 6, p. 2).

In addition, several employees indicated that neither they nor their coworkers had received adequate or even any training on silica's health effects (*e.g.*, Document ID 3582, Tr. 1892–1893; 3589, Tr. 4299–4300; 4032, Attachment 1, p. 1; 3477, p. 1).

Based on the evidence showing the need for and positive impact of health hazard training and to ensure that covered employees receive that training, OSHA is requiring training on health hazards specifically associated with respirable crystalline silica. The requirement is contained in paragraph (j)(3)(i)(A) of the standard for general industry and maritime (paragraph (i)(2)(i)(A) of the standard for construction).

Proposed paragraph (i)(2)(i)(A) required that employees be trained on specific operations in the workplace that could result in exposure to respirable crystalline silica, especially operations where exposures may exceed the PEL. BCTD recommended that ''tasks'' rather than ''operations'' be used, because operations could include various tasks; it also requested that OSHA remove the statement ''especially operations where exposure may exceed the PEL'' (Document ID 2371, Attachment 1, pp. 23, 35). OSHA agrees that ''tasks'' is the more appropriate term. The Agency also agrees that employers and employees must understand all sources of potential respirable crystalline silica exposure and, therefore, removed the phrase ''especially operations where exposure may exceed the PEL.'' Therefore, OSHA has revised the proposed language so that paragraph (j)(3)(i)(B) of the standard for general industry and maritime (paragraph (i)(2)(i)(B) of the construction standard) now requires training on specific workplace tasks that could result in exposure to respirable crystalline silica.

Proposed paragraph (i)(2)(i)(B) required that employees be trained on procedures implemented by the employer to protect them from respirable crystalline silica exposure, including appropriate work practices and use of personal protective equipment (PPE), such as respirators and protective clothing. Labor unions and employee advocate groups, such as CWA, UAW, USW, NCOSH, AFSCME, IUOE, and BCTD, requested that OSHA also specify training on engineering controls (Document ID 2240, p. 4; 2282, Attachment 3, p. 24; 2336, p. 15; 3955, Attachment 2, p. 2; 4203, p. 7; 4025, Attachment 1, p. 2; 4223, p. 118). The value of training on engineering controls is demonstrated by the testimony of construction employee and New Labor Safety Liaison, Norlan Trejo, who stated that because of his training, he is aware of the types of engineering controls needed on job sites and he requests such controls if the employer does not provide them (Document ID 3583, Tr. 2462–2463).

Because engineering controls are a vital aspect of reducing exposures, OSHA has concluded that employees covered by this rule must understand how they work in order to use the appropriate work practices to fully and properly implement those controls and to be able to recognize if engineering controls are malfunctioning. Therefore, OSHA has revised the proposed provision to also require training on engineering controls. OSHA has also removed the term ''appropriate'' because it is implicit that any work practice or other methods used to protect employees be appropriate. In addition, ''personal protective equipment'' and ''protective clothing'' were removed from the paragraph because respirators are the only type of PPE required by the rule. Thus, paragraph (j)(3)(i)(C) of the standard for general industry and maritime (paragraph (i)(2)(i)(C) of the standard for construction) requires training on specific measures implemented by the employer to protect employees from respirable crystalline silica exposure, including engineering controls, work practices, and respirators to be used.

Several labor unions that represent employees in the construction industry highlighted additional training that they thought necessary for some construction employees. For example, BCTD requested that OSHA establish tiered training requirements in the construction standard to include: (1) Basic awareness training for all

employees potentially exposed to respirable crystalline silica, (2) additional equipment-specific training for employees who perform tasks that generate respirable crystalline silica, and (3) training for a competent person. BCTD noted that similar approaches were taken in other OSHA standards, such as asbestos (29 CFR 1926.1101(k)(9)) (Document ID 4223, pp. 114, 116–117). The tiered approach to training recommended by BCTD was also supported by IUOE, LHSFNA, and BAC (Document ID 3583, Tr. 2367–2368; 4207, p. 5; 4219, pp. 22–24).

In supporting a tiered approach, BCTD noted ''the effectiveness of the standard and the engineering controls used to limit silica exposure depend heavily on how the controls are used.'' (Document ID 4223, p. 117). Dr. Paul Schulte, Director of the Education and Information Division at the National Institute for Occupational Safety and Health, testified that engineering controls listed in Table 1 are only effective if they are maintained and employees are trained on their correct use (Document ID 3403, p. 6). Similar views regarding training and effectiveness of controls were expressed by Joel Guth, President of iQ Power Tools, Bill Kojola, and Tom Nunziata, instructor/training coordinator for LHSFNA; Mr. Nunziata also noted the importance of hands-on training (Document ID 3585, Tr. 2982–2983; 3586, Tr. 3204–3206; 3589, Tr. 4220–4221).

Evidence in the record further demonstrates knowledge of work practices that employees must have for controls to function effectively. For example, the user's manual for Stihl's gasoline-powered hand-held portable saws recommends training of operators, and it indicates that operators need to know minimum water flow rates, how to control flow rate to ensure an adequate volume of water to the cutting area, and to rinse the screen if no or little water is fed to the cutting wheel during use (Document ID 3998, Attachment 12a, pp. 3, 15, 23). Similarly, the effectiveness of local exhaust ventilation systems, another common method used to control exposures to respirable crystalline silica, is often enhanced by the use of proper work practices. For instance, when tuckpointing, employees should ensure that the shroud surrounding the grinding wheel remains flush against the working surface, when possible, to minimize the amount of dust that escapes from the collection system. Operating the grinder in one direction (counter to the direction of blade rotation) is effective in directing mortar debris into the exhaust system, and backing the blade off before removing it from the slot permits the exhaust system to clear accumulated dust (78 FR at 56474). Employees using vacuum controls also need to be aware of appropriate ways to clean the filter, such as using a valve on the vacuum to clean the filter with backpressure instead of pounding the filter on a surface (Document ID 3998, Attachment 13b, p. 460).

The record also contains evidence demonstrating the importance of employees understanding how to effectively operate and maintain controls on heavy equipment to prevent exposures to respirable crystalline silica in the construction industry. For example, IUOE noted that the role of operating engineers in ensuring integrity of enclosed cabs includes keeping windows and doors closed, maintaining good housekeeping practices, cleaning dust from boots before entering the cab, and reporting malfunctioning seals and air conditioning (Document ID 2262, pp. 35–36). In addition, IUOE noted that operator control of water flow rates for dust suppression is important for protecting employees from exposure and preventing excessive water runoff into the environment (Document ID 4234, Part 1, pp. 27–28). Anthony Bodway, Special Projects Manager at Payne & Dolan, Inc., representing the National Asphalt Pavement Association (NAPA), noted that all Payne & Dolan's operators have been trained to conduct daily maintenance checks of their equipment (Document ID 3583, Tr. 2194–2195). A best practices bulletin developed in part by NAPA requires machine operators to demonstrate knowledge of the machine's dust suppression system including flow rates, maintenance, troubleshooting, and visual inspections; in addition a letter from manufacturer Wirtgen America stressed the importance of operator training on operating and maintaining machines to minimize respirable dust (Document ID 2181, pp. 25, 52).

OSHA agrees that actions, such as controlling water flow rates, ensuring integrity of controls, addressing a non-functioning control, and proper housekeeping in cabs, are work practices that promote effectiveness of controls. However, the Agency does not agree that construction employees who perform tasks that generate respirable crystalline silica dust require training beyond what paragraph (i)(2)(i)(C) of the standard for construction already requires. As noted above, paragraph (i)(2)(i)(C) of the standard for construction requires employers to ensure that employees covered by the standard can demonstrate knowledge and understanding of specific measures the employer has implemented to protect them from respirable crystalline silica exposure, including engineering controls, work practices, and respirators to be used. Under this provision, the knowledge required of each employee depends on the tasks he or she performs. That was the intent of the proposed standard and it has not changed in the standard. OSHA concludes that this provision, as written, requires employers to provide employees with the different types and levels of training they need, depending on the types of tasks they conduct. For example, laborers who do not operate equipment that generates respirable crystalline silica dust would only need to be aware of the general types of controls used, such as water and local exhaust. However, those laborers would need to know about work practices for tasks they perform, such as appropriate clean-up of respirable crystalline silica dust accumulations. On the other hand, employees who operate tools with built-in controls, such as saws with integrated water delivery systems, would need to demonstrate knowledge and understanding of the full and proper implementation of the controls on those tools.

OSHA is also not mandating additional training for a competent person in paragraph (i) of the standard for construction. As discussed in more detail in the summary and explanation of *Written Exposure Control Plan*, the training requirements mandated by this standard already impart a high level of competence. OSHA recognizes that there may be situations in which an employee needs additional training in order to ensure that he or she has the knowledge, skill, and ability to be a designated competent person, but because of unique scenarios in construction environments, those training requirements would vary widely. OSHA concludes, therefore, that it is the employer's responsibility to identify and provide any additional training that the competent person would need to implement the written exposure control plan.

AFL–CIO and USW requested that the standard for general industry also mandate a tiered approach that includes a higher level of training for employees who perform silica dust-generating tasks and training of a competent person; both those groups and UAW noted the importance of workplace- or job-specific training on engineering controls and work practices (Document ID 2282, Attachment 3, p. 24; 4204, p. 99; 4214, p. 14).

OSHA concludes that employees are already required to demonstrate workplace- and job-specific knowledge and understanding of work practices associated with the tasks they conduct under paragraph (j)(3)(i)(C) of the standard for general industry and maritime. That was the intent of the proposed standard and it has not changed in the standard. Engineering controls in general industry commonly involve measures such as ventilation systems that protect several employees, and are often not subject to the direct control of the employee performing the task (*see* Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis). In those cases, training would include a description of the specific types of engineering controls used at that facility, including signs that the controls may not be working effectively (*e.g.*, visible dust emission). Training would also address any work practices needed for the controls to function effectively (*e.g.*, not opening windows near local exhaust sources, positioning the local exhaust hood directly over the exposure source). If employees covered by the general industry and maritime standard operate equipment with built in controls that are under their control, those employees are required to demonstrate knowledge and understanding of the full and proper implementation of those controls. Therefore, OSHA is not requiring additional training for general industry and maritime employees who perform tasks that generate respirable crystalline silica dust because it is already required by paragraph (j)(3)(i)(C) of the standard for general industry and maritime.

Training of a competent person is not applicable to the general industry and maritime standard because OSHA is not requiring a competent person. As explained in the summary and explanation of *Written Exposure Control Plan*, OSHA is not requiring a competent person because reasons for designating a competent person in construction are not applicable to most general industry worksites. For example, general industry worksites usually have less environmental variability and it is reasonable and generally feasible to establish regulated areas to limit access and perform exposure assessments to verify effective control of exposure.

OSHA has retained the proposed requirement for training on the contents of the respirable crystalline silica rule in paragraph (j)(3)(i)(D) of the standard for general industry and maritime (paragraph (i)(2)(i)(D) of the standard for construction). This paragraph parallels the HCS requirement to inform employees about the requirements of the HCS section (29 CFR 1910.1200(h)(2)(i)), and similar paragraphs have been included in all OSHA substance-specific standards.

Proposed paragraph (i)(2)(i)(D) required employers to train employees about the purpose and description of the medical surveillance program, and OSHA has retained that requirement in the rule under paragraph (j)(3)(i)(E) of the standard for general industry and maritime (paragraph (i)(2)(i)(F) of the standard for construction). Paragraph (i) of the standard for general industry and maritime (paragraph (h) of the standard for construction) describes the requirements of the medical surveillance program, such as the examinations that must be offered to qualifying employees. OSHA finds that employees will benefit from learning about the purpose of medical surveillance and symptoms associated with respirable crystalline silica-related diseases, as described in the summary and explanation of *Medical Surveillance*. OSHA recommends that employers in construction or other high-turnover industries inform employees to keep their copy of the physician or other licensed health care professional's written medical opinion for the employer as proof of a current medical examination and that proof of a current examination could ensure that employees get timely examinations or spare employees from unnecessary testing, such as X-rays. OSHA also recommends that employers inform employees that they cannot be retaliated against for participating in medical surveillance. This information will help to ensure that employees are able to effectively participate in medical surveillance.

The proposed rule did not require employees to be trained on the identity of the competent person. Several labor unions, including IUOE, LHSFNA, BAC, and BCTD requested that employees receive training on the written exposure control plan or identity of the competent person (Document ID 3583, Tr. 2367–2368; 3589, Tr. 4222; 2329, p. 5; 4223, p. 118). Paragraph (g)(4) of the standard for construction requires employers to designate a competent person to make frequent and regular inspections of job sites, materials, and equipment to implement the written exposure control plan. The written exposure control plan in the construction standard describes tasks in the workplace that involve exposure to respirable crystalline silica; engineering controls, work practices, and respiratory protection used to limit employee exposures; housekeeping methods used to limit employee exposures; and procedures used to restrict access, when necessary, to minimize employees exposed and their level of exposure, including exposures generated by other employers or sole proprietors (paragraph (g)(1)(i)–(iv)). OSHA is not requiring the identity of the competent person to be listed in the written exposure control plan because it could change daily. However, construction employees must be able to identify the competent person in situations where they have a question or concern about the subjects covered in the written exposure control plan. For example, if an engineering control is not working properly, an employee may need to contact the competent person for help in addressing the problem. Therefore, paragraph (i)(2)(i)(E) of the standard for construction requires employees to be informed of the competent person's identity. However, OSHA is not specifying training on the written exposure control plan because the contents of that plan, including its availability to employees, is already addressed by training on the contents of this section under paragraph (i)(2)(i)(D) of the standard for construction.

Some stakeholders requested that OSHA provide greater specificity on training requirements. For example, Fann Contracting, Inc. asked OSHA to spell out what training is required for different industries (Document ID 2116, Attachment 1, p. 46). NAHB stated that specifying training requirements would simplify training for construction employers (Document ID 2296, p. 44). John Scardella, Program Administrator for USW, testified that training should not be left to the discretion of employers because they might not prioritize employee health and safety (Document ID 3479, p. 2). USW and LHSFNA requested more detailed training requirements, such as those of the asbestos standard (29 CFR 1910.1001; 1926.1101) that specify what is to be addressed under each major training topic (Document ID 2336, pp. 14–15; 3589, Tr. 4219).

Although OSHA agrees with these commenters that comprehensive training is a key part of hazard communication, the Agency recognizes that it is difficult to provide more specificity as a result of unique scenarios among different employers and industries. However, to help employers develop training programs that are comprehensive for general training subjects that apply to most covered industries, OSHA has developed a number of guidance products that are already available

through its Web site. In addition, the Agency is planning to develop guidance products specific to the rule, as has been suggested by NAHB (Document ID 2296, p. 39). Numerous governmental and other organizations have already developed guidance products for training (*e.g.,* Document ID 1722; 4025, Attachment 2; 4053, Exhibit 3a–3e and 4; 4073, Attachment 8i). As has been the case with all OSHA standards, OSHA expects that the private sector will develop training products and programs, which will further help ensure comprehensive training.

Commenters also argued that OSHA should include requirements for training on other topics. For example, IUOE requested training on topics such as SDSs, signs, use and care of respiratory protection, and work practices for heavy machine operators (Document ID 2262, pp. 36–38; 4025, Attachment 1, p. 2). LHSFNA and BCTD requested training on exposure assessment (Document ID 3589, Tr. 4222; 4223, p. 118). AFSCME requested training on personal hygiene (Document ID 4203, p. 7).

OSHA concludes, however, that the employee information and training provisions in the respirable crystalline silica rule and the HCS are sufficiently informative. For example, the HCS requires employers to provide training on SDSs and on the signal words and hazard statements that are used on the signs required by the general industry and maritime standard. Under the HCS, employers must also train employees about the location and availability of the written HCS program, including the required list(s) of hazardous chemicals and SDSs. The HCS also requires employers to train employees on the methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area; in the case of respirable crystalline silica, this could include a description of the employer's exposure assessments methods (*e.g.,* objective assessments, personal breathing zone air sampling, direct readings of respirable dust) and warnings that visible dust emissions might indicate a problem.

Because employers must meet the requirements of the HCS, OSHA does not find it necessary to repeat the training requirements of that standard in their entirety in the respirable crystalline silica rule. Moreover, even if all training requirements of the HCS were repeated in the respirable crystalline silica rule, most employers would still have to consult the hazard communication requirements of other hazardous chemicals, because they have employees exposed to other chemicals in their workplace. Consequently, OSHA concludes that these provisions, and the other requirements of the HCS and this standard, are sufficient.

OSHA also concludes that additional training on respiratory protection or personal hygiene is unnecessary. Training on the use and care of respiratory protection is already required under the respiratory protection standard (29 CFR 1910.134). OSHA similarly concludes that training in personal hygiene is not needed as a required training topic in this rule because personal hygiene measures relevant to respirable crystalline silica exposure, such as avoiding use of compressed air as a method to clean dust off of clothing, are adequately addressed by other requirements of the rule and are covered by training on work practices. Some training topics suggested by commenters, such as communication methods for employees in enclosed cabs, are specific to certain work scenarios. OSHA has concluded that employers are in the best position to determine which additional, unique training requirements are relevant to their type of industry. For example, in construction, the competent person might be able to identify situations where employees need more training because they are not demonstrating knowledge and understanding of a specific measure the employee has implemented to protect them.

OSHA's proposed rule required the employer to make a copy of the standard readily available without cost to each employee covered by the respirable crystalline silica rule, and OSHA has retained this requirement in paragraph (j)(3)(ii) of the standard for general industry and maritime (paragraph (i)(2)(ii) of the standard for construction). This is a common requirement in OSHA standards such as chromium (VI) (29 CFR 1910.1026), acrylonitrile (29 CFR 1910.1045), and cotton dust (29 CFR 1910.1043). The provision leaves employers free to determine the best way to make the standard available, such as a printed or electronic copy in a central location that employees can easily access. OSHA concludes that employees need to be familiar with and have access to the respirable crystalline silica standard for general industry and maritime or construction, as applicable, and be aware of the employer's obligations to comply with it.

OSHA did not propose a requirement for labels or signs in languages other than English. Ameren requested the rule include a requirement that labels include appropriate languages for employees who do not understand English (Document ID 2315, p. 4). Charles Gordon and BAC requested that warning signs be presented in a language or manner that employees can understand, and, as noted by BAC, the method could include graphics (Document ID 3588, Tr. 3805; 4219, p. 27). Requirements for labels on hazardous chemicals are set forth in paragraph (f) of the HCS, which does not require languages other than English. However, the HCS requires the inclusion of certain information on labels on shipped containers, including pictograms (29 CFR 1910.1200(f)(1)(iv)), and mandates that containers in the workplace be labeled either in accordance with the rules for shipping containers or with product identifier and combinations of words, pictures, or symbols to warn of hazards. OSHA has concluded that with training required under the HCS (29 CFR 1910.1200(h)(3)(iv)), even employees who are not literate in English will have sufficient knowledge of respirable crystalline silica hazards. Likewise, with training, employees will be able to recognize the meaning of signs at the entrances to regulated areas and the need for respiratory protection in these areas.

OSHA's proposed rule did not specify when and how often employees must be trained. Some stakeholders offered opinions about when an employer's obligation to train covered employees should begin. For example, USW, NCOSH, and LHSFNA requested that the rule for respirable crystalline silica require training before or at the time employees are assigned or placed in a job with respirable crystalline silica exposure (Document ID 3479, p.1; 3955, Attachment 2, p. 1; 3589, Tr. 4222). CWA, Upstate Medical College, UAW, AFSCME, AFL–CIO, and BCTD requested that the rule for respirable crystalline silica require training before employees are assigned to or placed in a job or task with respirable crystalline silica exposure (Document ID 2240, p. 4; 2244, p. 4; 2282, Attachment 3, pp. 24–25; 4203 p. 7; 4204, p. 99; 4223, p. 117).

OSHA agrees that each employee needs to be trained sufficiently to understand the specified training elements at the time of initial assignment to a position involving exposure to respirable crystalline silica. The rule requires the employer to ensure that each employee can demonstrate knowledge and understanding of the specified training elements; this requirement applies from the time that the employee is covered by the rule. This requirement is consistent with the HCS, which requires that employers provide employees with

effective information and training on hazardous chemicals in their work area at the time of their initial assignment (29 CFR 1910.1200(h)(1)).

Stakeholders also commented on how often employers should be required to train their employees. CWA, Upstate Medical College, UAW, NCOSH, AFSCME, and LHSFNA recommended periodic refresher training and additional training if methods, equipment, or controls change (Document ID 2240, p. 4; 2244, p. 4; 2282, Attachment 3, pp. 24–25; 3955, Attachment 2, p. 2; 4203 p. 8; 3589, Tr. 4222). Similarly, USW and AFL–CIO asked that OSHA require periodic refresher training (Document ID 3479, p.1; 4204, p. 99). In addition, BCTD recommended additional training when the employer believes an employee requires more training because of a lack of skill or understanding (Document ID 4223, p. 117).

OSHA agrees with commenters that additional or repeated training may be necessary under certain circumstances but does not consider it appropriate to impose a fixed schedule of periodic training. Therefore, the requirement for training is performance-oriented in order to allow flexibility for employers to provide training as needed to ensure that each employee can demonstrate the knowledge and understanding required under the rule. For example, if an employer observes an employee engaging in activities that contradict knowledge gained through training, it is a sign to the employer that the employee may require a reminder or periodic retraining on work practices.

Because paragraph (j)(3)(i)(C) of the standard for general industry and maritime (paragraph (i)(2)(i)(C) of the standard for construction) requires training on the specific measures the employee has implemented to protect employees, additional training is already required after new engineering controls are installed, new work practices are implemented, or employees are given new types of respirators. Because this provision requires employers to provide additional training following changes in protective measures or equipment, they ensure that employees are able to properly use the new controls, implement work practices relating to those controls, and properly use respirators to actively protect themselves under the conditions found in the workplace, even if those conditions change.

OSHA did not include a requirement for employees to be certified as having received training in the proposed rule. Commenters including Dr. Ruth Ruttenberg, representing the AFL–CIO, have voiced support for a portable training record or certification-based approach; Dr. Ruttenberg noted that this would reduce costs by avoiding the need for each new employer to conduct full training (Document ID 1950, pp. 11–12; 2256, Attachment 4, p. 5; 4235, p. 14). OSHA is not including a requirement for a portable training record in the rule. This approach is consistent with the HCS, which neither requires nor precludes a training record that could be portable. Employee training requirements might be partially fulfilled by training obtained through trade associations, unions, colleges, or professional schools. However, the employer is always ultimately responsible for ensuring that employees are adequately trained, regardless of the method relied upon to comply with the training requirements.

OSHA concludes that a portable training record is unlikely to eliminate the need for employer-specific or site-specific training. For example, Barbara McCabe, Program Manager for IUOE, testified that IUOE local unions train employees but employees would need site-specific training when they report to the worksite (Document ID 3583, Tr. 2368). An example of a case where site-specific training is needed was noted by BAC, who commented that an employee who operated a saw with water controls at one site may be given a saw with vacuum controls at another site (Document ID 4219, p. 23).

OSHA concludes that some site-specific or employer-specific training is always necessary, such as training on specific tasks that could result in exposures, controls or work practices that the employer has implemented, or the identity of the competent person (paragraphs (j)(3)(i)(B) and (C) of the standard for general industry and maritime and paragraphs (i)(2)(i)(B), (C), and (E) of the standard for construction). Full training would not be required if an employee is already able to demonstrate knowledge in health hazards, the contents of the respirable crystalline silica rule, or medical surveillance for respirable crystalline silica (paragraphs (j)(3)(i)(A), (D), and (E) of the standard for general industry and maritime, paragraphs (i)(2)(i)(A), (D) and (F) of the standard for construction). Site-specific training is unlikely to be costly or time-consuming. OSHA concludes that assessing an employee's knowledge to determine the type and level of additional training required is more meaningful than simply accepting a certificate of training.

Bill Kojola requested that the rule specify that training be provided at no cost to the employee and during work hours (Document ID 3955, Attachment 2, p. 2). In addition, Norlan Trejo from New Labor testified that he never saw an employer pay for training (Document ID 3583, Tr. 2469). As stated above, an employer may rely on an employee's previous training, if the employee can demonstrate knowledge in training requisites. Any training provided by the employer to meet the requirements of the rule must be provided at no cost to the employee. Employees must also be paid for time spent in training. This is consistent with other OSHA standards that do not include an explicit requirement for employer payment for training in the regulatory text, *e.g.,* the HCS requires training (1910.1200(h)(3)) but does not mention cost; the compliance directive (CPL 02–02–079 says ''Training is required to be provided at no cost to the employees. Employees must be paid for the time they spend at training.)''

In the Notice of Proposed Rulemaking, OSHA asked whether labeling of substances containing more than 0.1 percent crystalline silica was appropriate, as required by the HCS, or if the threshold for labeling should be greater than 1 percent crystalline silica (78 FR at 56291). A number of industry groups suggested a threshold for including respirable crystalline silica on labels or SDSs. With the exception of NISA, who favored a 0.1 percent threshold, the commenters requested a threshold of 1 percent or greater or thought that a 0.1 percent threshold could be problematic (Document ID 1785, p. 4; 2179, pp. 3–4; 2101, pp. 8–9; 2284, p. 10; 2296, p. 44; 2312, p. 3; 2317, p. 3; 2319, p. 120; 2327, Attachment 1, p. 14; 4208, pp. 19–20). The International Diatomite Producers Association agreed with NISA that the threshold for hazard communication should be 0.1 percent for respirable crystalline silica but requested an exception for respirable crystalline silica in natural (uncalcined) diatomaceous earth, according to OSHA's current policy (Document ID 4212, pp. 6–7).

The classification of hazardous chemicals, including chemicals containing silica, is determined by the HCS. As explained in Section V, Health Effects, OSHA has determined, consistent with the National Toxicology Program and International Agency for Research on Cancer classifications, that respirable crystalline silica is a carcinogen. Under the HCS, a mixture that contains a carcinogen must itself be classified as a carcinogen when at least one ingredient in it has been classified as a Category 1 or Category 2 carcinogen

and is present at or above the appropriate cut-off value/concentration limit specified in HCS Table A.6.1 (29 CFR 1910.1200, Appendix A, A.6.3.1). Table A.6.1 sets the cut-off value at greater than or equal to 0.1 percent. Footnote 7 to 1910.1200, Appendix A, A.6.3 notes that the cut-off value is the primary means of classification of carcinogens and may only be modified on a case-by-case evaluation based on available test data for the mixture as a whole. Classification of a chemical under the HCS triggers labeling requirements under that standard, and OSHA does not find it appropriate to impose different requirements in this rule. To do so would be at odds with the concept of harmonizing national and international requirements for classification and labelling of chemicals that is the basis of the GHS and HCS.

OSHA also did not propose requirements related to the creation and retention of training records, but some commenters expressed opinions on this issue. For example, CISC commented that they would agree to document that employees completed training and demonstrated knowledge (Document ID 4217, p. 25). Consistent with the HCS, employers are not required to keep records of training under the rule for respirable crystalline silica, but employers may find it valuable to do so. Comments on this issue and OSHA's rationale for this decision are discussed in the summary and explanation of *Recordkeeping*.

ASTM standards. The training requirements in the respirable crystalline silica standards are generally consistent with but differ slightly from ASTM International (ASTM) standards ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica and ASTM E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities (Section 4.8 in both E 1132–06 and E 2625–09) (Document ID 1466, p. 6; 1504, p. 6). The E 1132–06 standard requires training for employees exposed at any level and the E 2625–09 standard for construction and demolition requires training for employees potentially exposed to high levels. The ASTM standards also include: (1) More specificity on training requirements such as annual training (E 1132–06 only), training when employees demonstrate unsafe work practices, training in an appropriate language and manner, and documentation of training (certification in the case of E 1132–06); (2) training on tuberculosis and relationships between smoking and silica exposure in both standards and no training for autoimmune and kidney hazards in E 2625–09; (3) training on respirator use and hygiene; and (4) warning signs for construction and demolition workplaces in E 2625–09.

OSHA is requiring that each employee covered by the rule receive training; employees may be at significant risk even if they are not exposed to ''high levels'' of respirable crystalline silica. In comparison to the ASTM standards, the requirements for training under the respirable crystalline silica rule are more performance-based in terms of when training is required. The health hazards addressed in the rule are based upon OSHA's health effects assessments and consistency with health hazard classification in the HCS. OSHA already requires training on respirator use under its respiratory protection standard (29 CFR 1910.134). The rule does not specify training on hygiene because personal hygiene is addressed by other requirements of the rule and training on work practices. OSHA is not requiring warning signs in the standard for construction because employers are in the best position to determine if and when signs are appropriate for restricting access to work areas to limit employee exposure to respirable crystalline silica. For the reasons described above, OSHA concludes that the requirements of the rule better effectuate the purposes of the OSH Act of 1970 than the ASTM standards.

Recordkeeping

Paragraph (k) of the standard for general industry and maritime (paragraph (j) of the standard for construction) requires employers to make and maintain air monitoring data, objective data, and medical surveillance records. The recordkeeping requirements are in accordance with section 8(c) of the Occupational Safety and Health (OSH) Act (29 U.S.C. 657(c)), which authorizes OSHA to require employers to keep and make available records as necessary or appropriate for the enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational accidents and illnesses.

Paragraph (k)(1)(i) of the standard for general industry and maritime (paragraph (j)(1)(i) of the standard for construction) is substantively unchanged from the proposed rule. It requires the employer to make and maintain accurate records of all exposure measurements taken to assess employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of the standard for general industry and maritime (paragraph (d)(2) of the standard for construction). OSHA has added the words ''make and'' prior to ''maintain'' in order to clarify that the employer's obligation is to create and preserve such records. This clarification has also been made for other records required by the silica rule. In addition, OSHA now refers to ''measurements taken to assess employee exposure'' rather than ''measurement results used or relied on to characterize employee exposure.'' This change is editorial, and is intended to clarify OSHA's intent that all measurements of employee exposure to respirable crystalline silica be maintained. Paragraph (k)(1)(ii) of the standard for general industry and maritime (paragraph (j)(1)(ii) of the standard for construction) requires that such records include the following information: The date of measurement for each sample taken; the task monitored; sampling and analytical methods used; the number, duration, and results of samples taken; the identity of the laboratory that performed the analysis; the type of personal protective equipment, such as respirators, worn by the employees monitored; and the name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

OSHA has made one editorial modification that differs from the proposed rule in paragraph (k)(1)(ii)(B) of the standard for general industry and maritime (paragraph (j)(1)(ii)(B) of the standard for construction) and that is to change ''the operation monitored'' to ''the task monitored.'' Both ''task'' and ''operation'' are commonly used in describing work. However, OSHA uses the term ''task'' throughout the rule, and the Agency is using ''task'' in the recordkeeping provision for consistency and to avoid any potential misunderstanding that could result from using a different term. This editorial change neither increases nor decreases an employer's obligations as set forth in the proposed rule.

The recordkeeping provision that received the most comments was proposed paragraph (j)(1)(ii)(G) (now paragraph (k)(1)(ii)(G) of the standard for general industry and maritime, paragraph (j)(1)(ii)(G) of the standard for construction), which, consistent with existing recordkeeping requirements in OSHA health standards, requires the employer to include in the standard's mandated records the employee's social security number. Morgan Electro Ceramics, National Electrical Carbon Products, Inc. (NECP), Southern Company, the National Tile Contractors

Association (NTCA), Dow Chemical Company, the Asphalt Roofing Manufacturers Association (ARMA), the American Petroleum Institute (API), the Marcellus Shale Coalition, Ameren Corporation, the North American Insulation Manufacturers Association (NAIMA), Edison Electric Institute (EEI), the Tile Council of North America (TCNA), the American Foundry Society (AFS), the Nevada Mining Association (NMA), Newmont Mining Corporation (NM), and others opposed the requirement (*e.g.*, Document ID 1772, p.1; 1785, pp. 9–10; 2185, pp. 8; 2267, p. 7; 2270, p. 3; 2291, p. 26; 2301, Attachment 1, pp. 80–81; 2311, p. 3; 2315, p. 7; 2348, Attachment 1, p. 39; 2357, pp. 36–37; 2363, p. 7; 2379, Appendix 1, p. 73; 2107, p. 4; 1963, p. 3). The commenters, citing employee privacy and identity theft concerns, wanted to be allowed to use an identifier other than the social security number, such as an employee identification number, an employee driver's license number, or another unique personal identification number. For example, NAIMA stated ''Using social security numbers is a dangerous threat to personal privacy and identify theft that OSHA should affirmatively discourage'' (Document ID 2348, Attachment 1, p. 39). Commenters acknowledged that social security numbers must be used for some reports to the government and thus are present in some employer records, but that access to these records is usually more restricted than to air monitoring records.

OSHA has considered the comments it received on this issue and has decided to retain the requirement for including the employee's social security number in the recordkeeping requirements of the rule. The requirement to use an employee's social security number is a long-standing OSHA practice, based on the fact that it is a number that is both unique to an individual and is retained for a lifetime, and does not change as an employee changes employers. The social security number is therefore a useful tool for tracking employee exposures, particularly where exposures are associated with diseases such as silicosis that generally have a long latency period and can develop over a period of time during which an employee may have several employers.

OSHA is cognizant of the privacy concerns expressed by commenters regarding this requirement, and understands the need to balance that interest against the public health interest in requiring the social security identifier. Instances of identity theft and breeches of personal privacy are widely reported and concerning. However, OSHA has concluded that this rule should adhere to the past, consistent practice of requiring employee social security numbers on exposure records mandated by every OSHA substance-specific health standard, and that any change to the Agency's requirements for including employee social security numbers on exposure records should be comprehensive. Some employers who are covered by this rule, such as employers who perform abrasive blasting on surfaces coated with lead, cadmium, or chromium (VI), will be covered by more than one OSHA standard. OSHA examined alternative forms of identification in Phase II of the Agency's Standards Improvement Project, but did not revise requirements for the use of social security numbers (70 FR 1111–1144 (1/5/2005)). Nevertheless, given increasing concerns regarding identity theft and privacy issues, as evidenced by stakeholder comments in this rulemaking record, OSHA intends to examine the requirements for social security numbers in all of its substance-specific health standards in a future rulemaking. In the meantime, the requirement to use and retain social security numbers to comply with this rule remains.

The remaining requirements of paragraph (k)(1)(ii) of the standard for general industry and maritime (paragraph (j)(1)(ii) of the standard for construction) are generally consistent with those found in other OSHA standards, such as the standards for methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). The additional requirement to include the identity of the laboratory that performed the analysis of exposure measurements is for the reason stated in the preamble to the Notice of Proposed Rulemaking (NPRM), which is that analysis of crystalline silica samples must conform with the requirements listed in the rule (*i.e.,* in Appendix A), and that can only be determined by knowing the identity of the laboratory that performed the analysis.

Fann Contracting, Inc. commented that OSHA's proposed rule would create a ''recordkeeping nightmare'' and raised concerns about the difficulties of managing air monitoring data for over 200 employees scattered around the state, with 7 to 8 ongoing projects and 12 to 15 total projects per year (Document ID 2116, Attachment 1, p. 11). The American Subcontractors Association expressed concerns about the high costs of transferring data to new technology or keeping records in paper format (Document ID 2187, p. 7).

OSHA understands that, as with any recordkeeping requirement in a comparable rule, there will be time, effort, and expense involved in developing and maintaining records. However, OSHA expects that even employers who manage multiple projects will have a system for maintaining these records, just as they do for their other business records. As for high expenses of transferring data to new technology, the Agency understands that there are multiple ways to maintain these records and there are expenses involved in doing so. Therefore, the Agency is allowing employers the option to use whatever method works best for them, paper or electronic.

Paragraph (k)(1)(iii) of the standard for general industry and maritime (paragraph (j)(1)(iii) of the standard for construction) is unchanged from the proposed rule. It requires the employer to ensure that exposure records are maintained and made available in accordance with OSHA's access to employee exposure and medical records standard, which specifies that exposure records must be maintained for 30 years (29 CFR 1910.1020(d)(i)(ii)). Commenters addressed the issue of how long an employer should maintain exposure records. The National Industrial Sand Association (NISA) noted that its occupational health program requires NISA members to retain employee air monitoring records indefinitely (Document ID 2195, p. 35). NISA supported the proposed requirement that air monitoring records be retained for 30 years (Document ID 2195, p. 46). Other commenters advocated recordkeeping durations ranging from 10 years to 40 years (*e.g.*, Document ID 2210, Attachment 1, p. 8; 2319, p. 122; 2339, p. 10; 4025, pp. 8–9). The American Society of Safety Engineers (ASSE) recommended that air monitoring records should be retained for 40 years or the duration of employment plus 20 years, whichever is longer, due to latency periods of some silica-related illnesses (Document ID 2339, p. 10). The International Union of Operating Engineers indicated that 10 years is more than adequate time to retain air monitoring data; it commented that British Columbia, Canada requires retention for 10 years (Document ID 4025, pp. 8–9). The Construction Industry Safety Coalition and the National Federation of Independent Business (NFIB) expressed the view that 30 years is too long, but did not make recommendations for what they considered a suitable duration (Document ID 2319, pp. 121–122; 2210, Attachment 1, p. 8). NFIB alleged that employers will have to maintain and

make available records of all activities relating to each requirement of the rule if the company wants to ensure it can show a good-faith effort to comply, and indicated that keeping records for 30 years would lead to a ''staggering'' amount of paperwork (Document ID 2210, Attachment 1, p. 8).

After reviewing the comments in this record, OSHA has concluded that the best approach is to maintain consistency with 29 CFR 1910.1020 and its required time period for retention of exposure records of 30 years. OSHA explained in that rulemaking that it is necessary to keep exposure records for this extended time period because of the long latency period between exposure and development of silica-related disease (45 FR 35212, 35268–35271 (5/23/80)). For example, silicosis is often not detected until 20 years or more after initial exposure. The extended record retention period is therefore needed because establishing causality of disease in employees is assisted by, and in some cases can only be made by, having present and past exposure data (as well as any objective data relied on by the employer and present and past medical surveillance records, as discussed below).

In retaining the 30-year retention period, OSHA does not agree with commenters who recommended extending it to at least 40 years, or even indefinitely. The Agency concludes that the 30-year retention period specified in 29 CFR 1910.1020 represents a reasonable balance between the need to maintain exposure records and the administrative burdens associated with maintaining those records for extended time periods. Because the 30-year records-retention requirement is included in 29 CFR 1910.1020, this duration is consistent with longstanding Agency and employer practice. Other substance-specific rules are also subject to the retention requirements of 29 CFR 1910.1020, such as the standards addressing exposure to methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). The Agency also disagrees that the 30-year retention requirement will lead to a ''staggering'' amount of paperwork, as NFIB commented (Document ID 2210, Attachment 1, p. 8). Electronic recordkeeping has become commonplace. Commenters such as the Association of Energy Service Companies and ASSE support the use of electronic or digital records to ease paperwork burdens (Document ID 2344, p. 2; 2339, p. 5). Thus, OSHA finds that the 30-year retention period is necessary and appropriate for air monitoring data.

Paragraph (k)(2)(i) of the standard for general industry and maritime (paragraph (j)(2)(i) of the standard for construction) is substantively unchanged from the proposed rule. It requires employers who rely on objective data to keep accurate records of the objective data. Paragraph (k)(2)(ii) of the standard for general industry and maritime (paragraph (j)(2)(ii) of the standard for construction) requires the record to include: The crystalline silica-containing material in question; the source of the objective data; the testing protocol and results of testing; a description of the process, task, or activity on which the objective data were based; and other data relevant to the process, task, activity, material, or exposures on which the objective data were based. Paragraphs (k)(2)(ii)(D) and (E) of the standard for general industry and maritime (paragraphs (j)(2)(ii)(D) and (E) of the standard for construction) have been modified from the proposed rule to substitute the word ''task'' for ''operation'' and to clarify the requirements for records of objective data. These changes are editorial, and do not affect the employer's obligations as set forth in the proposed rule.

Since the rule allows objective data to be used to exempt the employer from monitoring requirements and to provide a basis for selection of respirators, OSHA considers it critical that the use of objective data be documented. As authorized in the rule, reliance on objective data is intended to provide the same degree of assurance that employer monitoring of employee exposures by taking air samples does. The specified content elements are required to ensure that the records are capable of demonstrating to OSHA a reasonable basis for the conclusions drawn by the employer from the objective data.

OSHA considers objective data to be employee exposure records that must be maintained. Paragraph (k)(2)(iii) of the standard for general industry and maritime (paragraph (j)(2)(iii) of the standard for construction) is unchanged from the proposed rule. It requires the employer to ensure that objective data are maintained and made available for 30 years in accordance with 29 CFR 1910.1020(d)(1)(ii)).

The National Asphalt Pavement Association recommended that OSHA clarify that ''. . . for an operation provided the controls outlined in Table 1, no further records of objective data would be required'' (Document ID 2181, p. 13). OSHA confirms that an employer who fully and properly implements the control measures in Table 1 does not need to have objective data since no exposure assessment (including those based on objective data) is required when the employer is following Table 1. Therefore, following Table 1 does not trigger a recordkeeping or retention requirement.

Associated Builders and Contractors, Inc. (ABC) and ASSE addressed the issue of retaining objective data records for 30 years (Document ID 2289, p. 8; 2339, p. 10). ABC expressed concerns that data could be lost or destroyed during the 30-year period, and thought it would be difficult to enforce this provision. Furthermore, it commented that there is a ''. . . large and burdensome amount of records that an employer would need to store and maintain'' (Document ID 2289, p. 8). ABC did not make a recommendation on how long employers should maintain objective data records. ASSE commented that 30 years is too short and recommended that objective data records be retained for 40 years or the duration of the employment plus 20 years, whichever is longer, due to latency periods of some silica-related illnesses (Document ID 2339, p. 10). For the same reasons noted in the explanation above for retaining air monitoring data pursuant to paragraph (k)(1)(iii) of the standard for general industry and maritime (paragraph (j)(1)(iii) of the standard for construction), OSHA finds that the 30-year retention period is necessary and appropriate for objective data.

Paragraph (k)(3)(i) of the standard for general industry and maritime (paragraph (j)(3)(i) of the standard for construction) requires the employer to make and maintain an accurate record for each employee subject to medical surveillance under paragraph (i) of the standard for general industry and maritime (paragraph (h) of the standard for construction). Paragraph (k)(3)(ii) of the standard for general industry and maritime (paragraph (j)(3)(ii) of the standard for construction) lists the categories of information that an employer is required to record: The name and social security number of the employee; a copy of the PLHCPs' and specialists' written medical opinions for the employer; and a copy of the information provided to the PLHCPs and specialists where required by paragraph (i)(4) of the standard for general industry and maritime (paragraph (h)(4) of the standard for construction). The information provided to the PLHCPs and specialists includes the employee's duties as they relate to crystalline silica exposure, crystalline silica exposure levels, descriptions of personal protective equipment used by the employee, and information from employment-related medical

examinations previously provided to the employee (paragraph (i)(4) of the standard for general industry and maritime, paragraph (h)(4) of the standard for construction).

In paragraph (k)(3)(ii)(B) of the standard for general industry and maritime (paragraph (j)(3)(ii)(B) of the standard for construction), OSHA has changed the ''PLHCP's and pulmonary specialist's written opinions'' to the ''PLHCPs' and specialists' written medical opinions.'' The change, consistent with paragraph (i) of the standard for general industry and maritime (paragraph (h) of the standard for construction), is made to reflect the revised definition for the term ''specialist'' included in the rule.

Paragraph (k)(3)(iii) of the standard for general industry and maritime (paragraph (j)(3)(iii) of the standard for construction) is unchanged from the proposed rule. It requires that medical records must be maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020(d)(1)(i), which governs application of the retention requirements in this rule. Pursuant to 29 CFR 1910.1020(d)(1)(i)(C), medical records of employees who have worked for less than one year for the employer need not be retained beyond the term of employment if they are provided to the employee upon the termination of employment. This exception allows employers flexibility and the option not to retain medical records in these circumstances (53 FR 38140, 38153–38155 (9/29/88)). This provision greatly reduces the recordkeeping burden on employers of short-term employees, including many construction employees covered by this rule. Of course, neither this rule nor 29 CFR 1910.1020 prohibits employers from keeping the medical records of employees who worked less than one year, and some employers may choose to keep the records. As indicated earlier, employers have the option to keep records in electronic or paper form.

The employer is responsible for the maintenance of records in his or her possession (*e.g.,* the PLHCP's written medical opinion for the employer described in paragraph (i)(6) of the standard for general industry and maritime (paragraph (h)(6) of the standard for construction)). The employer is also responsible for ensuring the retention of records in the possession of the PLHCP (*e.g.,* the written medical report for the employee described in paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction)) that are created pursuant to this rule's medical surveillance requirements. This responsibility, which derives from 29 CFR 1910.1020(b), means that employers must ensure that the PLHCP retains a copy of medical records for the employee's duration of employment plus 30 years. The employer can generally fulfill this obligation by including the retention requirement in the agreement between the employer and the PLHCP.

Commenters objecting to the recordkeeping requirements for medical records were concerned with privacy and costs. OSCO Industries asserted that the medical recordkeeping provisions would be subject to the Health Insurance Portability and Accountability Act (HIPAA), and thus employers would be denied access to the records (Document ID 1992, p. 12). The National Electrical Contractors Association (NECA) also expressed concerns about the application of HIPAA (Document ID 2295, p. 2). NECA indicated that the recordkeeping requirements would ''. . . inundate most businesses with paperwork . . .'' and would be ''. . . an economic burden to employers in the construction industry . . .'' (Document ID 2295, p. 2). Fann Contracting and Leading Builders of America said that medical records would be very expensive and difficult to maintain (Document ID 2116, Attachment 1, p. 11; 2269, p. 19). Fann Contracting commented that they have multiple projects, as many as 7 to 8 ongoing and 12 to 15 per year, with over 200 employees scattered around the state, which makes the new requirements ''a recordkeeping nightmare'' (Document ID 2116, Attachment 1, p. 11).

As to the expense and difficulty of maintaining the medical records, OSHA recognizes that there will be time, effort, and expense involved in maintaining medical records. However, as stated earlier, OSHA expects that employers who manage multiple projects will have a system for maintaining these records, just as they do for their other business records. The adverse health effects associated with crystalline silica are very serious, and OSHA has concluded that the recordkeeping requirements are necessary to ensure that records are available to assist PLHCPs in identifying health conditions that may place employees at increased risk from exposure, as well as identifying and treating adverse health effects that may develop among employees. Therefore, OSHA concludes that the requirements for making and maintaining medical records are reasonable, and are essential for the health and safety of employees.

As to the concerns expressed regarding the application of HIPAA, the requirement for retention of medical records in this standard (like those in other OSHA standards) is consistent with HIPAA. HIPAA allows for disclosure of certain health information to an employer where needed to comply with OSHA requirements for medical surveillance (45 CFR 164.512). Moreover, this standard's requirement that medical surveillance reports be provided to workers rather than to employers eliminates much of this concern.

Morgan Electro Ceramics, NECP, Southern Company, NTCA, Dow Chemical, ARMA, API, the Marcellus Shale Coalition, Ameren, NAIMA, EEI, TCNA, AFS, NMA, NM and others also questioned the requirement that the employee's social security number be included in medical records (Document ID 1772, p. 1; 1785, pp. 9–10; 2185, pp. 8; 2267, p. 7; 2270, p. 3; 2291, p. 26; 2301, Attachment 1, pp. 80–81; 2311, p. 3; 2315, p. 7; 2348, Attachment 1, p. 39; 2357, pp. 36–37; 2363, p. 7; and 2379, Appendix 1, p. 73; 2107, p. 4; 1963, p. 3).

As noted above in the discussion on air monitoring data, OSHA finds the privacy and security issues associated with the required use of social security numbers are of concern. However, for the same reasons discussed above with regard to employee exposure records, the Agency has decided to retain the requirement for use of social security numbers in medical records. As stated above, OSHA intends separately from this rulemaking to examine the requirements for social security numbers in all of its substance-specific health standards in order to address the issue comprehensively and ensure consistency among standards.

In total, the recordkeeping requirements fulfill the purposes of Section 8(c) of the OSH Act, and help protect employees because such records contribute to the evaluation of employees' health and enable employees and their healthcare providers to make informed health care decisions. These records are especially important when an employee's medical condition places him or her at increased risk of health impairment from further exposure to respirable crystalline silica. Furthermore, the records can be used by the Agency and others to identify illnesses and deaths that may be attributable to respirable crystalline silica exposure, evaluate compliance programs, and assess the efficacy of the standard. OSHA concludes that medical surveillance records, like exposure records, are necessary and appropriate

for protection of employee health, enforcement of the standard, and development of information regarding the causes and prevention of occupational illnesses.

Commenters, such as NISA and ASSE, addressed the issue of duration of retention of medical records (Document ID 2339, p. 10; 2195, p. 35). NISA indicated that 30 years is an appropriate retention period (Document ID 2195, p. 35). ASSE indicated that medical records should be retained for 40 years or the duration of the employment plus 20 years, whichever is longer, due to latency periods of some silica-related illnesses (Document ID 2339, p. 10).

As with exposure records and objective data records, OSHA has concluded that the best approach is to maintain consistency with 29 CFR 1910.1020 and its required retention period for medical records; that period is the duration of employment plus 30 years. It is necessary to keep medical records for this extended time period because of the long latency period between exposure and development of silica-related disease (45 FR at 35268–35271). OSHA recognizes that in some cases, the latency period for silica-related diseases may extend beyond 30 years. However, the Agency concludes that the retention period specified in 29 CFR 1910.1020 represents a reasonable balance between the need to maintain records and the administrative burdens associated with maintaining those records for extended time periods. Because the duration of employment plus the 30-year records retention requirement is currently included in 29 CFR 1910.1020, this time period is consistent with longstanding Agency and employer practice.

Charles Gordon, a retired occupational safety and health attorney, advocated for a provision for trade associations, unions, and medical practices to provide medical exams and keep medical records (Document ID 2163, Testimony 1, p. 14). After considering this suggestion, OSHA decided not to incorporate it into the rule. OSHA anticipates that, in some cases, employers may be able to work with unions or trade associations to ensure that medical examinations are provided that meet the requirements of the rule, and that records are maintained. However, in many cases, unions and trade associations will not be available to provide such services. And in any case, the employer is ultimately responsible for ensuring that medical examinations are provided in accordance with the rule. Consistent with OSHA's access to employee exposure and medical records standard (29 CFR 1910.1020), the rule therefore requires the employer to maintain such records, and the employer must ensure the PLHCP retains the medical records for the employee's duration of employment plus 30 years. As stated earlier, the employer can generally fulfill this obligation by including the retention requirement in the contractual agreement between the employer and the PLHCP.

Commenters such as the International Union of Bricklayers and Allied Craftworkers (BAC) and ASSE stated that records should be made available to the employee and the employee's designated representative(s), at the request of the employee (*e.g.,* Document ID 2329, p. 8; 2339, p. 5). OSHA agrees, and employees and their representatives are permitted to obtain a copy of exposure and medical records pursuant to 29 CFR 1910.1020(e)(iii).

Commenters such as the Building and Construction Trades Department, AFL–CIO (BCTD) and BAC requested the addition of a provision for retaining training records in the rule (*e.g.,* Document ID 2371, Attachment 1, p. 50; 2329, p. 8). BAC recommended that employers in the construction industry could use a portable training management system that is designed to track employees' training throughout their career (Document ID 4053, Attachment 1 and Exhibit 2). To keep track of training records, BCTD recommended that employers could use the same portable training management system recommended by BAC or use a portable database, as described in a report by the Mount Sinai Irving J. Selikoff Center for Occupational and Environmental Medicine (Document ID 4223, p. 126; 4073, Attachment 2b).

OSHA is not including a provision for retaining training records in the rule because the Agency has concluded that requiring such records is not necessary. The performance-oriented requirements for training in paragraph (j) of the standard for general industry and maritime (paragraph (i) of the standard for construction) specify that employees must be able to demonstrate knowledge of the health hazards associated with exposure to respirable crystalline silica; tasks that could result in exposure; procedures to protect employees from exposure; as well as the silica standard and the medical surveillance program it requires. These requirements will be sufficient to ensure that employees are adequately trained with regard to recognizing silica hazards and taking protective measures. Moreover, adding a provision for retention of training records would involve additional paperwork burdens for employers. The absence of a requirement for retention of training records in the rule is consistent with OSHA's hazard communication standard (29 CFR 1910.1200), addressing training for all hazardous chemicals, as well as the most recent OSHA substance-specific health standards, addressing exposure to 1,3-butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026).

The recordkeeping requirements of the rule are also generally consistent with the recordkeeping provisions of the industry consensus standards, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica and ASTM E 2625–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities. The main substantive differences are related to the use of social security numbers and duration of retention of records. ASTM E 1132–06 and ASTM E 2625–09 specify that the employer should include an identification number for each employee monitored for dust exposure, but do not indicate that the number must be a social security number, whereas OSHA's rule requires the employer to include the employee's social security number. As noted above, although OSHA intends to reconsider this policy for all standards in a future rulemaking, the Agency has determined that the use of social security numbers is appropriate for this rule. ASTM E 1132–06 specifies that medical and exposure records should be retained for 40 years or the duration of employment plus 20 years, whichever is longer. ASTM E 2625–09 does not specify a duration for retaining exposure or medical records. OSHA has determined that the retention requirements of 29 CFR 1910.1020 are appropriate for exposure and medical records collected under this rule, because the requirements represent a reasonable balance between the need to maintain records and the administrative burdens associated with maintaining those records, and are consistent with longstanding practice by the Agency with which employers are familiar and to which they are accustomed; changing the duration of retention requirement for this one rule could therefore cause confusion.

Dates

Paragraph (l) of the standard for general industry and maritime (paragraph (k) of the standard for construction) sets forth the effective date of the standard and the date(s) for

compliance with the requirements of the standard. OSHA proposed identical requirements for both standards: An effective date 60 days after publication of the rule; a date for compliance with all provisions except engineering controls and laboratory requirements of 180 days after the effective date; a date for compliance with engineering controls requirements, which was one year after the effective date; and a date for compliance with laboratory requirements of two years after the effective date.

The United Steelworkers supported the proposed effective and start-up dates, arguing that they provide adequate time for employers to come into compliance with the rule (Document ID 2336, p. 16). Employers and industry representatives such as the American Exploration and Production Council, the Tile Council of North America, and Ameren requested that the effective date of the rule be extended (*e.g.*, Document ID 2147, p. 2; 2267, p. 7; 2315, p. 4; 2375, Attachment 1, p. 3; 2363 p. 7).

OSHA sets the effective date to allow sufficient time for employers to obtain the standard, read and understand its requirements, and undertake the necessary planning and preparation for compliance. Section 6(b)(4) of the OSH Act allows the effective date of a standard to be delayed for up to 90 days from the date of publication in the **Federal Register**. Given the requests by commenters, OSHA's interest in having employers implement effective compliance efforts, and the minimal effect of an additional 30 day delay, the Agency has decided that it is appropriate to set the effective date at 90 days from publication, rather than at 60 days. Accordingly, the rule will become effective 90 days after publication in the **Federal Register**.

Paragraphs (l)(2), (3) and (4) of the standard for general industry and maritime (paragraphs (k)(2) and (3) of the standard for construction) establish dates for compliance with the requirements of the standard. Employers and industry representatives such as the American Petroleum Institute, the National Industrial Sand Association, Dow Chemical Company, the Glass Association of North America (GANA), and the American Foundry Society (AFS) contended that substantially more time was needed to implement engineering controls than the one year from the effective date that had been proposed (*e.g.*, Document ID 2195, pp. 8, 22; 2147, p. 1; 2267, p. 3; 2149, p. 2; 2277, p. 1; 1992, pp. 4, 12; 2023, p. 4; 2315 pp. 4, 9; 2137; 2047; 2215, p. 10; 2311, p. 3; 2291, p. 16; 2105. p. 1; 2348, Attachment 1, p. 40; 2357, p. 18; 2365, pp. 10–22; 2301, Attachment 1, pp. 64, 82; 2302, p. 9; 2327, Attachment 1; 2270, p. 1; 2279, pp. 6, 11; 2290, pp. 3–4; 2296, p. 36; 2384, p. 6; 2493, p. 5; 2379, Appendix 1, pp. 22, 73–74; 2544, p. 11).

General industry employers and trade associations were concerned with the length of time needed for the design, approval, and installation of engineering controls. For example, the AFS provided examples of how implementation of engineering controls could take longer than one year for foundries:

> The proposed compliance period fails to account for the substantial time required for a comprehensive engineering evaluation of the overall silica exposure at the facility and the design of a proposed engineering control system. The engineering phase alone for a 10,000 cfm or larger system typically takes 4 to 6 months—longer for large or complex exposure problems. This issue is further complicated by the fact that the current national economy has substantially reduced the number of firms offering these environmental services, and all of the affected foundries will be competing for these limited services. The compliance period also fails to take into effect the fact that to attempt to meet the proposed PEL with local exhaust ventilation would require custom control equipment (primarily baghouses) which are not stock items and are custom built for each application. These control systems typically require a minimum of 2 to 4 months for manufacture after the completion of the engineering specifications and submission of an order. This period is significantly longer for specialized or large orders (Document ID 2379, Attachment B, p. 37).

Another issue raised by general industry representatives and employers such as Morgan Electro Ceramics, the Asphalt Roofing Manufacturers Association, the Fertilizer Institute, and the National Association of Manufacturers, was the potential length of time involved in environmental permitting processes (*e.g.*, Document ID 1772, p. 1; 1992, Attachment 1, p. 4; 2291, Attachment 1, pp. 16–17; 3487, pp. 26–27; 3492, Attachment 1, pp. 5–6; 3584, Tr. 2845; 2290, Attachment 1, p. 3; 2380, Attachment 2, p. 20). The AFS testified on the permitting issue:

> Because many of the controls involve additions or changes to ventilation systems, OSHA must recognize the additional time required for modelling and permitting by state or federal EPA authorities. The proposed one year compliance period is totally unrealistic. In some states, the mandatory permitting requirement for both new and modified systems requires up to 18 months, and this does not include the design and modelling work necessary to prepare the permit application, or the construction and installation time after approval. For foundries which have a Title V permit, the approval includes an additional time period for the US EPA to review and make comments, and if the facility is subject to the federal Prevention of Significant Deterioration (PSD) or Lowest Achievable Emission Rate (LAER) rules the permit approval can take an additional 6 to 18 months for the detailed review and approval necessary (Document ID 3487, p. 26).

OSHA is persuaded that the concerns expressed by commenters regarding the time needed to implement engineering controls are reasonable, and is extending the compliance deadline for general industry and maritime to allow two years from the effective date for employers to comply with the standard. In extending the proposed compliance date for engineering controls in the general industry and maritime standard by one year, OSHA has concluded that engineering controls can be implemented within two years of the effective date in most general industry and maritime workplaces. However, because permit requirements and application processes vary by jurisdiction, OSHA is willing to use its enforcement discretion in situations where an employer can show it has made good faith efforts to implement engineering controls, but has been unable to implement such controls due to the time needed for environmental permitting.

OSHA understands that some general industry employers may face difficulties in implementing engineering controls due to continuous operation of facilities in particular industries. Trade associations such as the North American Insulation Manufacturers Association (NAIMA) and the GANA noted that their industries have plants that run constantly and shut down only on rare occasions, making installation of engineering controls, which would require a shutdown, unusually difficult and expensive (*e.g.*, Document ID 2348, Attachment 1, p. 40; 2215, Attachment 1, p. 10). OSHA is willing to provide latitude and work with such employers on an individual basis to schedule implementation of engineering controls during shutdowns, provided they are working in good faith toward compliance and that they provide and assure employees use appropriate respirators until engineering controls are installed.

Paragraph (l)(3)(ii) of the standard for general industry and maritime allows five years from the effective date—four years more than the proposed standard—for employers to comply with obligations for engineering controls in hydraulic fracturing operations in the

oil and gas industry. Additional time is provided to implement engineering controls in this industry to allow employers to take advantage of further development of emerging technologies discussed in Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA). Paragraph (l)(3)(iii) specifies that obligations for medical surveillance in paragraph (i)(l)(i) commence in accordance with paragraph (l)(4) for hydraulic fracturing operations in the oil and gas industry. Paragraph (l)(4) is discussed below.

Paragraph (k)(2) of the standard for construction allows one year after the effective date to come into compliance with all obligations other than the requirements for methods of sample analysis. This extends the time (one year compared to 180 days) for compliance with the standard's ancillary provisions and retains the one year period after the effective date for engineering controls. Commenting on the proposed compliance dates for construction work, several stakeholders raised issues that might impact the ability of employers to implement engineering controls within one year after the effective date (*e.g.*, Document ID 2296, Attachment 1, p. 36; 2357, p. 18). OSHA expects that the vast majority of construction employers will choose to implement the controls specified in paragraph (c) of the construction standard. These controls are generally commercial products that are readily available and can be purchased and put into use in a very short period of time. For the limited number of construction tasks that require more sophisticated controls (*e.g.*, enclosed cabs on heavy equipment used during the demolition of concrete or masonry structures), the controls are already either commonly in use or could be implemented within one year. Moreover, by implementing the controls specified in paragraph (c) of the construction standard, employers will not be required to assess employee exposures to respirable crystalline silica, so no time will be needed for assessing employee exposures prior to implementing engineering controls. OSHA finds that the ready availability of engineering controls for construction will enable construction employers to implement engineering controls within one year of the effective date, and the Agency is therefore requiring that construction employers implement engineering controls required by the standard within one year of the effective date.

In requiring that general industry and maritime employers comply with most obligations of the standard two years after the effective date, and in requiring that construction employers comply with all ancillary and engineering controls one year after the effective date, OSHA has aligned the compliance dates for other provisions of the standards with the compliance dates for engineering controls. This will allow employers to focus their efforts on implementation of engineering controls. OSHA decided that staggering the compliance dates for some provisions of the rule could serve to divert attention and resources away from the implementation of engineering controls. For example, if respiratory protection were to be required six months after the effective date (as OSHA proposed), employers would need to assess employee exposures, and would need to develop a respiratory protection program and provide appropriate respirators to employees exposed above the PEL, while simultaneously working to implement engineering controls. A requirement for respiratory protection prior to implementation of engineering controls would be particularly problematic where construction employers implement the controls specified in paragraph (c) of the construction standard. This is because those employers would not otherwise be required to assess employee exposures.

In determining the compliance dates for provisions other than engineering controls, OSHA considered the relatively short time period before engineering controls must be implemented in construction work. The Agency recognizes the longer time period allowed for general industry and maritime employers to implement engineering controls. However, general industry employers must comply with a PEL that is approximately equivalent to 100 μg/m^3 during the period before compliance with the revised PEL of 50 μg/m^3 is required, whereas construction work will be subject to a higher PEL of approximately 250 μg/m^3. The lower PEL of approximately 100 μg/m^3 that will apply to general industry will mitigate respirable crystalline silica exposures in this sector to some extent during the interim period. Moreover, because employers will be using this time to implement engineering controls, OSHA expects that exposures will continue to decline during this period. Construction will continue to be subject to the higher PEL of approximately 250 μg/m^3 during this interim, but that period will only be one year from the effective date, compared to two years from the effective date for general industry and maritime. OSHA finds that establishing consistent compliance dates for engineering controls and other provisions of the standards is less confusing, more practical, and will better enable employers to focus their time and resources on implementing the control measures that will best protect employees. For hydraulic fracturing operations in the oil and gas industry, OSHA is providing an extra three years—a total of five years from the effective date—for employers to implement engineering controls for hydraulic fracturing operations. During these additional three years, employers must comply with all other requirements of the standard, including requirements for respiratory protection to protect employees exposed to respirable crystalline silica at levels that exceed the revised PEL of 50 μg/m^3.

The issue of how much time to allow for laboratories to come into compliance with respect to methods of sample analysis received considerable comment during the rulemaking. Employers and trade and professional associations such as the National Tile Contractors Association, the Fertilizer Institute, OSCO Industries, Edison Electric Institute, and Fann Contracting, Inc. expressed concerns about the proposed rule's provisions that gave all employers one year to implement engineering controls and allowed two years before employers would be required to follow requirements for methods of sample analysis (*e.g.*, Document ID 2267, pp. 6–7; 2149, p. 2; 1992, pp. 10, 12; 2179, p. 3; 2312, p. 2; 2317, p. 2; 2314, p. 3; 2357, pp. 18–19; 2365, p. 22; 2116, Attachment 1, p. 48; 2327, p. 29; 2368, p. 3; 2379, Attachment B, p. 37; 3398, pp. 1–2; 3487, p. 27; 3491, p. 5; 2363, p. 6). For example, Andy Fulton of ME Global stated:

> OSHA is giving laboratories 2 years to improve their procedures for accurate silica analysis. However, OSHA is requiring foundries to install expensive engineering controls within one year, before accurate exposure levels are available. This does not make sense, especially when it could involve millions of dollars (Document ID 2149, p. 2).

In proposing to require employers to implement engineering controls and comply with other provisions of the rule before the laboratory requirements came into effect, OSHA intended to allow time for laboratory capacity to develop. As indicated in Chapter IV of the FEA, OSHA finds that it is feasible to measure exposures to respirable crystalline silica at the revised PEL and action level with a reasonable degree of accuracy and precision using methods that are currently available. Many laboratories are capable of analyzing samples in accordance with the laboratory requirements of the silica rule; OSHA

encourages employers to follow these requirements prior to the time that they are mandated. There are approximately 40 laboratories that are accredited by AIHA Laboratory Accreditation Programs for the analysis of crystalline silica (Document ID 3586, Tr. 3284). These laboratories are already capable of analyzing samples in accordance with the laboratory requirements of the silica rule.

OSHA anticipates that the additional demand for respirable crystalline silica exposure monitoring and associated laboratory analysis with the rule will be modest. Most construction employers are expected to implement the specified exposure control measures in paragraph (c) of the construction standard, and will therefore not be required to assess employee exposures, thus placing no demands on laboratories. The performance option for exposure assessment provided in both the general industry and maritime standard at paragraph (d)(2) and the construction standard at paragraph (d)(2)(ii) also serves to lessen the anticipated volume of exposure monitoring. The additional time allowed for compliance with the general industry and maritime standard further serves to diminish concerns about laboratory capacity by providing additional time for laboratory capacity to increase and distributing demand for sample analysis over an extended period of time. OSHA therefore concludes that the compliance date for methods of sample analysis of two years after the effective date is reasonable in both the general industry/maritime and construction standards. OSHA also anticipates that construction employers who perform air monitoring before the laboratory requirements go into effect (*see* paragraph (k)(3) of the construction standard) will be able to obtain reliable measurements of their employees' exposures to respirable crystalline silica.

Paragraph (l)(4) of the standard for general industry and maritime specifies that obligations in paragraph (i)(1)(i) regarding medical surveillance take effect for employees who will be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year beginning two years after the effective date. Obligations in paragraph (i)(l)(i) for employees who will be occupationally exposed to respirable crystalline silica at or above the action level (but at or below the PEL) for 30 or more days per year will commence four years after the effective date. In other words, medical surveillance will be triggered by exposures above the PEL for 30 or more days per year, beginning two years after the effective date and continuing through four years after the effective date, and will then be triggered by exposures at or above the action level for 30 or more days per year beginning four years after the effective date. As indicated in the Summary and Explanation for *Medical Surveillance*, this approach focuses initial medical surveillance efforts on those employees who are at greatest risk, while giving most employers additional time to fully evaluate the engineering controls they have implemented in order to determine which employees meet the action level trigger for medical surveillance.

Commenters such as NAIMA and the National Concrete Masonry Association voiced concerns about the proposed rule's effects on small businesses, and asked for compliance extensions for small businesses (*e.g.,* Document ID 2348, Attachment 1, p. 41; 2279, Attachment 1, p. 10). OSHA has considered these concerns, and has found that the compliance dates set forth in this section are reasonable for employers of all sizes. Therefore, OSHA has not created exceptions extending the compliance period for specific business classes or sizes.

OSHA also considered comments from the U.S. Chamber of Commerce and the National Stone, Sand, and Gravel Association, among others, expressing concern that the rule would create increased demand for health and safety professionals and for medical professionals; they alleged there are not enough professionals in those fields to service the demand that would be created by the rule (*e.g.,* Document ID 2365, Attachment 1, p. 10; 2237, Attachment 1, p. 4; 3578, Tr. 1127). The Agency does not find these arguments convincing. Most of the provisions of the rule do not generally require the involvement of a health or safety professional, or require only limited oversight from a health or safety professional. For example, exposure monitoring does not need to be performed by certified industrial hygienists; technicians and other trained employees can perform this task. Employer compliance with the specified exposure control methods in paragraph (c) of the construction standard can generally be accomplished without the involvement of a health or safety professional. Compliance with other obligations, such as housekeeping and training requirements, can also be achieved without the involvement of a health or safety professional or with minimal oversight from them. There are a sufficient number of medical professionals available for employers to implement the medical surveillance provisions of the rule. The availability of medical professionals is confirmed and discussed in detail in the summary and explanation of *Medical Surveillance* in this preamble. Therefore, the Agency finds no evidence in the record that a shortage of available health and safety professionals, or a shortage of medical professionals, will preclude employers from complying with the rule by the dates set forth in this paragraph.

Thus, the effect of changes made to the proposed rule is that: (1) All obligations (*i.e.,* exposure assessment and other ancillary provisions, engineering controls) for general industry and maritime employers (other than hydraulic fracturing operations in the oil and gas industry and an action level trigger for medical surveillance for all general industry and maritime employers) will become enforceable two years after the 90-day effective date of the rule; (2) all obligations for hydraulic fracturing operations in the oil and gas industry (except obligations for engineering controls and an action level trigger for medical surveillance) will become enforceable two years after the 90-day effective date; (3) obligations for engineering controls for hydraulic fracturing operations in the oil and gas industry will become enforceable five years after the 90-day effective date; (4) obligations for an action level trigger for medical surveillance in the standard for general industry and maritime, including hydraulic fracturing operations in the oil and gas industry, will become enforceable four years after the 90-day effective date; (5) all obligations (other than requirements for methods of sample analysis) for construction employers will become enforceable one year after the 90-day effective date; and (6) requirements for methods of sample analysis, applicable to laboratories covered by paragraph (d)(2)(v) of the standard for construction, become enforceable two years after the effective date, *i.e.,* one year after the other requirements in the construction standard and on the same date as all obligations in general industry and maritime (other than hydraulic fracturing).

Appendix A to § 1910.1053 and § 1926.1153—Methods of Sample Analysis

Appendix A, which specifies methods of sample analysis, is included as part of each standard, 29 CFR 1910.1053 and 29 CFR 1926.1153. Employers must ensure that all samples taken to satisfy monitoring requirements of the standards are evaluated by a laboratory that analyzes air samples for respirable crystalline silica in accordance with the

procedures in Appendix A (paragraph (d)(5) of the standard for general industry and maritime and paragraph (d)(2)(v) of the standard for construction).

OSHA proposed analysis requirements that it had included as part of paragraph (d) of both standards. The Southern Company recommended that OSHA require use of accredited laboratories and move all other laboratory requirements to an Appendix as a guide for laboratories that analyze silica samples (Document ID 2185, p. 7).

OSHA has retained the substance of the proposed provisions addressing analysis of samples, but has moved these provisions to a new appendix in each standard. The Agency has decided that segregating these specifications in an appendix to each final standard provides greater clarity for both employers and the laboratories that analyze samples.

Appendix A specifies procedures for the laboratories conducting the analysis, but employers must ensure samples taken to satisfy the monitoring requirements of the standard are analyzed by an accredited laboratory using the methods and quality control procedures described in this Appendix. Putting the requirements in a separate appendix, rather than in the regulatory text, facilitates the communication of these requirements to the laboratory analyzing samples. The appendix approach is also meant to clarify that an employer who engages a laboratory to analyze respirable crystalline silica samples may rely on an assurance from that laboratory that the specified requirements were met. For example, the laboratory could include a statement that it complied with the requirements of the standard along with the sampling results provided to the employer, or the employer could obtain the information from the laboratory or industrial hygiene service provider.

Appendix A to the final standards describes the specific analytical methods to be used, as well as the qualifications of the laboratories at which the samples are analyzed. As discussed in greater detail in Chapter IV of the Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA), the sampling and analysis methods required by the rule are technologically feasible in that they are widely used and accepted as the best available methods for measuring individual exposures to respirable crystalline silica. The Agency has determined that the provisions in Appendix A are needed to ensure the accuracy of monitoring required by the rule to measure employee exposures.

OSHA has typically included specifications for the accuracy of exposure monitoring methods in substance-specific standards, but has not always specified the analytical methods to be used or the qualifications of the laboratory that analyzes the samples. Exceptions are the asbestos standards for general industry (29 CFR 1910.1001, Appendix A) and construction (29 CFR 1926.1101, Appendix A), which specify the sampling and analytical methods to be used, as well as quality control procedures to be implemented by laboratories.

Consistent with the evaluation of sampling and analysis methods in the FEA, under the Appendix (A.1), all samples taken to satisfy the monitoring requirements of this section must be evaluated using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500, NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7. OSHA has determined based on inter-laboratory comparisons that laboratory analysis by either X-ray diffraction (XRD) or infrared (IR) spectroscopy is required to ensure the accuracy of the monitoring results. The specified analytical methods are the XRD or IR methods for analysis of respirable crystalline silica that have been established by OSHA, NIOSH, or MSHA.

To ensure the accuracy of air sampling data relied on by employers to achieve compliance with the standard, the standard requires that employers must have air samples analyzed only at laboratories that meet requirements listed in A.2 through A.6.3. The requirements were developed based on recommendations for quality control procedures to improve agreement in analytical results obtained by laboratories (Eller *et al.,* 1999, Document ID 1688, pp. 23–24). According to Dr. Rosa Key-Schwartz, NIOSH's expert in crystalline silica analysis, NIOSH worked closely with AIHA Laboratory Accreditation Programs to implement a silica emphasis program for site visitors who audit accredited laboratories to ensure that these quality control procedures are being followed (Document ID 3579, Tr. 153). As discussed in the FEA, analysis of recent data from the AIHA Proficiency Analytical Testing (PAT) program showed that laboratory performance has improved in recent years, resulting in greater agreement between labs, and this has been attributed to improvement in quality control procedures (Document ID 3998, Attachment 8; *see* also Section IV of the FEA).

A.2 requires employers to ensure that samples taken to monitor employee exposures are analyzed by a laboratory that is accredited to ANS/ISO/IEC Standard 17025 ''General requirements for the competence of testing and calibration laboratories'' (EN ISO/IEC 17025:2005) by an accrediting organization that can demonstrate compliance with the requirements of ISO/IEC 17011 ''Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies'' (EN ISO/IEC 17011:2004). ANS/ISO/IEC 17025 is a consensus standard that was developed by the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) and approved by the American Society for Testing and Materials (ASTM). This standard establishes criteria by which laboratories can demonstrate proficiency in conducting laboratory analysis through the implementation of quality control measures. To demonstrate competence, laboratories must implement a quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error (SAE) when reporting samples. ISO/IEC 17011 establishes criteria for organizations that accredit laboratories under ISO/IEC 17025. For example, the AIHA accredits laboratories for proficiency in the analysis of crystalline silica using criteria based on the ISO 17025 and other criteria appropriate for the scope of the accreditation.

Appendix A.3–A.6.3 contain additional quality control procedures for laboratories that have been demonstrated to improve accuracy and reliability through inter-laboratory comparisons. The proposed rule would have required that laboratories participate in a round robin testing program with at least two other independent laboratories at least every six months. OSHA deleted this requirement in the final rule since accredited laboratories must participate in the AIHA PAT program. The laboratory must use the most current National Institute of Standards and Technology (NIST) or NIST-traceable standards for instrument calibration or instrument calibration verification (Appendix A.3). The laboratory must have an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error (Appendix A.4). The

laboratory must characterize the sample material by identifying polymorphs of respirable crystalline silica present, identifying the presence of any interfering compounds that might affect the analysis, and making the corrections necessary in order to obtain accurate sample analysis (Appendix A.5). The laboratory must analyze quantitatively for respirable crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, and corrects for analytical interferences (Appendix A.6). The laboratory must perform routine calibration checks with standards that bracket the sample concentrations using five or more calibration standard levels to prepare calibration curves, and use instruments optimized to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL (Appendix A.6.1–A.6.3).

Several stakeholders commented that requiring employers to analyze samples for all polymorphs (*e.g.,* quartz, cristobalite, tridymite) would be unnecessarily burdensome, especially where the employer knows that some polymorphs are not present in its operations (Document ID 2215, p. 9; 2291, p. 24; 2348, Attachment 1, pp. 33–34; 4213, p. 4; 3588, Tr. 3968). OSHA does not intend for A.5 to require analysis for all polymorphs for every sample. Employers can consult with their laboratories or industrial hygiene service providers to determine which polymorphs are likely to be present in a sample given the nature of the material and processes employed. For example, if a material used by an employer is known to contain only quartz, and that material is not subjected to high temperatures, it is unlikely that cristobalite is present. Likewise, if prior sampling results failed to find cristobalite in airborne dust, there would be no need to analyze samples for cristobalite on a continuing basis. OSHA expects that laboratories and industrial hygiene service providers will be able to guide employers on the sample analyses necessary to ensure compliance with the rule without having to incur unnecessary analytical costs.

Appendix B to § 1910.1053 and § 1926.1153—Medical Surveillance

Appendix B of each standard, 29 CFR 1910.1053 and 29 CFR 1926.1153, contains medical surveillance guidelines to assist in complying with the medical surveillance provisions and provides other helpful recommendations and information. Appendix B is for informational and guidance purposes only and none of the statements in Appendix B should be construed as imposing a mandatory requirement on employers that is not otherwise imposed by the standard. In addition, this appendix is not intended to detract from any obligation that the rule imposes. American College of Occupational Medicine (ACOEM), National Institute for Occupational Safety and Health (NIOSH), American Public Health Association, and the National Consumers League supported the inclusion of an appendix for medical surveillance guidelines (Document ID 2080, p. 2; 2177, Attachment B, p. 41; 2178, Attachment 1, p. 4; 2373, p. 4).

The medical surveillance guidelines were in Appendix A of each proposed standard but were moved to Appendix B of the final standards, following the addition of Appendix A for methods of sample analysis. OSHA received some comments recommending corrections or clarifications to Appendix B. For example, NIOSH and the National Industrial Sand Association requested that OSHA update the discussion of digital radiography to include the most recent International Labour Office policy, as was done in the preamble, and NIOSH suggested several clarifications to the discussions on silicosis, specialists and specialist referrals, and tuberculosis (Document ID 2177, Attachment B, pp. 41, 48–50; 2195, pp. 44, 46). OSHA considered those comments and made changes as needed. In addition, OSHA revised Appendix B to make it consistent with the updates to the rule.

American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) requested that the appendix discuss medical confidentiality and provide guidance on information that may be provided to the employer without the employee's informed consent (Document ID 4204, p. 90). OSHA agrees that it is important to discuss this type of information in Appendix B because the information that the physician or licensed health care professional (PLHCP) is to provide to the employer under the standards has changed substantially from the proposal, and Appendix B may serve as the PLHCP's primary source of information about medical surveillance under the standards. Therefore OSHA has included a discussion on medical confidentiality. In addition, OSHA has included examples of the PLHCP's written medical report for the employee, the PLHCP's written medical opinion for the employer, and an authorization form to allow limitations on respirable crystalline silica exposure or recommendations for a specialist examination to be reported to the employer. OSHA expects the example report, opinion, and authorization form will greatly clarify the type of information that is to be reported to the employer.

Some commenters requested that additional information be added to the appendix. ACOEM, NIOSH and Building and Construction Trades Department, AFL–CIO requested that the appendix include spirometry guidelines or reference values (Document ID 2080, p. 9; 2177, Attachment B, pp. 45–46; 4223, pp. 128–130). Collegium Ramazzini requested that the appendix include a standardized medical and exposure history (Document ID 3541, pp. 3, 6). AFL–CIO recommended that the appendix include a discussion on low dose computed tomography (LDCT) screening for lung cancer (Document ID, 4204, p. 82). OSHA is not including the information requested by these commenters in Appendix B for reasons discussed more fully in the summary and explanation for *Medical Surveillance.* OSHA is not including spirometry guidance because of the widespread availability of useful guidance, including an OSHA spirometry guidance available through OSHA's Web site. Instead of including a standardized medical and exposure history form, Appendix B includes a discussion of the information to be collected as part of a history that will allow PLHCPs to easily update their current history forms. Appendix B also does not include a discussion about LDCT screening for lung cancer because too little is currently known about the risks and benefits of such screening for employees exposed to respirable crystalline silica.

List of Subjects in 29 CFR Parts 1910, 1915, and 1926

Cancer, Chemicals, Cristobalite, Crystalline silica, Hazardous substances, Health, Lung Diseases, Occupational safety and health, Quartz, Reporting and recordkeeping requirements, Silica, Silicosis, Tridymite.

Authority and Signature

This document was prepared under the direction of David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

The Agency issues the sections under the following authorities: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 107 of the Contract Work

Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 3704); section 41 of the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order 1–2012 (77 FR 3912 (1/25/2012)); and 29 CFR part 1911.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons set forth in the preamble, 29 CFR parts 1910, 1915, and 1926, of the Code of Federal Regulations are amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart Z—[Amended]

■ 1. The authority citation for subpart Z of part 1910 is revised to read as follows:

Authority: Secs. 4, 6, 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911. All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act of 1970, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

■ 2. In § 1910.1000, paragraph (e):

■ a. Amend Table Z–1—Limits on Air Contaminants by:

■ i. Revising the entries for ''Silica, crystalline cristobalite, respirable dust''; ''Silica, crystalline quartz, respirable dust''; Silica, crystalline tripoli (as quartz), respirable dust''; and ''Silica, crystalline tridymite, respirable dust''; and

■ ii. Adding footnote 7.

■ b. Amend Table Z–3–Mineral Dusts by:

■ i. Revising the entries for ''Silica: Crystalline Quartz (Respirable)'', ''Silica: Crystalline Cristobalite'', and ''Silica: Crystalline Tridymite'';

■ ii. Removing entries in columns 1, 2, and 3 for ''Silica: Crystalline Quartz (Total Dust)'' and

■ iii. Adding footnote f.

The revisions and addition read as follows:

§ 1910.1000 Air contaminants.

* * * * *

The revisions and addition read as follows:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–1—LIMITS FOR AIR CONTAMINANTS

Substance	CAS No. (c)	ppm(a) [1]	mg/m³(b) [1]	Skin designation
* * * *	*	*	*	
Silica, crystalline, respirable dust				
Cristobalite; see 1910.1053 [7]	14464–46–1			
Quartz; see 1910.1053 [7]	14808–60–7			
Tripoli (as quartz); see 1910.1053 [7]	1317–95–9			
Tridymite; see 1910.1053 [7]	15468–32–3			
* * * *	*	*	*	

* * * * * * *

[1] The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

(a) Parts of vapor or gas per million parts of contaminated air by volume at 25 °C and 760 torr.

(b) Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

(c) The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

(d) The final benzene standard in 1910.1028 applies to all occupational exposures to benzene except in some circumstances the distribution and sale of fuels, sealed containers and pipelines, coke production, oil and gas drilling and production, natural gas processing, and the percentage exclusion for liquid mixtures; for the excepted subsegments, the benzene limits in Table Z–2 apply. See 1910.1028 for specific circumstances.

(e) This 8-hour TWA applies to respirable dust as measured by a vertical elutriator cotton dust sampler or equivalent instrument. The time-weighted average applies to the cottom waste processing operations of waste recycling (sorting, blending, cleaning and willowing) and garnetting. See also 1910.1043 for cotton dust limits applicable to other sectors.

(f) All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by the Particulates Not Otherwise Regulated (PNOR) limit which is the same as the inert or nuisance dust limit of Table Z–3.

* * * * * * *

[3] See Table Z–3.

* * * * * * *

[7] See Table Z–3 for the exposure limit for any operations or sectors where the exposure limit in § 1910.1053 is stayed or is otherwise not in effect.

* * * * * * *

TABLE Z–3—MINERAL DUSTS

Substance	mppcf [a]	mg/m³
Silica:		
Crystalline		

TABLE Z–3—MINERAL DUSTS—Continued

Substance	mppcf [a]	mg/m^3
Quartz (Respirable) [f]	250 [b]	10 mg/m^3 [e]
	%SiO_2+5	% SiO_2+2
Cristobalite: Use ½ the value calculated from the count or mass formulae for quartz [f]		
Tridymite: Use ½ the value calculated from the formulae for quartz [f]		
* * * * * * *		
* * * * * * *		

[a] Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques.

[b] The percentage of crystalline silica in the formula is the amount determined from airborne samples, except in those instances in which other methods have been shown to be applicable.

* * * * * * *

[e] Both concentration and percent quartz for the application of this limit are to be determined from the fraction passing a size-selector with the following characteristics:

Aerodynamic diameter (unit density sphere)	Percent passing selector
2	90
2.5	75
3.5	50
5.0	25
10	0

The measurements under this note refer to the use of an AEC (now NRC) instrument. The respirable fraction of coal dust is determined with an MRE; the figure corresponding to that of 2.4 mg/m^3 in the table for coal dust is 4.5 mg/m^{3K}.

[f] This standard applies to any operations or sectors for which the respirable crystalline silica standard, 1910.1053, is stayed or is otherwise not in effect.

■ 4. Add § 1910.1053 to read as follows:

§ 1910.1053 Respirable Crystalline Silica.

(a) *Scope and application.* (1) This section applies to all occupational exposures to respirable crystalline silica, except:

(i) Construction work as defined in 29 CFR 1910.12(b) (occupational exposures to respirable crystalline silica in construction work are covered under 29 CFR 1926.1153);

(ii) Agricultural operations covered under 29 CFR part 1928; and

(iii) Exposures that result from the processing of sorptive clays.

(2) This section does not apply where the employer has objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 micrograms per cubic meter of air (25 μg/m^3) as an 8-hour time-weighted average (TWA) under any foreseeable conditions.

(3) This section does not apply if the employer complies with 29 CFR 1926.1153 and:

(i) The task performed is indistinguishable from a construction task listed on Table 1 in paragraph (c) of 29 CFR 1926.1153; and

(ii) The task will not be performed regularly in the same environment and conditions.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne respirable crystalline silica of 25 μg/m^3, calculated as an 8-hour TWA.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Employee exposure means the exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (i) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.

Respirable crystalline silica means quartz, cristobalite, and/or tridymite contained in airborne particles that are determined to be respirable by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

Specialist means an American Board Certified Specialist in Pulmonary Disease or an American Board Certified Specialist in Occupational Medicine.

This section means this respirable crystalline silica standard, 29 CFR 1910.1053.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of respirable crystalline silica in excess of 50 μg/m^3, calculated as an 8-hour TWA.

(d) *Exposure assessment*—(1) *General.* The employer shall assess the exposure of each employee who is or may reasonably be expected to be exposed to respirable crystalline silica at or above

the action level in accordance with either the performance option in paragraph (d)(2) or the scheduled monitoring option in paragraph (d)(3) of this section.

(2) *Performance option.* The employer shall assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica.

(3) *Scheduled monitoring option.* (i) The employer shall perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet this requirement. In representative sampling, the employer shall sample the employee(s) who are expected to have the highest exposure to respirable crystalline silica.

(ii) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

(iii) Where the most recent exposure monitoring indicates that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring within six months of the most recent monitoring.

(iv) Where the most recent exposure monitoring indicates that employee exposures are above the PEL, the employer shall repeat such monitoring within three months of the most recent monitoring.

(v) Where the most recent (non-initial) exposure monitoring indicates that employee exposures are below the action level, the employer shall repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken 7 or more days apart, are below the action level, at which time the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this section.

(4) *Reassessment of exposures.* The employer shall reassess exposures whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred.

(5) *Methods of sample analysis.* The employer shall ensure that all samples taken to satisfy the monitoring requirements of paragraph (d) of this section are evaluated by a laboratory that analyzes air samples for respirable crystalline silica in accordance with the procedures in Appendix A to this section.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this section, the employer shall individually notify each affected employee in writing of the results of that assessment or post the results in an appropriate location accessible to all affected employees.

(ii) Whenever an exposure assessment indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(7) *Observation of monitoring.* (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to respirable crystalline silica.

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required for any workplace hazard, the employer shall provide the observer with protective clothing and equipment at no cost and shall ensure that the observer uses such clothing and equipment.

(e) *Regulated areas*—(1) *Establishment.* The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL.

(2) *Demarcation.* (i) The employer shall demarcate regulated areas from the rest of the workplace in a manner that minimizes the number of employees exposed to respirable crystalline silica within the regulated area.

(ii) The employer shall post signs at all entrances to regulated areas that bear the legend specified in paragraph (j)(2) of this section.

(3) *Access.* The employer shall limit access to regulated areas to:

(A) Persons authorized by the employer and required by work duties to be present in the regulated area;

(B) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; and

(C) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(4) *Provision of respirators.* The employer shall provide each employee and the employee's designated representative entering a regulated area with an appropriate respirator in accordance with paragraph (g) of this section and shall require each employee and the employee's designated representative to use the respirator while in a regulated area.

(f) *Methods of compliance*—(1) *Engineering and work practice controls.* The employer shall use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL, unless the employer can demonstrate that such controls are not feasible. Wherever such feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them with the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) *Written exposure control plan.* (i) The employer shall establish and implement a written exposure control plan that contains at least the following elements:

(A) A description of the tasks in the workplace that involve exposure to respirable crystalline silica;

(B) A description of the engineering controls, work practices, and respiratory protection used to limit employee exposure to respirable crystalline silica for each task; and

(C) A description of the housekeeping measures used to limit employee exposure to respirable crystalline silica.

(ii) The employer shall review and evaluate the effectiveness of the written exposure control plan at least annually and update it as necessary.

(iii) The employer shall make the written exposure control plan readily available for examination and copying, upon request, to each employee covered by this section, their designated representatives, the Assistant Secretary and the Director.

(3) *Abrasive blasting.* In addition to the requirements of paragraph (f)(1) of this section, the employer shall comply

with other OSHA standards, when applicable, such as 29 CFR 1910.94 (Ventilation), 29 CFR 1915.34 (Mechanical paint removers), and 29 CFR 1915 Subpart I (Personal Protective Equipment), where abrasive blasting is conducted using crystalline silica-containing blasting agents, or where abrasive blasting is conducted on substrates that contain crystalline silica.

(g) *Respiratory protection*—(1) *General.* Where respiratory protection is required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph and 29 CFR 1910.134. Respiratory protection is required:

(i) Where exposures exceed the PEL during periods necessary to install or implement feasible engineering and work practice controls;

(ii) Where exposures exceed the PEL during tasks, such as certain maintenance and repair tasks, for which engineering and work practice controls are not feasible;

(iii) During tasks for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL; and

(iv) During periods when the employee is in a regulated area.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(h) *Housekeeping.* (1) The employer shall not allow dry sweeping or dry brushing where such activity could contribute to employee exposure to respirable crystalline silica unless wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure are not feasible.

(2) The employer shall not allow compressed air to be used to clean clothing or surfaces where such activity could contribute to employee exposure to respirable crystalline silica unless:

(i) The compressed air is used in conjunction with a ventilation system that effectively captures the dust cloud created by the compressed air; or

(ii) No alternative method is feasible.

(i) *Medical surveillance*—(1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be occupationally exposed to respirable crystalline silica at or above the action level for 30 or more days per year.

(ii) The employer shall ensure that all medical examinations and procedures required by this section are performed by a PLHCP as defined in paragraph (b) of this section.

(2) *Initial examination.* The employer shall make available an initial (baseline) medical examination within 30 days after initial assignment, unless the employee has received a medical examination that meets the requirements of this section within the last three years. The examination shall consist of:

(i) A medical and work history, with emphasis on: Past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (*e.g.*, shortness of breath, cough, wheezing); history of tuberculosis; and smoking status and history;

(ii) A physical examination with special emphasis on the respiratory system;

(iii) A chest X-ray (a single posteroanterior radiographic projection or radiograph of the chest at full inspiration recorded on either film (no less than 14 x 17 inches and no more than 16 x 17 inches) or digital radiography systems), interpreted and classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader;

(iv) A pulmonary function test to include forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) and FEV_1/FVC ratio, administered by a spirometry technician with a current certificate from a NIOSH-approved spirometry course;

(v) Testing for latent tuberculosis infection; and

(vi) Any other tests deemed appropriate by the PLHCP.

(3) *Periodic examinations.* The employer shall make available medical examinations that include the procedures described in paragraph (i)(2) of this section (except paragraph (i)(2)(v)) at least every three years, or more frequently if recommended by the PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the PLHCP with the following information:

(i) A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

(ii) The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

(5) *PLHCP's written medical report for the employee.* The employer shall ensure that the PLHCP explains to the employee the results of the medical examination and provides each employee with a written medical report within 30 days of each medical examination performed. The written report shall contain:

(i) A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment;

(ii) Any recommended limitations on the employee's use of respirators;

(iii) Any recommended limitations on the employee's exposure to respirable crystalline silica; and

(iv) A statement that the employee should be examined by a specialist (pursuant to paragraph (i)(7) of this section) if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a specialist is otherwise deemed appropriate by the PLHCP.

(6) *PLHCP's written medical opinion for the employer.* (i) The employer shall obtain a written medical opinion from the PLHCP within 30 days of the medical examination. The written opinion shall contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this section; and

(C) Any recommended limitations on the employee's use of respirators.

(ii) If the employee provides written authorization, the written opinion shall also contain either or both of the following:

(A) Any recommended limitations on the employee's exposure to respirable crystalline silica;

(B) A statement that the employee should be examined by a specialist (pursuant to paragraph (i)(7) of this section) if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a specialist is

otherwise deemed appropriate by the PLHCP.

(iii) The employer shall ensure that each employee receives a copy of the written medical opinion described in paragraph (i)(6)(i) and (ii) of this section within 30 days of each medical examination performed.

(7) *Additional examinations.* (i) If the PLHCP's written medical opinion indicates that an employee should be examined by a specialist, the employer shall make available a medical examination by a specialist within 30 days after receiving the PLHCP's written opinion.

(ii) The employer shall ensure that the examining specialist is provided with all of the information that the employer is obligated to provide to the PLHCP in accordance with paragraph (i)(4) of this section.

(iii) The employer shall ensure that the specialist explains to the employee the results of the medical examination and provides each employee with a written medical report within 30 days of the examination. The written report shall meet the requirements of paragraph (i)(5) (except paragraph (i)(5)(iv)) of this section.

(iv) The employer shall obtain a written opinion from the specialist within 30 days of the medical examination. The written opinion shall meet the requirements of paragraph (i)(6) (except paragraph (i)(6)(i)(B) and (i)(6)(ii)(B)) of this section.

(j) *Communication of respirable crystalline silica hazards to employees*—(1) *Hazard communication.* The employer shall include respirable crystalline silica in the program established to comply with the hazard communication standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of crystalline silica and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (j)(3) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer, lung effects, immune system effects, and kidney effects.

(2) Signs. The employer shall post signs at all entrances to regulated areas that bear the following legend:

DANGER
RESPIRABLE CRYSTALLINE SILICA
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(3) *Employee information and training.* (i) The employer shall ensure that each employee covered by this section can demonstrate knowledge and understanding of at least the following:

(A) The health hazards associated with exposure to respirable crystalline silica;

(B) Specific tasks in the workplace that could result in exposure to respirable crystalline silica;

(C) Specific measures the employer has implemented to protect employees from exposure to respirable crystalline silica, including engineering controls, work practices, and respirators to be used;

(D) The contents of this section; and

(E) The purpose and a description of the medical surveillance program required by paragraph (i) of this section.

(ii) The employer shall make a copy of this section readily available without cost to each employee covered by this section.

(k) *Recordkeeping*—(1) *Air monitoring data.* (i) The employer shall make and maintain an accurate record of all exposure measurements taken to assess employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The task monitored;

(C) Sampling and analytical methods used;

(D) Number, duration, and results of samples taken;

(E) Identity of the laboratory that performed the analysis;

(F) Type of personal protective equipment, such as respirators, worn by the employees monitored; and

(G) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Objective data.* (i) The employer shall make and maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The crystalline silica-containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing;

(D) A description of the process, task, or activity on which the objective data were based; and

(E) Other data relevant to the process, task, activity, material, or exposures on which the objective data were based.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Medical surveillance.* (i) The employer shall make and maintain an accurate record for each employee covered by medical surveillance under paragraph (i) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCPs' and specialists' written medical opinions; and

(C) A copy of the information provided to the PLHCPs and specialists.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(l) *Dates.* (1) This section is effective June 23, 2016.

(2) Except as provided for in paragraphs (l)(3) and (4) of this section, all obligations of this section commence June 23, 2018.

(3) For hydraulic fracturing operations in the oil and gas industry:

(i) All obligations of this section, except obligations for medical surveillance in paragraph (i)(1)(i) and engineering controls in paragraph (f)(1) of this section, commence June 23, 2018;

(ii) Obligations for engineering controls in paragraph (f)(1) of this section commence June 23, 2021; and

(iii) Obligations for medical surveillance in paragraph (i)(1)(i) commence in accordance with paragraph (l)(4) of this section.

(4) The medical surveillance obligations in paragraph (i)(1)(i) commence on June 23, 2018, for employees who will be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year. Those obligations commence June 23, 2020, for employees who will be occupationally exposed to respirable crystalline silica at or above the action level for 30 or more days per year.

Appendix A to § 1910.1053—Methods of Sample Analysis

This appendix specifies the procedures for analyzing air samples for respirable crystalline silica, as well as the quality control procedures that employers must ensure that laboratories use when performing an analysis required under 29 CFR 1910.1053 (d)(5). Employers must ensure that such a laboratory:

1. Evaluates all samples using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500; NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7;

2. Is accredited to ANS/ISO/IEC Standard 17025:2005 with respect to crystalline silica analyses by a body that is compliant with ISO/IEC Standard 17011:2004 for implementation of quality assessment programs;

3. Uses the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification;

4. Implements an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error;

5. Characterizes the sample material by identifying polymorphs of respirable crystalline silica present, identifies the presence of any interfering compounds that might affect the analysis, and makes any corrections necessary in order to obtain accurate sample analysis; and

6. Analyzes quantitatively for crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, corrects for analytical interferences, and uses a method that meets the following performance specifications:

6.1 Each day that samples are analyzed, performs instrument calibration checks with standards that bracket the sample concentrations;

6.2 Uses five or more calibration standard levels to prepare calibration curves and ensures that standards are distributed through the calibration range in a manner that accurately reflects the underlying calibration curve; and

6.3 Optimizes methods and instruments to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL based on sample air volume.

Appendix B to § 1910.1053—Medical Surveillance Guidelines

Introduction

The purpose of this Appendix is to provide medical information and recommendations to aid physicians and other licensed health care professionals (PLHCPs) regarding compliance with the medical surveillance provisions of the respirable crystalline silica standard (29 CFR 1910.1053). Appendix B is for informational and guidance purposes only and none of the statements in Appendix B should be construed as imposing a mandatory requirement on employers that is not otherwise imposed by the standard.

Medical screening and surveillance allow for early identification of exposure-related health effects in individual employee and groups of employees, so that actions can be taken to both avoid further exposure and prevent or address adverse health outcomes. Silica-related diseases can be fatal, encompass a variety of target organs, and may have public health consequences when considering the increased risk of a latent tuberculosis (TB) infection becoming active. Thus, medical surveillance of silica-exposed employees requires that PLHCPs have a thorough knowledge of silica-related health effects.

This Appendix is divided into seven sections. Section 1 reviews silica-related diseases, medical responses, and public health responses. Section 2 outlines the components of the medical surveillance program for employees exposed to silica. Section 3 describes the roles and responsibilities of the PLHCP implementing the program and of other medical specialists and public health professionals. Section 4 provides a discussion of considerations, including confidentiality. Section 5 provides a list of additional resources and Section 6 lists references. Section 7 provides sample forms for the written medical report for the employee, the written medical opinion for the employer and the written authorization.

1. Recognition of Silica-Related Diseases

1.1. Overview. The term ''silica'' refers specifically to the compound silicon dioxide (SiO2). Silica is a major component of sand, rock, and mineral ores. Exposure to fine (respirable size) particles of crystalline forms of silica is associated with adverse health effects, such as silicosis, lung cancer, chronic obstructive pulmonary disease (COPD), and activation of latent TB infections. Exposure to respirable crystalline silica can occur in industry settings such as foundries, abrasive blasting operations, paint manufacturing, glass and concrete product manufacturing, brick making, china and pottery manufacturing, manufacturing of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuck-pointing. New uses of silica continue to emerge. These include countertop manufacturing, finishing, and installation (Kramer *et al.* 2012; OSHA 2015) and hydraulic fracturing in the oil and gas industry (OSHA 2012).

Silicosis is an irreversible, often disabling, and sometimes fatal fibrotic lung disease. Progression of silicosis can occur despite removal from further exposure. Diagnosis of silicosis requires a history of exposure to silica and radiologic findings characteristic of silica exposure. Three different presentations of silicosis (chronic, accelerated, and acute) have been defined. Accelerated and acute silicosis are much less common than chronic silicosis. However, it is critical to recognize all cases of accelerated and acute silicosis because these are life-threatening illnesses and because they are caused by substantial overexposures to respirable crystalline silica. Although any case of silicosis indicates a breakdown in prevention, a case of acute or accelerated silicosis implies current high exposure and a very marked breakdown in prevention.

In addition to silicosis, employees exposed to respirable crystalline silica, especially those with accelerated or acute silicosis, are at increased risks of contracting active TB and other infections (ATS 1997; Rees and Murray 2007). Exposure to respirable crystalline silica also increases an employee's risk of developing lung cancer, and the higher the cumulative exposure, the higher the risk (Steenland *et al.* 2001; Steenland and Ward 2014). Symptoms for these diseases and other respirable crystalline silica-related diseases are discussed below.

1.2. Chronic Silicosis. Chronic silicosis is the most common presentation of silicosis and usually occurs after at least 10 years of exposure to respirable crystalline silica. The clinical presentation of chronic silicosis is:

1.2.1. Symptoms—shortness of breath and cough, although employees may not notice any symptoms early in the disease. Constitutional symptoms, such as fever, loss of appetite and fatigue, may indicate other diseases associated with silica exposure, such as TB infection or lung cancer. Employees with these symptoms should immediately receive further evaluation and treatment.

1.2.2. Physical Examination—may be normal or disclose dry rales or rhonchi on lung auscultation.

1.2.3. Spirometry—may be normal or may show only a mild restrictive or obstructive pattern.

1.2.4. Chest X-ray—classic findings are small, rounded opacities in the upper lung fields bilaterally. However, small irregular opacities and opacities in other lung areas can also occur. Rarely, ''eggshell calcifications'' in the hilar and mediastinal lymph nodes are seen.

1.2.5. Clinical Course—chronic silicosis in most cases is a slowly progressive disease. Under the respirable crystalline silica standard, the PLHCP is to recommend that employees with a 1/0 category X-ray be referred to an American Board Certified Specialist in Pulmonary Disease or Occupational Medicine. The PLHCP and/or Specialist should counsel employees regarding work practices and personal habits that could affect employees' respiratory health.

1.3. Accelerated Silicosis. Accelerated silicosis generally occurs within 5–10 years of exposure and results from high levels of exposure to respirable crystalline silica. The clinical presentation of accelerated silicosis is:

1.3.1. Symptoms—shortness of breath, cough, and sometimes sputum production. Employees with exposure to respirable crystalline silica, and especially those with accelerated silicosis, are at high risk for activation of TB infections, atypical mycobacterial infections, and fungal superinfections. Constitutional symptoms, such as fever, weight loss, hemoptysis (coughing up blood), and fatigue may herald one of these infections or the onset of lung cancer.

1.3.2. Physical Examination—rales, rhonchi, or other abnormal lung findings in relation to illnesses present. Clubbing of the digits, signs of heart failure, and cor pulmonale may be present in severe lung disease.

1.3.3. Spirometry—restrictive or mixed restrictive/obstructive pattern.

1.3.4. Chest X-ray—small rounded and/or irregular opacities bilaterally. Large opacities and lung abscesses may indicate infections, lung cancer, or progression to complicated silicosis, also termed progressive massive fibrosis.

1.3.5. Clinical Course—accelerated silicosis has a rapid, severe course. Under the respirable crystalline silica standard, the PLHCP can recommend referral to a Board Certified Specialist in either Pulmonary Disease or Occupational Medicine, as deemed appropriate, and referral to a Specialist is recommended whenever the diagnosis of accelerated silicosis is being considered.

1.4. Acute Silicosis. Acute silicosis is a rare disease caused by inhalation of extremely high levels of respirable crystalline silica particles. The pathology is similar to alveolar proteinosis with lipoproteinaceous material accumulating in the alveoli. Acute silicosis develops rapidly, often, within a few months to less than 2 years of exposure, and is almost always fatal. The clinical presentation of acute silicosis is as follows:

1.4.1. Symptoms—sudden, progressive, and severe shortness of breath. Constitutional symptoms are frequently present and include fever, weight loss, fatigue, productive cough, hemoptysis (coughing up blood), and pleuritic chest pain.

1.4.2. Physical Examination—dyspnea at rest, cyanosis, decreased breath sounds, inspiratory rales, clubbing of the digits, and fever.

1.4.3. Spirometry—restrictive or mixed restrictive/obstructive pattern.

1.4.4. Chest X-ray—diffuse haziness of the lungs bilaterally early in the disease. As the disease progresses, the ''ground glass'' appearance of interstitial fibrosis will appear.

1.4.5. Clinical Course—employees with acute silicosis are at especially high risk of TB activation, nontuberculous mycobacterial infections, and fungal superinfections. Acute silicosis is immediately life-threatening. The employee should be urgently referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for evaluation and treatment. Although any case of silicosis indicates a breakdown in prevention, a case of acute or accelerated silicosis implies a profoundly high level of silica exposure and may mean that other employees are currently exposed to dangerous levels of silica.

1.5. COPD. COPD, including chronic bronchitis and emphysema, has been documented in silica-exposed employees, including those who do not develop silicosis. Periodic spirometry tests are performed to evaluate each employee for progressive changes consistent with the development of COPD. In addition to evaluating spirometry results of individual employees over time, PLHCPs may want to be aware of general trends in spirometry results for groups of employees from the same workplace to identify possible problems that might exist at that workplace. (*See* Section 2 of this Appendix on Medical Surveillance for further discussion.) Heart disease may develop secondary to lung diseases such as COPD. A recent study by Liu *et al.* 2014 noted a significant exposure-response trend between cumulative silica exposure and heart disease deaths, primarily due to pulmonary heart disease, such as cor pulmonale.

1.6. Renal and Immune System. Silica exposure has been associated with several types of kidney disease, including glomerulonephritis, nephrotic syndrome, and end stage renal disease requiring dialysis. Silica exposure has also been associated with other autoimmune conditions, including progressive systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Studies note an association between employees with silicosis and serologic markers for autoimmune diseases, including antinuclear antibodies, rheumatoid factor, and immune complexes (Jalloul and Banks 2007; Shtraichman *et al.* 2015).

1.7. TB and Other Infections. Silica-exposed employees with latent TB are 3 to 30 times more likely to develop active pulmonary TB infection (ATS 1997; Rees and Murray 2007). Although respirable crystalline silica exposure does not cause TB infection, individuals with latent TB infection are at increased risk for activation of disease if they have higher levels of respirable crystalline silica exposure, greater profusion of radiographic abnormalities, or a diagnosis of silicosis. Demographic characteristics, such as immigration from some countries, are associated with increased rates of latent TB infection. PLHCPs can review the latest Centers for Disease Control and Prevention (CDC) information on TB incidence rates and high risk populations online (*See* Section 5 of this Appendix). Additionally, silica-exposed employees are at increased risk for contracting nontuberculous mycobacterial infections, including *Mycobacterium avium-intracellulare* and *Mycobacterium kansaii*.

1.8. Lung Cancer. The National Toxicology Program has listed respirable crystalline silica as a known human carcinogen since 2000 (NTP 2014). The International Agency for Research on Cancer (2012) has also classified silica as Group 1 (carcinogenic to humans). Several studies have indicated that the risk of lung cancer from exposure to respirable crystalline silica and smoking is greater than additive (Brown 2009; Liu *et al.* 2013). Employees should be counseled on smoking cessation.

2. Medical Surveillance

PLHCPs who manage silica medical surveillance programs should have a thorough understanding of the many silica-related diseases and health effects outlined in Section 1 of this Appendix. At each clinical encounter, the PLHCP should consider silica-related health outcomes, with particular vigilance for acute and accelerated silicosis. In this Section, the required components of medical surveillance under the respirable crystalline silica standard are reviewed, along with additional guidance and recommendations for PLHCPs performing medical surveillance examinations for silica-exposed employees.

2.1. History

2.1.1. The respirable crystalline silica standard requires the following: A medical and work history, with emphasis on: Past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (*e.g.*, shortness of breath, cough, wheezing); history of TB; and smoking status and history.

2.1.2. Further, the employer must provide the PLHCP with the following information:

2.1.2.1. A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

2.1.2.2. The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

2.1.2.3. A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

2.1.2.4. Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

2.1.3. Additional guidance and recommendations: A history is particularly important both in the initial evaluation and in periodic examinations. Information on past and current medical conditions (particularly a history of kidney disease, cardiac disease, connective tissue disease, and other immune diseases), medications, hospitalizations and surgeries may uncover health risks, such as immune suppression, that could put an employee at increased health risk from exposure to silica. This information is important when counseling the employee on risks and safe work practices related to silica exposure.

2.2. Physical Examination

2.2.1. The respirable crystalline silica standard requires the following: A physical examination, with special emphasis on the respiratory system. The physical examination must be performed at the initial examination and every three years thereafter.

2.2.2. Additional guidance and recommendations: Elements of the physical examination that can assist the PHLCP include: An examination of the cardiac system, an extremity examination (for clubbing, cyanosis, edema, or joint abnormalities), and an examination of other pertinent organ systems identified during the history.

2.3. TB Testing

2.3.1. The respirable crystalline silica standard requires the following: Baseline testing for TB on initial examination.

2.3.2. Additional guidance and recommendations:

2.3.2.1. Current CDC guidelines (*See* Section 5 of this Appendix) should be followed for the application and interpretation of Tuberculin skin tests (TST). The interpretation and documentation of TST reactions should be performed within 48 to 72 hours of administration by trained PLHCPs.

2.3.2.2. PLHCPs may use alternative TB tests, such as interferon-γ release assays (IGRAs), if sensitivity and specificity are comparable to TST (Mazurek *et al.* 2010; Slater *et al.* 2013). PLHCPs can consult the current CDC guidelines for acceptable tests for latent TB infection.

2.3.2.3. The silica standard allows the PLHCP to order additional tests or test at a greater frequency than required by the standard, if deemed appropriate. Therefore, PLHCPs might perform periodic (*e.g.*, annual) TB testing as appropriate, based on employees' risk factors. For example, according to the American Thoracic Society (ATS), the diagnosis of silicosis or exposure to silica for 25 years or more are indications for annual TB testing (ATS 1997). PLHCPs

should consult the current CDC guidance on risk factors for TB (*See* Section 5 of this Appendix).

2.3.2.4. Employees with positive TB tests and those with indeterminate test results should be referred to the appropriate agency or specialist, depending on the test results and clinical picture. Agencies, such as local public health departments, or specialists, such as a pulmonary or infectious disease specialist, may be the appropriate referral. Active TB is a nationally notifiable disease. PLHCPs should be aware of the reporting requirements for their region. All States have TB Control Offices that can be contacted for further information. (*See* Section 5 of this Appendix for links to CDC's TB resources and State TB Control Offices.)

2.3.2.5. The following public health principles are key to TB control in the U.S. (ATS–CDC–IDSA 2005):

(*1*) Prompt detection and reporting of persons who have contracted active TB;

(*2*) Prevention of TB spread to close contacts of active TB cases;

(*3*) Prevention of active TB in people with latent TB through targeted testing and treatment; and

(*4*) Identification of settings at high risk for TB transmission so that appropriate infection-control measures can be implemented.

2.4. Pulmonary Function Testing

2.4.1. The respirable crystalline silica standard requires the following: Pulmonary function testing must be performed on the initial examination and every three years thereafter. The required pulmonary function test is spirometry and must include forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and FEV_1/FVC ratio. Testing must be administered by a spirometry technician with a current certificate from a National Institute for Occupational Health and Safety (NIOSH)-approved spirometry course.

2.4.2. Additional guidance and recommendations: Spirometry provides information about individual respiratory status and can be used to track an employee's respiratory status over time or as a surveillance tool to follow individual and group respiratory function. For quality results, the ATS and the American College of Occupational and Environmental Medicine (ACOEM) recommend use of the third National Health and Nutrition Examination Survey (NHANES III) values, and ATS publishes recommendations for spirometry equipment (Miller *et al.* 2005; Townsend 2011; Redlich *et al.* 2014). OSHA's publication, *Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals,* provides helpful guidance (See Section 5 of this Appendix). Abnormal spirometry results may warrant further clinical evaluation and possible recommendations for limitations on the employee's exposure to respirable crystalline silica.

2.5. Chest X-ray

2.5.1. The respirable crystalline silica standard requires the following: A single posteroanterior (PA) radiographic projection or radiograph of the chest at full inspiration recorded on either film (no less than 14 x 17 inches and no more than 16 x 17 inches) or digital radiography systems. A chest X-ray must be performed on the initial examination and every three years thereafter. The chest X-ray must be interpreted and classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader.

Chest radiography is necessary to diagnose silicosis, monitor the progression of silicosis, and identify associated conditions such as TB. If the B reading indicates small opacities in a profusion of 1/0 or higher, the employee is to receive a recommendation for referral to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine.

2.5.2. Additional guidance and recommendations: Medical imaging has largely transitioned from conventional film-based radiography to digital radiography systems. The ILO Guidelines for the Classification of Pneumoconioses has historically provided film-based chest radiography as a referent standard for comparison to individual exams. However, in 2011, the ILO revised the guidelines to include a digital set of referent standards that were derived from the prior film-based standards. To assist in assuring that digitally-acquired radiographs are at least as safe and effective as film radiographs, NIOSH has prepared guidelines, based upon accepted contemporary professional recommendations (*See* Section 5 of this Appendix). Current research from Laney *et al.* 2011 and Halldin *et al.* 2014 validate the use of the ILO digital referent images. Both studies conclude that the results of pneumoconiosis classification using digital references are comparable to film-based ILO classifications. Current ILO guidance on radiography for pneumoconioses and B-reading should be reviewed by the PLHCP periodically, as needed, on the ILO or NIOSH Web sites (*See* Section 5 of this Appendix).

2.6. Other Testing. Under the respirable crystalline silica standards, the PLHCP has the option of ordering additional testing he or she deems appropriate. Additional tests can be ordered on a case-by-case basis depending on individual signs or symptoms and clinical judgment. For example, if an employee reports a history of abnormal kidney function tests, the PLHCP may want to order a baseline renal function tests (*e.g.*, serum creatinine and urinalysis). As indicated above, the PLHCP may order annual TB testing for silica-exposed employees who are at high risk of developing active TB infections. Additional tests that PLHCPs may order based on findings of medical examinations include, but is not limited to, chest computerized tomography (CT) scan for lung cancer or COPD, testing for immunologic diseases, and cardiac testing for pulmonary-related heart disease, such as cor pulmonale.

3. Roles and Responsibilities

3.1. PLHCP. The PLHCP designation refers to ''an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required'' by the respirable crystalline silica standard. The legally permitted scope of practice for the PLHCP is determined by each State. PLHCPs who perform clinical services for a silica medical surveillance program should have a thorough knowledge of respirable crystalline silica-related diseases and symptoms. Suspected cases of silicosis, advanced COPD, or other respiratory conditions causing impairment should be promptly referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine.

Once the medical surveillance examination is completed, the employer must ensure that the PLHCP explains to the employee the results of the medical examination and provides the employee with a written medical report within 30 days of the examination. The written medical report must contain a statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment. In addition, the PLHCP's written medical report must include any recommended limitations on the employee's use of respirators, any recommended limitations on the employee's exposure to respirable crystalline silica, and a statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational medicine if the chest X-ray is classified as 1/0 or higher by the B Reader, or if referral to a Specialist is otherwise deemed appropriate by the PLHCP.

The PLHCP should discuss all findings and test results and any recommendations regarding the employee's health, worksite safety and health practices, and medical referrals for further evaluation, if indicated. In addition, it is suggested that the PLHCP offer to provide the employee with a complete copy of their examination and test results, as some employees may want this information for their own records or to provide to their personal physician or a future PLHCP. Employees are entitled to access their medical records.

Under the respirable crystalline silica standard, the employer must ensure that the PLHCP provides the employer with a written medical opinion within 30 days of the employee examination, and that the employee also gets a copy of the written medical opinion for the employer within 30 days. The PLHCP may choose to directly provide the employee a copy of the written medical opinion. This can be particularly helpful to employees, such as construction employees, who may change employers frequently. The written medical opinion can be used by the employee as proof of up-to-date medical surveillance. The following lists the elements of the written medical report for the employee and written medical opinion for the employer. (Sample forms for the written medical report for the employee, the written medical opinion for the employer, and the written authorization are provided in Section 7 of this Appendix.)

3.1.1. The written medical report for the employee must include the following information:

3.1.1.1. A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment;

3.1.1.2. Any recommended limitations upon the employee's use of a respirator;

3.1.1.3. Any recommended limitations on the employee's exposure to respirable crystalline silica; and

3.1.1.4. A statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine, where the standard requires or where the PLHCP has determined such a referral is necessary. The standard requires referral to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for a chest X-ray B reading indicating small opacities in a profusion of 1/0 or higher, or if the PHLCP determines that referral to a Specialist is necessary for other silica-related findings.

3.1.2. The PLHCP's written medical opinion for the employer must include only the following information:

3.1.2.1. The date of the examination;

3.1.2.2. A statement that the examination has met the requirements of this section; and

3.1.2.3. Any recommended limitations on the employee's use of respirators.

3.1.2.4. If the employee provides the PLHCP with written authorization, the written opinion for the employer shall also contain either or both of the following:

(1) Any recommended limitations on the employee's exposure to respirable crystalline silica; and

(2) A statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a Specialist is otherwise deemed appropriate.

3.1.2.5. In addition to the above referral for abnormal chest X-ray, the PLHCP may refer an employee to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for other findings of concern during the medical surveillance examination if these findings are potentially related to silica exposure.

3.1.2.6. Although the respirable crystalline silica standard requires the employer to ensure that the PLHCP explains the results of the medical examination to the employee, the standard does not mandate how this should be done. The written medical opinion for the employer could contain a statement that the PLHCP has explained the results of the medical examination to the employee.

3.2. Medical Specialists. The silica standard requires that all employees with chest X-ray B readings of 1/0 or higher be referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine. If the employee has given written authorization for the employer to be informed, then the employer shall make available a medical examination by a Specialist within 30 days after receiving the PLHCP's written medical opinion.

3.2.1. The employer must provide the following information to the Board Certified Specialist in Pulmonary Disease or Occupational Medicine:

3.2.1.1. A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

3.2.1.2. The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

3.2.1.3. A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

3.2.1.4. Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

3.2.2. The PLHCP should make certain that, with written authorization from the employee, the Board Certified Specialist in Pulmonary Disease or Occupational Medicine has any other pertinent medical and occupational information necessary for the specialist's evaluation of the employee's condition.

3.2.3. Once the Board Certified Specialist in Pulmonary Disease or Occupational Medicine has evaluated the employee, the employer must ensure that the Specialist explains to the employee the results of the medical examination and provides the employee with a written medical report within 30 days of the examination. The employer must also ensure that the Specialist provides the employer with a written medical opinion within 30 days of the employee examination. (Sample forms for the written medical report for the employee, the written medical opinion for the employer and the written authorization are provided in Section 7 of this Appendix.)

3.2.4. The Specialist's written medical report for the employee must include the following information:

3.2.4.1. A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment;

3.2.4.2. Any recommended limitations upon the employee's use of a respirator; and

3.2.4.3. Any recommended limitations on the employee's exposure to respirable crystalline silica.

3.2.5. The Specialist's written medical opinion for the employer must include the following information:

3.2.5.1. The date of the examination; and

3.2.5.2. Any recommended limitations on the employee's use of respirators.

3.2.5.3. If the employee provides the Board Certified Specialist in Pulmonary Disease or Occupational Medicine with written authorization, the written medical opinion for the employer shall also contain any recommended limitations on the employee's exposure to respirable crystalline silica.

3.2.5.4. Although the respirable crystalline silica standard requires the employer to ensure that the Board Certified Specialist in Pulmonary Disease or Occupational Medicine explains the results of the medical examination to the employee, the standard does not mandate how this should be done. The written medical opinion for the employer could contain a statement that the Specialist has explained the results of the medical examination to the employee.

3.2.6. After evaluating the employee, the Board Certified Specialist in Pulmonary Disease or Occupational Medicine should provide feedback to the PLHCP as appropriate, depending on the reason for the referral. OSHA believes that because the PLHCP has the primary relationship with the employer and employee, the Specialist may want to communicate his or her findings to the PLHCP and have the PLHCP simply update the original medical report for the employee and medical opinion for the employer. This is permitted under the standard, so long as all requirements and time deadlines are met.

3.3. Public Health Professionals. PLHCPs might refer employees or consult with public health professionals as a result of silica medical surveillance. For instance, if individual cases of active TB are identified, public health professionals from state or local health departments may assist in diagnosis and treatment of individual cases and may evaluate other potentially affected persons, including coworkers. Because silica-exposed employees are at increased risk of progression from latent to active TB, treatment of latent infection is recommended. The diagnosis of active TB, acute or accelerated silicosis, or other silica-related diseases and infections should serve as sentinel events suggesting high levels of exposure to silica and may require consultation with the appropriate public health agencies to investigate potentially similarly exposed coworkers to assess for disease clusters. These agencies include local or state health departments or OSHA. In addition, NIOSH can provide assistance upon request through their Health Hazard Evaluation program. (*See* Section 5 of this Appendix)

4. Confidentiality and Other Considerations

The information that is provided from the PLHCP to the employee and employer under the medical surveillance section of OSHA's respirable crystalline silica standard differs from that of medical surveillance requirements in previous OSHA standards. The standard requires two separate written communications, a written medical report for the employee and a written medical opinion for the employer. The confidentiality requirements for the written medical opinion are more stringent than in past standards. For example, the information the PLHCP can (and must) include in his or her written medical opinion for the employer is limited to: The date of the examination, a statement that the examination has met the requirements of this section, and any recommended limitations on the employee's use of respirators. If the employee provides written authorization for the disclosure of

any limitations on the employee's exposure to respirable crystalline silica, then the PLHCP can (and must) include that information in the written medical opinion for the employer as well. Likewise, with the employee's written authorization, the PLHCP can (and must) disclose the PLHCP's referral recommendation (if any) as part of the written medical opinion for the employer. However, the opinion to the employer must not include information regarding recommended limitations on the employee's exposure to respirable crystalline silica or any referral recommendations without the employee's written authorization.

The standard also places limitations on the information that the Board Certified Specialist in Pulmonary Disease or Occupational Medicine can provide to the employer without the employee's written authorization. The Specialist's written medical opinion for the employer, like the PLHCP's opinion, is limited to (and must contain): The date of the examination and any recommended limitations on the employee's use of respirators. If the employee provides written authorization, the written medical opinion can (and must) also contain any limitations on the employee's exposure to respirable crystalline silica.

The PLHCP should discuss the implication of signing or not signing the authorization with the employee (in a manner and language that he or she understands) so that the employee can make an informed decision regarding the written authorization and its consequences. The discussion should include the risk of ongoing silica exposure, personal risk factors, risk of disease progression, and possible health and economic consequences. For instance, written authorization is required for a PLHCP to advise an employer that an employee should be referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for evaluation of an abnormal chest X-ray (B-reading 1/0 or greater). If an employee does not sign an authorization, then the employer will not know and cannot facilitate the referral to a Specialist and is not required to pay for the Specialist's examination. In the rare case where an employee is diagnosed with acute or accelerated silicosis, co-workers are likely to be at significant risk of developing those diseases as a result of inadequate controls in the workplace. In this case, the PLHCP and/or Specialist should explain this concern to the affected employee and make a determined effort to obtain written authorization from the employee so that the PLHCP and/or Specialist can contact the employer.

Finally, without written authorization from the employee, the PLHCP and/or Board Certified Specialist in Pulmonary Disease or Occupational Medicine cannot provide feedback to an employer regarding control of workplace silica exposure, at least in relation to an individual employee. However, the regulation does not prohibit a PLHCP and/or Specialist from providing an employer with general recommendations regarding exposure controls and prevention programs in relation to silica exposure and silica-related illnesses, based on the information that the PLHCP receives from the employer such as employees' duties and exposure levels. Recommendations may include increased frequency of medical surveillance examinations, additional medical surveillance components, engineering and work practice controls, exposure monitoring and personal protective equipment. For instance, more frequent medical surveillance examinations may be a recommendation to employers for employees who do abrasive blasting with silica because of the high exposures associated with that operation.

ACOEM's Code of Ethics and discussion is a good resource to guide PLHCPs regarding the issues discussed in this section (*See* Section 5 of this Appendix).

5. Resources

5.1. American College of Occupational and Environmental Medicine (ACOEM):

ACOEM Code of Ethics. Accessed at: *http://www.acoem.org/codeofconduct.aspx*

Raymond, L.W. and Wintermeyer, S. (2006) ACOEM evidenced-based statement on medical surveillance of silica-exposed workers: Medical surveillance of workers exposed to crystalline silica. *J Occup Environ Med,* 48, 95–101.

5.2. Center for Disease Control and Prevention (CDC)

Tuberculosis Web page: *http://www.cdc.gov/tb/default.htm*

State TB Control Offices Web page: *http://www.cdc.gov/tb/links/tboffices.htm*

Tuberculosis Laws and Policies Web page: *http://www.cdc.gov/tb/programs/laws/default.htm*

CDC. (2013). Latent Tuberculosis Infection: A Guide for Primary Health Care Providers. Accessed at: *http://www.cdc.gov/tb/publications/ltbi/pdf/targetedltbi.pdf*

5.3. International Labour Organization

International Labour Office (ILO). (2011) Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses, Revised edition 2011. Occupational Safety and Health Series No. 22: *http://www.ilo.org/safework/info/publications/WCMS_168260/lang-en/index.htm*

5.4. National Institute of Occupational Safety and Health (NIOSH)

NIOSH B Reader Program Web page. (Information on interpretation of X-rays for silicosis and a list of certified B-readers). Accessed at: *http://www.cdc.gov/niosh/topics/chestradiography/breader-info.html*

NIOSH Guideline (2011). Application of Digital Radiography for the Detection and Classification of Pneumoconiosis. NIOSH publication number 2011–198. Accessed at: *http://www.cdc.gov/niosh/docs/2011-198/.*

NIOSH Hazard Review (2002), Health Effects of Occupational Exposure to Respirable Crystalline Silica. NIOSH publication number 2002–129: Accessed at *http://www.cdc.gov/niosh/docs/2002-129/*

NIOSH Health Hazard Evaluations Programs. (Information on the NIOSH Health Hazard Evaluation (HHE) program, how to request an HHE and how to look up an HHE report). Accessed at: *http://www.cdc.gov/niosh/hhe/*

5.5. National Industrial Sand Association:

Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry. National Industrial Sand Association, 2nd ed. 2010. Can be ordered at: *http://www.sand.org/silica-occupational-health-program*

5.6. Occupational Safety and Health Administration (OSHA)

Contacting OSHA: *http://www.osha.gov/html/Feed_Back.html*

OSHA's Clinicians Web page. (OSHA resources, regulations and links to help clinicians navigate OSHA's Web site and aid clinicians in caring for workers.) Accessed at: *http://www.osha.gov/dts/oom/clinicians/index.html*

OSHA's Safety and Health Topics Web page on Silica. Accessed at: *http://www.osha.gov/dsg/topics/silicacrystalline/index.html*

OSHA (2013). Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals. (OSHA 3637–03 2013). Accessed at: *http://www.osha.gov/Publications/OSHA3637.pdf*

OSHA/NIOSH (2011). Spirometry: OSHA/NIOSH Spirometry InfoSheet (OSHA 3415–1–11). (Provides guidance to employers). Accessed at *http://www.osha.gov/Publications/osha3415.pdf*

OSHA/NIOSH (2011) Spirometry: OSHA/NIOSH Spirometry Worker Info. (OSHA 3418–3–11). Accessed at *http://www.osha.gov/Publications/osha3418.pdf*

5.7. Other

Steenland, K. and Ward E. (2014). Silica: A lung carcinogen. *CA Cancer J Clin,* 64, 63–69. (This article reviews not only silica and lung cancer but also all the known silica-related health effects. Further, the authors provide guidance to clinicians on medical surveillance of silica-exposed workers and worker counselling on safety practices to minimize silica exposure.)

6. References

American Thoracic Society (ATS). Medical Section of the American Lung Association (1997). Adverse effects of crystalline silica exposure. *Am J Respir Crit Care Med,* 155, 761–765.

American Thoracic Society (ATS), Centers for Disease Control (CDC), Infectious Diseases Society of America (IDSA) (2005). Controlling Tuberculosis in the United States. *Morbidity and Mortality Weekly Report (MMWR),* 54(RR12), 1–81. Accessed at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm.*

Brown, T. (2009). Silica exposure, smoking, silicosis and lung cancer—complex interactions. *Occupational Medicine,* 59, 89–95.

Halldin, C.N., Petsonk, E.L., and Laney, A.S. (2014). Validation of the International Labour Office digitized standard images for recognition and classification of radiographs of pneumoconiosis. *Acad Radiol,* 21, 305–311.

International Agency for Research on Cancer. (2012). Monographs on the evaluation of carcinogenic risks to humans: Arsenic, Metals, Fibers, and Dusts Silica Dust, Crystalline, in the Form of Quartz or Cristobalite. A Review of Human Carcinogens. Volume 100 C. Geneva, Switzerland: World Health Organization.

Jalloul, A.S. and Banks D.E. (2007). Chapter 23. The health effects of silica exposure. In: Rom, W.N. and Markowitz, S.B. (Eds). Environmental and Occupational Medicine, 4th edition. Lippincott, Williams and Wilkins, Philadelphia, 365–387.

Kramer, M.R., Blanc, P.D., Fireman, E., Amital, A., Guber, A., Rahman, N.A., and Shitrit, D. (2012). Artifical stone silicosis: Disease resurgence among artificial stone workers. *Chest,* 142, 419–424.

Laney, A.S., Petsonk, E.L., and Attfield, M.D. (2011). Intramodality and intermodality comparisons of storage phosphor computed radiography and conventional film-screen radiography in the recognition of small pneumonconiotic opacities. *Chest,* 140, 1574–1580.

Liu, Y., Steenland, K., Rong, Y., Hnizdo, E., Huang, X., Zhang, H., Shi, T., Sun, Y., Wu, T., and Chen, W. (2013). Exposure-response analysis and risk assessment for lung cancer in relationship to silica exposure: A 44-year cohort study of 34,018 workers. *Am J Epi,* 178, 1424–1433.

Liu, Y., Rong, Y., Steenland, K., Christiani, D.C., Huang, X., Wu, T., and Chen, W. (2014). Long-term exposure to crystalline silica and risk of heart disease mortality. *Epidemiology,* 25, 689–696.

Mazurek, G.H., Jereb, J., Vernon, A., LoBue, P., Goldberg, S., Castro, K. (2010). Updated guidelines for using interferon gamma release assays to detect Mycobacterium tuberculosis infection—United States. *Morbidity and Mortality Weekly Report (MMWR),* 59(RR05), 1–25.

Miller, M.R., Hankinson, J., Brusasco, V., Burgos, F., Casaburi, R., Coates, A., Crapo, R., Enright, P., van der Grinten, C.P., Gustafsson, P., Jensen, R., Johnson, D.C., MacIntyre, N., McKay, R., Navajas, D., Pedersen, O.F., Pellegrino, R., Viegi, G., and Wanger, J. (2005).

American Thoracic Society/European Respiratory Society (ATS/ERS) Task Force: Standardisation of Spirometry. *Eur Respir J,* 26, 319–338.

National Toxicology Program (NTP) (2014). Report on Carcinogens, Thirteenth Edition. Silica, Crystalline (respirable Size). Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. *http://ntp.niehs.nih.gov/ntp/roc/content/profiles/silica.pdf.*

Occupational Safety and Health Administration/National Institute for Occupational Safety and Health (OSHA/NIOSH) (2012). Hazard Alert. Worker exposure to silica during hydraulic fracturing.

Occupational Safety and Health Administration/National Institute for Occupational Safety and Health (OSHA/NIOSH) (2015). Hazard alert. Worker exposure to silica during countertop manufacturing, finishing, and installation. (OSHA–HA–3768–2015).

Redlich, C.A., Tarlo, S.M., Hankinson, J.L., Townsend, M.C, Eschenbacher, W.L., Von Essen, S.G., Sigsgaard, T., Weissman, D.N. (2014). Official American Thoracic Society technical standards: Spirometry in the occupational setting. *Am J Respir Crit Care Med*; 189, 984–994.

Rees, D. and Murray, J. (2007). Silica, silicosis and tuberculosis. *Int J Tuberc Lung Dis*, 11(5), 474–484.

Shtraichman, O., Blanc, P.D., Ollech, J.E., Fridel, L., Fuks, L., Fireman, E., and Kramer, M.R. (2015). Outbreak of autoimmune disease in silicosis linked to artificial stone. *Occup Med,* 65, 444–450.

Slater, M.L., Welland, G., Pai, M., Parsonnet, J., and Banaei, N. (2013). Challenges with QuantiFERON–TB gold assay for large-scale, routine screening of U.S. healthcare workers. *Am J Respir Crit Care Med,* 188, 1005–1010.

Steenland, K., Mannetje, A., Boffetta, P., Stayner, L., Attfield, M., Chen, J., Dosemeci, M., DeKlerk, N., Hnizdo, E., Koskela, R., and Checkoway, H. (2001). International Agency for Research on Cancer. Pooled exposure-response analyses and risk assessment for lung cancer in 10 cohorts of silica-exposed workers: An IARC multicentre study. *Cancer Causes Control,* 12(9):773–84.

Steenland, K. and Ward E. (2014). Silica: A lung carcinogen. *CA Cancer J Clin,* 64, 63–69.

Townsend, M.C. ACOEM Guidance Statement. (2011). Spirometry in the occupational health setting—2011 Update. *J Occup Environ Med,* 53, 569–584.

7. Sample Forms

Three sample forms are provided. The first is a sample written medical report for the employee. The second is a sample written medical opinion for the employer. And the third is a sample written authorization form that employees sign to clarify what information the employee is authorizing to be released to the employer.

BILLING CODE 4510–26–P

WRITTEN MEDICAL REPORT FOR EMPLOYEE

EMPLOYEE NAME: _____ **DATE OF EXAMINATION**: _____

TYPE OF EXAMINATION:
[ ] Initial examination [ ] Periodic examination [ ] Specialist examination
[ ] Other: _____

RESULTS OF MEDICAL EXAMINATION:

Physical Examination –	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed
Chest X-Ray –	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed
Breathing Test (Spirometry) –	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed
Test for Tuberculosis –	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed
Other:_____	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed

Results reported as abnormal: _____
_____

[ ] Your health may be at increased risk from exposure to respirable crystalline silica due to the following:
_____

RECOMMENDATIONS:
[ ] No limitations on respirator use
[ ] Recommended limitations on use of respirator: _____
[ ] Recommended limitations on exposure to respirable crystalline silica: _____
_____

Dates for recommended limitations, if applicable: _____ to _____
MM/DD/YYYY MM/DD/YYYY

[ ] I recommend that you be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine

[ ] Other recommendations*:
_____
_____

Your next periodic examination for silica exposure should be in: [ ] 3 years [ ] Other: _____
MM/DD/YYYY

Examining Provider: _____ Date: _____
(signature)

Provider Name: _____
Office Address: _____ Office Phone: _____

*These findings may not be related to respirable crystalline silica exposure or may not be work-related, and therefore may not be covered by the employer. These findings may necessitate follow-up and treatment by your personal physician.

Respirable Crystalline Silica standard (§ 1910.1053 or 1926.1153)

WRITTEN MEDICAL OPINION FOR EMPLOYER

EMPLOYER: _____

EMPLOYEE NAME: _____ **DATE OF EXAMINATION:** _____

TYPE OF EXAMINATION:
[ ] Initial examination [ ] Periodic examination [ ] Specialist examination
[ ] Other: _____

USE OF RESPIRATOR:
[ ] No limitations on respirator use
[ ] Recommended limitations on use of respirator:_____

Dates for recommended limitations, if applicable: _____ to _____
MM/DD/YYYY MM/DD/YYYY

The employee has provided written authorization for disclosure of the following to the employer (if applicable):

[ ] This employee should be examined by an American Board Certified Specialist in Pulmonary Disease or Occupational Medicine
[ ] Recommended limitations on exposure to respirable crystalline silica:_____
_____

Dates for exposure limitations noted above: _____ to _____
MM/DD/YYYY MM/DD/YYYY

NEXT PERIODIC EVALUATION: [ ] 3 years [ ] Other: _____
MM/DD/YYYY

Examining Provider: _____ Date: _____
(signature)
Provider Name: _____ Provider's specialty:_____

Office Address: _____ Office Phone: _____

[ ] I attest that the results have been explained to the employee.

The following is required to be checked by the Physician or other Licensed Health Care Professional (PLHCP):
[ ] I attest that this medical examination has met the requirements of the medical surveillance section of the OSHA Respirable Crystalline Silica standard (§ 1910.1053(h) or 1926.1153(h)).

AUTHORIZATION FOR CRYSTALLINE SILICA OPINION TO EMPLOYER

This medical examination for exposure to crystalline silica could reveal a medical condition that results in recommendations for (1) limitations on respirator use, (2) limitations on exposure to crystalline silica, or (3) examination by a specialist in pulmonary disease or occupational medicine. Recommended limitations on respirator use will be included in the written opinion to the employer. If you want your employer to know about limitations on crystalline silica exposure or recommendations for a specialist examination, you will need to give authorization for the written opinion to the employer to include one or both of those recommendations.

I hereby authorize the opinion to the employer to contain the following information, if relevant (please check all that apply):

☐ Recommendations for limitations on crystalline silica exposure

☐ Recommendation for a specialist examination

OR

☐ I do not authorize the opinion to the employer to contain anything other than recommended limitations on respirator use.

Please read and initial:

___ I understand that if I do not authorize my employer to receive the recommendation for specialist examination, the employer will not be responsible for arranging and covering costs of a specialist examination.

_____
Name (printed)

_____ _____
Signature Date

BILLING CODE 4510–26–C

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

■ 5. The authority citation for part 1915 is revised to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; 29 CFR part 1911.

Sections 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

■ 6. In § 1915.1000, amend Table Z by:

■ a. Revising the entries for ''Silica, crystalline cristobalite, respirable dust'', ''Silica, crystalline quartz, respirable

dust'', ''Silica, crystalline tripoli (as quartz), respirable dust'', and ''Silica, crystalline tridymite, respirable dust'';

■ b. Under the ''MINERAL DUSTS'' heading of the table, revising the entry for ''Silica: Cystalline Quartz'';
■ c. Adding footnote 5; and
■ d. Add footnote p.

The revisions and additions should read as follows:

§ 1915.1000 Air contaminants.

* * * * *

TABLE Z—SHIPYARDS

Substance	CAS No.[d]	ppm[a]*	mg/m[3] [b]*	Skin designation
* * * * * * *				
Silica, crystalline, respirable dust				
Cristobalite; see 1915.1053	14464–46–1			
Quartz; see 1915.1053[5]	14808–60–7			
Tripoli (as quartz); see 1915.1053[5]	1317–95–9			
Trydimite; see 1915.1053	15468–32–3			
* * * * * * *				

MINERAL DUSTS

Substance	mppcf[(j)]
SILICA:	
Crystalline	250[(k)]
Quartz. Threshold Limit calculated from the formula[(p)]	% SiO^2+5
* * * * * * *	

* * * * * * *

[5] See Mineral Dusts table for the exposure limit for any operations or sectors where the exposure limit in § 1915.1053 is stayed or is otherwise not in effect.

* The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25 °C and 760 torr.

[b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

* * * * * * *

[p] This standard applies to any operations or sectors for which the respirable crystalline silica standard, 1915.1053, is stayed or otherwise is not in effect.

■ 7. Add § 1915.1053 to read as follows:

§ 1915.1053 Respirable crystalline silica.

The requirements applicable to shipyard employment under this section are identical to those set forth at § 1910.1053 of this chapter.

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart D—Occupational Health and Environmental Controls

■ 8. The authority citation for subpart D of part 1926 is revised to read as follows:

Authority: Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

Sections 1926.58, 1926.59, 1926.60, and 1926.65 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1926.61 also issued under 49 U.S.C. 1801–1819 and 6 U.S.C. 553.

Section 1926.62 also issued under section 1031 of the Housing and Community Development Act of 1992 (42 U.S.C. 4853).

Section 1926.65 also issued under section 126 of the Superfund Amendments and Reauthorization Act of 1986, as amended (reprinted at 29 U.S.C.A. 655 Note), and 5 U.S.C. 553.

■ 9. In § 1926.55, amend appendix A:
■ a. By revising the entries for ''Silica, crystalline cristobalite, respirable dust'', ''Silica, crystalline quartz, respirable dust'', ''Silica, crystalline tripoli (as quartz), respirable dust'', and ''Silica, crystalline tridymite, respirable dust'';
■ b. Under the ''MINERAL DUSTS'' heading of the table, by revising the entry for ''Silica: Cystalline Quartz'' in column 1;
■ c. Adding footnote 5; and
■ d. Adding footnote p .

The revisions and additions read as follows:

§ 1926.55 Gases, vapors, fumes, dusts, and mists.

* * * * *

Appendix A to § 1926.55—1970 American Conference of Governmental Industrial Hygienists' Threshold Limit Values of Airborne Contaminants

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION

Substance	CAS No.[d]	ppm[a]*	mg/m[3] [b]*	Skin designation
* * * * * * *				
Silica, crystalline, respirable dust				

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION—Continued

Substance	CAS No.[d]	ppm[a] *	mg/m[3] [b] *	Skin designation
Cristobalite; see 1926.1153	14464–46–1			
Quartz; see 1926.1153[5]	14808–60–7			
Tripoli (as quartz); see 1926.1153[5]	1317–95–9			
Trydimite; see 1926.1153	15468–32–3			
* * * * * * *				
MINERAL DUSTS				
SILICA:				
Crystalline				250 (k)
Quartz. Threshold Limit calculated from the formula (p)				% SiO_2+5
* * * * * * *				

Footnotes.

* * * * * * *

[5] See Mineral Dusts table for the exposure limit for any operations or sectors where the exposure limit in § 1926.1153 is stayed or is otherwise not in effect.

* * * * * * *

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25 °C and 760 torr.

[b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

* * * * * * *

[d] The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

* * * * * * *

[p] This standard applies to any operations or sectors for which the respirable crystalline silica standard, 1926.1153, is stayed or otherwise is not in effect.

Subpart Z—Toxic and Hazardous Substances

■ 10. The authority for subpart Z of part 1926 is revised to read as follows:

Authority: Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

Section 1926.1102 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

■ 11. Add § 1926.1153 to read as follows:

§ 1926.1153 Respirable crystalline silica.

(a) *Scope and application.* This section applies to all occupational exposures to respirable crystalline silica in construction work, except where employee exposure will remain below 25 micrograms per cubic meter of air (25 $\mu g/m^3$) as an 8-hour time-weighted average (TWA) under any foreseeable conditions.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne respirable crystalline silica of 25 $\mu g/m^3$, calculated as an 8-hour TWA.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Competent person means an individual who is capable of identifying existing and foreseeable respirable crystalline silica hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The competent person must have the knowledge and ability necessary to fulfill the responsibilities set forth in paragraph (g) of this section.

Employee exposure means the exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing monodispersed particles of 0.3 micrometers in diameter.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] means an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (h) of this section.

Respirable crystalline silica means quartz, cristobalite, and/or tridymite contained in airborne particles that are determined to be respirable by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

Specialist means an American Board Certified Specialist in Pulmonary Disease or an American Board Certified Specialist in Occupational Medicine.

This section means this respirable crystalline silica standard, 29 CFR 1926.1153.

(c) *Specified exposure control methods.* (1) For each employee engaged in a task identified on Table 1, the

employer shall fully and properly implement the engineering controls, work practices, and respiratory protection specified for the task on Table 1, unless the employer assesses and limits the exposure of the employee to respirable crystalline silica in accordance with paragraph (d) of this section.

TABLE 1—SPECIFIED EXPOSURE CONTROL METHODS WHEN WORKING WITH MATERIALS CONTAINING CRYSTALLINE SILICA

Equipment/task	Engineering and work practice control methods	Required respiratory protection and minimum assigned protection factor (APF)	
		≤4 hours/shift	>4 hours/shift
(i) Stationary masonry saws	Use saw equipped with integrated water delivery system that continuously feeds water to the blade. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions.	None	None.
(ii) Handheld power saws (any blade diameter).	Use saw equipped with integrated water delivery system that continuously feeds water to the blade. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions:		
	—When used outdoors	None	APF 10.
	—When used indoors or in an enclosed area	APF 10	APF 10.
(iii) Handheld power saws for cutting fiber-cement board (with blade diameter of 8 inches or less).	For tasks performed outdoors only: Use saw equipped with commercially available dust collection system. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions. Dust collector must provide the air flow recommended by the tool manufacturer, or greater, and have a filter with 99% or greater efficiency.	None.	None.
(iv) Walk-behind saws	Use saw equipped with integrated water delivery system that continuously feeds water to the blade. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions:		
	—When used outdoors	None	None.
	—When used indoors or in an enclosed area	APF 10	APF 10.
(v) Drivable saws	For tasks performed outdoors only: Use saw equipped with integrated water delivery system that continuously feeds water to the blade. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions.	None	None.
(vi) Rig-mounted core saws or drills.	Use tool equipped with integrated water delivery system that supplies water to cutting surface. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions.	None	None.
(vii) Handheld and stand-mounted drills (including impact and rotary hammer drills).	Use drill equipped with commercially available shroud or cowling with dust collection system. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions. Dust collector must provide the air flow recommended by the tool manufacturer, or greater, and have a filter with 99% or greater efficiency and a filter-cleaning mechanism. Use a HEPA-filtered vacuum when cleaning holes.	None	None.
(viii) Dowel drilling rigs for concrete	For tasks performed outdoors only: Use shroud around drill bit with a dust collection system. Dust collector must have a filter with 99% or greater efficiency and a filter-cleaning mechanism. Use a HEPA-filtered vacuum when cleaning holes.	APF 10	APF 10.
(ix) Vehicle-mounted drilling rigs for rock and concrete.	Use dust collection system with close capture hood or shroud around drill bit with a low-flow water spray to wet the dust at the discharge point from the dust collector.	None	None.
	OR		
	Operate from within an enclosed cab and use water for dust suppression on drill bit.	None	None.
(x) Jackhammers and handheld powered chipping tools.	Use tool with water delivery system that supplies a continuous stream or spray of water at the point of impact:		
	—When used outdoors	None	APF 10.
	—When used indoors or in an enclosed area	APF 10	APF 10.
	OR Use tool equipped with commercially available shroud and dust collection system. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions.		

TABLE 1—SPECIFIED EXPOSURE CONTROL METHODS WHEN WORKING WITH MATERIALS CONTAINING CRYSTALLINE SILICA—Continued

Equipment/task	Engineering and work practice control methods	Required respiratory protection and minimum assigned protection factor (APF)	
		≤4 hours/shift	>4 hours/shift
	Dust collector must provide the air flow recommended by the tool manufacturer, or greater, and have a filter with 99% or greater efficiency and a filter-cleaning mechanism:		
	—When used outdoors	None	APF 10.
	—When used indoors or in an enclosed area	APF 10	APF 10.
(xi) Handheld grinders for mortar removal (*i.e.*, tuckpointing).	Use grinder equipped with commercially available shroud and dust collection system. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions. Dust collector must provide 25 cubic feet per minute (cfm) or greater of airflow per inch of wheel diameter and have a filter with 99% or greater efficiency and a cyclonic pre-separator or filter-cleaning mechanism.	APF 10	APF 25.
(xii) Handheld grinders for uses other than mortar removal.	For tasks performed outdoors only: Use grinder equipped with integrated water delivery system that continuously feeds water to the grinding surface. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions. OR Use grinder equipped with commercially available shroud and dust collection system. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions. Dust collector must provide 25 cubic feet per minute (cfm) or greater of airflow per inch of wheel diameter and have a filter with 99% or greater efficiency and a cyclonic pre-separator or filter-cleaning mechanism:	None	None.
	—When used outdoors	None	None.
	—When used indoors or in an enclosed area	None	APF 10.
(xiii) Walk-behind milling machines and floor grinders.	Use machine equipped with integrated water delivery system that continuously feeds water to the cutting surface. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions. OR	None	None.
	Use machine equipped with dust collection system recommended by the manufacturer. Operate and maintain tool in accordance with manufacturer's instructions to minimize dust emissions. Dust collector must provide the air flow recommended by the manufacturer, or greater, and have a filter with 99% or greater efficiency and a filter-cleaning mechanism. When used indoors or in an enclosed area, use a HEPA-filtered vacuum to remove loose dust in between passes.	None	None.
(xiv) Small drivable milling machines (less than half-lane).	Use a machine equipped with supplemental water sprays designed to suppress dust. Water must be combined with a surfactant. Operate and maintain machine to minimize dust emissions.	None	None.
(xv) Large drivable milling machines (half-lane and larger).	For cuts of any depth on asphalt only: Use machine equipped with exhaust ventilation on drum enclosure and supplemental water sprays designed to suppress dust. Operate and maintain machine to minimize dust emissions.	None	None.
	For cuts of four inches in depth or less on any substrate: Use machine equipped with exhaust ventilation on drum enclosure and supplemental water sprays designed to suppress dust. Operate and maintain machine to minimize dust emissions.	None	None.
	OR Use a machine equipped with supplemental water spray designed to suppress dust. Water must be combined with a surfactant. Operate and maintain machine to minimize dust emissions.	None	None.
(xvi) Crushing machines	Use equipment designed to deliver water spray or mist for dust suppression at crusher and other points where dust is generated (*e.g.*, hoppers, conveyers, sieves/sizing or vibrating components, and discharge points). Operate and maintain machine in accordance with manufacturer's instructions to minimize dust emissions. Use a ventilated booth that provides fresh, climate-controlled air to the operator, or a remote control station.	None	None.

TABLE 1—SPECIFIED EXPOSURE CONTROL METHODS WHEN WORKING WITH MATERIALS CONTAINING CRYSTALLINE SILICA—Continued

Equipment/task	Engineering and work practice control methods	Required respiratory protection and minimum assigned protection factor (APF)	
		≤4 hours/shift	>4 hours/shift
(xvii) Heavy equipment and utility vehicles used to abrade or fracture silica-containing materials (*e.g.*, hoe-ramming, rock ripping) or used during demolition activities involving silica-containing materials.	Operate equipment from within an enclosed cab When employees outside of the cab are engaged in the task, apply water and/or dust suppressants as necessary to minimize dust emissions.	None None	None. None.
(xviii) Heavy equipment and utility vehicles for tasks such as grading and excavating but not including: Demolishing, abrading, or fracturing silica-containing materials.	Apply water and/or dust suppressants as necessary to minimize dust emissions. OR	None	None.
	When the equipment operator is the only employee engaged in the task, operate equipment from within an enclosed cab.	None	None.

(2) When implementing the control measures specified in Table 1, each employer shall:

(i) For tasks performed indoors or in enclosed areas, provide a means of exhaust as needed to minimize the accumulation of visible airborne dust;

(ii) For tasks performed using wet methods, apply water at flow rates sufficient to minimize release of visible dust;

(iii) For measures implemented that include an enclosed cab or booth, ensure that the enclosed cab or booth:

(A) Is maintained as free as practicable from settled dust;

(B) Has door seals and closing mechanisms that work properly;

(C) Has gaskets and seals that are in good condition and working properly;

(D) Is under positive pressure maintained through continuous delivery of fresh air;

(E) Has intake air that is filtered through a filter that is 95% efficient in the 0.3–10.0 μm range (*e.g.*, MERV–16 or better); and

(F) Has heating and cooling capabilities.

(3) Where an employee performs more than one task on Table 1 during the course of a shift, and the total duration of all tasks combined is more than four hours, the required respiratory protection for each task is the respiratory protection specified for more than four hours per shift. If the total duration of all tasks on Table 1 combined is less than four hours, the required respiratory protection for each task is the respiratory protection specified for less than four hours per shift.

(d) *Alternative exposure control methods.* For tasks not listed in Table 1, or where the employer does not fully and properly implement the engineering controls, work practices, and respiratory protection described in Table 1:

(1) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of respirable crystalline silica in excess of 50 μg/m^3, calculated as an 8-hour TWA.

(2) *Exposure assessment*—(i) *General.* The employer shall assess the exposure of each employee who is or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level in accordance with either the performance option in paragraph (d)(2)(ii) or the scheduled monitoring option in paragraph (d)(2)(iii) of this section.

(ii) *Performance option.* The employer shall assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica.

(iii) *Scheduled monitoring option.* (A) The employer shall perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet this requirement. In representative sampling, the employer shall sample the employee(s) who are expected to have the highest exposure to respirable crystalline silica.

(B) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

(C) Where the most recent exposure monitoring indicates that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring within six months of the most recent monitoring.

(D) Where the most recent exposure monitoring indicates that employee exposures are above the PEL, the employer shall repeat such monitoring within three months of the most recent monitoring.

(E) Where the most recent (non-initial) exposure monitoring indicates that employee exposures are below the action level, the employer shall repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken seven or more days apart, are below the action level, at which time the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring, except as otherwise provided in paragraph (d)(2)(iv) of this section.

(iv) *Reassessment of exposures.* The employer shall reassess exposures whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred.

(v) *Methods of sample analysis.* The employer shall ensure that all samples taken to satisfy the monitoring requirements of paragraph (d)(2) of this section are evaluated by a laboratory that analyzes air samples for respirable crystalline silica in accordance with the procedures in Appendix A to this section.

(vi) Employee notification of assessment results. (A) Within five working days after completing an exposure assessment in accordance with paragraph (d)(2) of this section, the employer shall individually notify each affected employee in writing of the results of that assessment or post the results in an appropriate location accessible to all affected employees.

(B) Whenever an exposure assessment indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(vii) *Observation of monitoring.* (A) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to respirable crystalline silica.

(B) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required for any workplace hazard, the employer shall provide the observer with protective clothing and equipment at no cost and shall ensure that the observer uses such clothing and equipment.

(3) *Methods of compliance*—(i) *Engineering and work practice controls.* The employer shall use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL, unless the employer can demonstrate that such controls are not feasible. Wherever such feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them with the use of respiratory protection that complies with the requirements of paragraph (e) of this section.

(ii) *Abrasive blasting.* In addition to the requirements of paragraph (d)(3)(i) of this section, the employer shall comply with other OSHA standards, when applicable, such as 29 CFR 1926.57 (Ventilation), where abrasive blasting is conducted using crystalline silica-containing blasting agents, or where abrasive blasting is conducted on substrates that contain crystalline silica.

(e) *Respiratory protection*—(1) *General.* Where respiratory protection is required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph and 29 CFR 1910.134. Respiratory protection is required:

(i) Where specified by Table 1 of paragraph (c) of this section; or

(ii) For tasks not listed in Table 1, or where the employer does not fully and properly implement the engineering controls, work practices, and respiratory protection described in Table 1:

(A) Where exposures exceed the PEL during periods necessary to install or implement feasible engineering and work practice controls;

(B) Where exposures exceed the PEL during tasks, such as certain maintenance and repair tasks, for which engineering and work practice controls are not feasible; and

(C) During tasks for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(3) *Specified exposure control methods.* For the tasks listed in Table 1 in paragraph (c) of this section, if the employer fully and properly implements the engineering controls, work practices, and respiratory protection described in Table 1, the employer shall be considered to be in compliance with paragraph (e)(1) of this section and the requirements for selection of respirators in 29 CFR 1910.134(d)(1)(iii) and (d)(3) with regard to exposure to respirable crystalline silica.

(f) *Housekeeping.* (1) The employer shall not allow dry sweeping or dry brushing where such activity could contribute to employee exposure to respirable crystalline silica unless wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure are not feasible.

(2) The employer shall not allow compressed air to be used to clean clothing or surfaces where such activity could contribute to employee exposure to respirable crystalline silica unless:

(i) The compressed air is used in conjunction with a ventilation system that effectively captures the dust cloud created by the compressed air; or

(ii) No alternative method is feasible.

(g) *Written exposure control plan.* (1) The employer shall establish and implement a written exposure control plan that contains at least the following elements:

(i) A description of the tasks in the workplace that involve exposure to respirable crystalline silica;

(ii) A description of the engineering controls, work practices, and respiratory protection used to limit employee exposure to respirable crystalline silica for each task;

(iii) A description of the housekeeping measures used to limit employee exposure to respirable crystalline silica; and

(iv) A description of the procedures used to restrict access to work areas, when necessary, to minimize the number of employees exposed to respirable crystalline silica and their level of exposure, including exposures generated by other employers or sole proprietors.

(2) The employer shall review and evaluate the effectiveness of the written exposure control plan at least annually and update it as necessary.

(3) The employer shall make the written exposure control plan readily available for examination and copying, upon request, to each employee covered by this section, their designated representatives, the Assistant Secretary and the Director.

(4) The employer shall designate a competent person to make frequent and regular inspections of job sites, materials, and equipment to implement the written exposure control plan.

(h) *Medical surveillance*—(1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be required under this section to use a respirator for 30 or more days per year.

(ii) The employer shall ensure that all medical examinations and procedures required by this section are performed by a PLHCP as defined in paragraph (b) of this section.

(2) *Initial examination.* The employer shall make available an initial (baseline) medical examination within 30 days after initial assignment, unless the employee has received a medical examination that meets the requirements of this section within the last three years. The examination shall consist of:

(i) A medical and work history, with emphasis on: Past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and

symptoms of respiratory disease (*e.g.*, shortness of breath, cough, wheezing); history of tuberculosis; and smoking status and history;

(ii) A physical examination with special emphasis on the respiratory system;

(iii) A chest X-ray (a single posteroanterior radiographic projection or radiograph of the chest at full inspiration recorded on either film (no less than 14 x 17 inches and no more than 16 x 17 inches) or digital radiography systems), interpreted and classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader;

(iv) A pulmonary function test to include forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) and FEV_1/FVC ratio, administered by a spirometry technician with a current certificate from a NIOSH-approved spirometry course;

(v) Testing for latent tuberculosis infection; and

(vi) Any other tests deemed appropriate by the PLHCP.

(3) *Periodic examinations.* The employer shall make available medical examinations that include the procedures described in paragraph (h)(2) of this section (except paragraph (h)(2)(v)) at least every three years, or more frequently if recommended by the PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the PLHCP with the following information:

(i) A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

(ii) The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

(5) *PLHCP's written medical report for the employee.* The employer shall ensure that the PLHCP explains to the employee the results of the medical examination and provides each employee with a written medical report within 30 days of each medical examination performed. The written report shall contain:

(i) A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment;

(ii) Any recommended limitations on the employee's use of respirators;

(iii) Any recommended limitations on the employee's exposure to respirable crystalline silica; and

(iv) A statement that the employee should be examined by a specialist (pursuant to paragraph (h)(7) of this section) if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a specialist is otherwise deemed appropriate by the PLHCP.

(6) *PLHCP's written medical opinion for the employer.* (i) The employer shall obtain a written medical opinion from the PLHCP within 30 days of the medical examination. The written opinion shall contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this section; and

(C) Any recommended limitations on the employee's use of respirators.

(ii) If the employee provides written authorization, the written opinion shall also contain either or both of the following:

(A) Any recommended limitations on the employee's exposure to respirable crystalline silica;

(B) A statement that the employee should be examined by a specialist (pursuant to paragraph (h)(7) of this section) if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a specialist is otherwise deemed appropriate by the PLHCP.

(iii) The employer shall ensure that each employee receives a copy of the written medical opinion described in paragraph (h)(6)(i) and (ii) of this section within 30 days of each medical examination performed.

(7) *Additional examinations.* (i) If the PLHCP's written medical opinion indicates that an employee should be examined by a specialist, the employer shall make available a medical examination by a specialist within 30 days after receiving the PLHCP's written opinion.

(ii) The employer shall ensure that the examining specialist is provided with all of the information that the employer is obligated to provide to the PLHCP in accordance with paragraph (h)(4) of this section.

(iii) The employer shall ensure that the specialist explains to the employee the results of the medical examination and provides each employee with a written medical report within 30 days of the examination. The written report shall meet the requirements of paragraph (h)(5) (except paragraph (h)(5)(iv)) of this section.

(iv) The employer shall obtain a written opinion from the specialist within 30 days of the medical examination. The written opinion shall meet the requirements of paragraph (h)(6) (except paragraph (h)(6)(i)(B) and (ii)(B)) of this section.

(i) *Communication of respirable crystalline silica hazards to employees*—(1) *Hazard communication.* The employer shall include respirable crystalline silica in the program established to comply with the hazard communication standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of crystalline silica and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (i)(2) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer, lung effects, immune system effects, and kidney effects.

(2) *Employee information and training.* (i) The employer shall ensure that each employee covered by this section can demonstrate knowledge and understanding of at least the following:

(A) The health hazards associated with exposure to respirable crystalline silica;

(B) Specific tasks in the workplace that could result in exposure to respirable crystalline silica;

(C) Specific measures the employer has implemented to protect employees from exposure to respirable crystalline silica, including engineering controls, work practices, and respirators to be used;

(D) The contents of this section;

(E) The identity of the competent person designated by the employer in accordance with paragraph (g)(4) of this section; and

(F) The purpose and a description of the medical surveillance program required by paragraph (h) of this section.

(ii) The employer shall make a copy of this section readily available without cost to each employee covered by this section.

(j) *Recordkeeping*—(1) *Air monitoring data.* (i) The employer shall make and

maintain an accurate record of all exposure measurements taken to assess employee exposure to respirable crystalline silica, as prescribed in paragraph (d)(2) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The task monitored;

(C) Sampling and analytical methods used;

(D) Number, duration, and results of samples taken;

(E) Identity of the laboratory that performed the analysis;

(F) Type of personal protective equipment, such as respirators, worn by the employees monitored; and

(G) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Objective data.* (i) The employer shall make and maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The crystalline silica-containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing;

(D) A description of the process, task, or activity on which the objective data were based; and

(E) Other data relevant to the process, task, activity, material, or exposures on which the objective data were based.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Medical surveillance.* (i) The employer shall make and maintain an accurate record for each employee covered by medical surveillance under paragraph (h) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCPs' and specialists' written medical opinions; and

(C) A copy of the information provided to the PLHCPs and specialists.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(k) *Dates.* (1) This section shall become effective June 23, 2016.

(2) All obligations of this section, except requirements for methods of sample analysis in paragraph (d)(2)(v), shall commence June 23, 2017.

(3) Requirements for methods of sample analysis in paragraph (d)(2)(v) of this section commence June 23, 2018.

Appendix A to § 1926.1153—Methods of Sample Analysis

This This appendix specifies the procedures for analyzing air samples for respirable crystalline silica, as well as the quality control procedures that employers must ensure that laboratories use when performing an analysis required under 29 CFR 1926.1153 (d)(2)(v). Employers must ensure that such a laboratory:

1. Evaluates all samples using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500; NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7;

2. Is accredited to ANS/ISO/IEC Standard 17025:2005 with respect to crystalline silica analyses by a body that is compliant with ISO/IEC Standard 17011:2004 for implementation of quality assessment programs;

3. Uses the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification;

4. Implements an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error;

5. Characterizes the sample material by identifying polymorphs of respirable crystalline silica present, identifies the presence of any interfering compounds that might affect the analysis, and makes any corrections necessary in order to obtain accurate sample analysis; and

6. Analyzes quantitatively for crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, corrects for analytical interferences, and uses a method that meets the following performance specifications:

6.1 Each day that samples are analyzed, performs instrument calibration checks with standards that bracket the sample concentrations;

6.2 Uses five or more calibration standard levels to prepare calibration curves and ensures that standards are distributed through the calibration range in a manner that accurately reflects the underlying calibration curve; and

6.3 Optimizes methods and instruments to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL based on sample air volume.

Appendix B to § 1926.1153—Medical Surveillance Guidelines

Introduction

The purpose of this Appendix is to provide medical information and recommendations to aid physicians and other licensed health care professionals (PLHCPs) regarding compliance with the medical surveillance provisions of the respirable crystalline silica standard (29 CFR 1926.1153). Appendix B is for informational and guidance purposes only and none of the statements in Appendix B should be construed as imposing a mandatory requirement on employers that is not otherwise imposed by the standard.

Medical screening and surveillance allow for early identification of exposure-related health effects in individual employee and groups of employees, so that actions can be taken to both avoid further exposure and prevent or address adverse health outcomes. Silica-related diseases can be fatal, encompass a variety of target organs, and may have public health consequences when considering the increased risk of a latent tuberculosis (TB) infection becoming active. Thus, medical surveillance of silica-exposed employees requires that PLHCPs have a thorough knowledge of silica-related health effects.

This Appendix is divided into seven sections. Section 1 reviews silica-related diseases, medical responses, and public health responses. Section 2 outlines the components of the medical surveillance program for employees exposed to silica. Section 3 describes the roles and responsibilities of the PLHCP implementing the program and of other medical specialists and public health professionals. Section 4 provides a discussion of considerations, including confidentiality. Section 5 provides a list of additional resources and Section 6 lists references. Section 7 provides sample forms for the written medical report for the employee, the written medical opinion for the employer and the written authorization.

1. Recognition of Silica-Related Diseases

1.1. Overview. The term ''silica'' refers specifically to the compound silicon dioxide (SiO_2). Silica is a major component of sand, rock, and mineral ores. Exposure to fine (respirable size) particles of crystalline forms of silica is associated with adverse health effects, such as silicosis, lung cancer, chronic obstructive pulmonary disease (COPD), and activation of latent TB infections. Exposure to respirable crystalline silica can occur in industry settings such as foundries, abrasive blasting operations, paint manufacturing, glass and concrete product manufacturing, brick making, china and pottery manufacturing, manufacturing of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuck-pointing. New uses of silica continue to emerge. These include countertop manufacturing, finishing, and installation (Kramer *et al.* 2012; OSHA 2015) and hydraulic fracturing in the oil and gas industry (OSHA 2012).

Silicosis is an irreversible, often disabling, and sometimes fatal fibrotic lung disease. Progression of silicosis can occur despite removal from further exposure. Diagnosis of silicosis requires a history of exposure to silica and radiologic findings characteristic of silica exposure. Three different presentations of silicosis (chronic, accelerated, and acute) have been defined. Accelerated and acute silicosis are much less common than chronic silicosis. However, it is critical to recognize all cases of accelerated and acute silicosis because these are life-threatening illnesses

and because they are caused by substantial overexposures to respirable crystalline silica. Although any case of silicosis indicates a breakdown in prevention, a case of acute or accelerated silicosis implies current high exposure and a very marked breakdown in prevention.

In addition to silicosis, employees exposed to respirable crystalline silica, especially those with accelerated or acute silicosis, are at increased risks of contracting active TB and other infections (ATS 1997; Rees and Murray 2007). Exposure to respirable crystalline silica also increases an employee's risk of developing lung cancer, and the higher the cumulative exposure, the higher the risk (Steenland *et al.* 2001; Steenland and Ward 2014). Symptoms for these diseases and other respirable crystalline silica-related diseases are discussed below.

1.2. Chronic Silicosis. Chronic silicosis is the most common presentation of silicosis and usually occurs after at least 10 years of exposure to respirable crystalline silica. The clinical presentation of chronic silicosis is:

1.2.1. Symptoms—shortness of breath and cough, although employees may not notice any symptoms early in the disease. Constitutional symptoms, such as fever, loss of appetite and fatigue, may indicate other diseases associated with silica exposure, such as TB infection or lung cancer. Employees with these symptoms should immediately receive further evaluation and treatment.

1.2.2. Physical Examination—may be normal or disclose dry rales or rhonchi on lung auscultation.

1.2.3. Spirometry—may be normal or may show only a mild restrictive or obstructive pattern.

1.2.4. Chest X-ray—classic findings are small, rounded opacities in the upper lung fields bilaterally. However, small irregular opacities and opacities in other lung areas can also occur. Rarely, ''eggshell calcifications'' in the hilar and mediastinal lymph nodes are seen.

1.2.5. Clinical Course—chronic silicosis in most cases is a slowly progressive disease. Under the respirable crystalline silica standard, the PLHCP is to recommend that employees with a 1/0 category X-ray be referred to an American Board Certified Specialist in Pulmonary Disease or Occupational Medicine. The PLHCP and/or Specialist should counsel employees regarding work practices and personal habits that could affect employees' respiratory health.

1.3. Accelerated Silicosis. Accelerated silicosis generally occurs within 5–10 years of exposure and results from high levels of exposure to respirable crystalline silica. The clinical presentation of accelerated silicosis is:

1.3.1. Symptoms—shortness of breath, cough, and sometimes sputum production. Employees with exposure to respirable crystalline silica, and especially those with accelerated silicosis, are at high risk for activation of TB infections, atypical mycobacterial infections, and fungal superinfections. Constitutional symptoms, such as fever, weight loss, hemoptysis (coughing up blood), and fatigue may herald one of these infections or the onset of lung cancer.

1.3.2. Physical Examination—rales, rhonchi, or other abnormal lung findings in relation to illnesses present. Clubbing of the digits, signs of heart failure, and cor pulmonale may be present in severe lung disease.

1.3.3. Spirometry—restrictive or mixed restrictive/obstructive pattern.

1.3.4. Chest X-ray—small rounded and/or irregular opacities bilaterally. Large opacities and lung abscesses may indicate infections, lung cancer, or progression to complicated silicosis, also termed progressive massive fibrosis.

1.3.5. Clinical Course—accelerated silicosis has a rapid, severe course. Under the respirable crystalline silica standard, the PLHCP can recommend referral to a Board Certified Specialist in either Pulmonary Disease or Occupational Medicine, as deemed appropriate, and referral to a Specialist is recommended whenever the diagnosis of accelerated silicosis is being considered.

1.4. Acute Silicosis. Acute silicosis is a rare disease caused by inhalation of extremely high levels of respirable crystalline silica particles. The pathology is similar to alveolar proteinosis with lipoproteinaceous material accumulating in the alveoli. Acute silicosis develops rapidly, often, within a few months to less than 2 years of exposure, and is almost always fatal. The clinical presentation of acute silicosis is as follows:

1.4.1. Symptoms—sudden, progressive, and severe shortness of breath. Constitutional symptoms are frequently present and include fever, weight loss, fatigue, productive cough, hemoptysis (coughing up blood), and pleuritic chest pain.

1.4.2. Physical Examination—dyspnea at rest, cyanosis, decreased breath sounds, inspiratory rales, clubbing of the digits, and fever.

1.4.3. Spirometry—restrictive or mixed restrictive/obstructive pattern.

1.4.4. Chest X-ray—diffuse haziness of the lungs bilaterally early in the disease. As the disease progresses, the ''ground glass'' appearance of interstitial fibrosis will appear.

1.4.5. Clinical Course—employees with acute silicosis are at especially high risk of TB activation, nontuberculous mycobacterial infections, and fungal superinfections. Acute silicosis is immediately life-threatening. The employee should be urgently referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for evaluation and treatment. Although any case of silicosis indicates a breakdown in prevention, a case of acute or accelerated silicosis implies a profoundly high level of silica exposure and may mean that other employees are currently exposed to dangerous levels of silica.

1.5. COPD. COPD, including chronic bronchitis and emphysema, has been documented in silica-exposed employees, including those who do not develop silicosis. Periodic spirometry tests are performed to evaluate each employee for progressive changes consistent with the development of COPD. In addition to evaluating spirometry results of individual employees over time, PLHCPs may want to be aware of general trends in spirometry results for groups of employees from the same workplace to identify possible problems that might exist at that workplace. (*See* Section 2 of this Appendix on Medical Surveillance for further discussion.) Heart disease may develop secondary to lung diseases such as COPD. A recent study by Liu *et al.* 2014 noted a significant exposure-response trend between cumulative silica exposure and heart disease deaths, primarily due to pulmonary heart disease, such as cor pulmonale.

1.6. Renal and Immune System. Silica exposure has been associated with several types of kidney disease, including glomerulonephritis, nephrotic syndrome, and end stage renal disease requiring dialysis. Silica exposure has also been associated with other autoimmune conditions, including progressive systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Studies note an association between employees with silicosis and serologic markers for autoimmune diseases, including antinuclear antibodies, rheumatoid factor, and immune complexes (Jalloul and Banks 2007; Shtraichman *et al.* 2015).

1.7. TB and Other Infections. Silica-exposed employees with latent TB are 3 to 30 times more likely to develop active pulmonary TB infection (ATS 1997; Rees and Murray 2007). Although respirable crystalline silica exposure does not cause TB infection, individuals with latent TB infection are at increased risk for activation of disease if they have higher levels of respirable crystalline silica exposure, greater profusion of radiographic abnormalities, or a diagnosis of silicosis. Demographic characteristics, such as immigration from some countries, are associated with increased rates of latent TB infection. PLHCPs can review the latest Centers for Disease Control and Prevention (CDC) information on TB incidence rates and high risk populations online (*See* Section 5 of this Appendix). Additionally, silica-exposed employees are at increased risk for contracting nontuberculous mycobacterial infections, including *Mycobacterium avium-intracellulare* and *Mycobacterium kansaii.*

1.8. Lung Cancer. The National Toxicology Program has listed respirable crystalline silica as a known human carcinogen since 2000 (NTP 2014). The International Agency for Research on Cancer (2012) has also classified silica as Group 1 (carcinogenic to humans). Several studies have indicated that the risk of lung cancer from exposure to respirable crystalline silica and smoking is greater than additive (Brown 2009; Liu *et al.* 2013). Employees should be counseled on smoking cessation.

2. Medical Surveillance

PLHCPs who manage silica medical surveillance programs should have a thorough understanding of the many silica-related diseases and health effects outlined in Section 1 of this Appendix. At each clinical encounter, the PLHCP should consider silica-related health outcomes, with particular vigilance for acute and accelerated silicosis. In this Section, the required components of

medical surveillance under the respirable crystalline silica standard are reviewed, along with additional guidance and recommendations for PLHCPs performing medical surveillance examinations for silica-exposed employees.

2.1. History.

2.1.1. The respirable crystalline silica standard requires the following: A medical and work history, with emphasis on: Past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (*e.g.,* shortness of breath, cough, wheezing); history of TB; and smoking status and history.

2.1.2. Further, the employer must provide the PLHCP with the following information:

2.1.2.1. A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

2.1.2.2. The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

2.1.2.3. A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

2.1.2.4. Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

2.1.3. Additional guidance and recommendations: A history is particularly important both in the initial evaluation and in periodic examinations. Information on past and current medical conditions (particularly a history of kidney disease, cardiac disease, connective tissue disease, and other immune diseases), medications, hospitalizations and surgeries may uncover health risks, such as immune suppression, that could put an employee at increased health risk from exposure to silica. This information is important when counseling the employee on risks and safe work practices related to silica exposure.

2.2. *Physical Examination.*

2.2.1. The respirable crystalline silica standard requires the following: A physical examination, with special emphasis on the respiratory system. The physical examination must be performed at the initial examination and every three years thereafter.

2.2.2. Additional guidance and recommendations: Elements of the physical examination that can assist the PHLCP include: An examination of the cardiac system, an extremity examination (for clubbing, cyanosis, edema, or joint abnormalities), and an examination of other pertinent organ systems identified during the history.

2.3. TB Testing.

2.3.1. The respirable crystalline silica standard requires the following: Baseline testing for TB on initial examination.

2.3.2. Additional guidance and recommendations:

2.3.2.1. Current CDC guidelines (*See* Section 5 of this Appendix) should be followed for the application and interpretation of Tuberculin skin tests (TST). The interpretation and documentation of TST reactions should be performed within 48 to 72 hours of administration by trained PLHCPs.

2.3.2.2. PLHCPs may use alternative TB tests, such as interferon-γ release assays (IGRAs), if sensitivity and specificity are comparable to TST (Mazurek *et al.* 2010; Slater *et al.* 2013). PLHCPs can consult the current CDC guidelines for acceptable tests for latent TB infection.

2.3.2.3. The silica standard allows the PLHCP to order additional tests or test at a greater frequency than required by the standard, if deemed appropriate. Therefore, PLHCPs might perform periodic (*e.g.*, annual) TB testing as appropriate, based on employees' risk factors. For example, according to the American Thoracic Society (ATS), the diagnosis of silicosis or exposure to silica for 25 years or more are indications for annual TB testing (ATS 1997). PLHCPs should consult the current CDC guidance on risk factors for TB (*See* Section 5 of this Appendix).

2.3.2.4. Employees with positive TB tests and those with indeterminate test results should be referred to the appropriate agency or specialist, depending on the test results and clinical picture. Agencies, such as local public health departments, or specialists, such as a pulmonary or infectious disease specialist, may be the appropriate referral. Active TB is a nationally notifiable disease. PLHCPs should be aware of the reporting requirements for their region. All States have TB Control Offices that can be contacted for further information. (*See* Section 5 of this Appendix for links to CDC's TB resources and State TB Control Offices.)

2.3.2.5. The following public health principles are key to TB control in the U.S. (ATS–CDC–IDSA 2005):

(1) Prompt detection and reporting of persons who have contracted active TB;

(2) Prevention of TB spread to close contacts of active TB cases;

(3) Prevention of active TB in people with latent TB through targeted testing and treatment; and

(4) Identification of settings at high risk for TB transmission so that appropriate infection-control measures can be implemented.

2.4. Pulmonary Function Testing.

2.4.1. The respirable crystalline silica standard requires the following: Pulmonary function testing must be performed on the initial examination and every three years thereafter. The required pulmonary function test is spirometry and must include forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and FEV_1/FVC ratio. Testing must be administered by a spirometry technician with a current certificate from a National Institute for Occupational Health and Safety (NIOSH)-approved spirometry course.

2.4.2. Additional guidance and recommendations: Spirometry provides information about individual respiratory status and can be used to track an employee's respiratory status over time or as a surveillance tool to follow individual and group respiratory function. For quality results, the ATS and the American College of Occupational and Environmental Medicine (ACOEM) recommend use of the third National Health and Nutrition Examination Survey (NHANES III) values, and ATS publishes recommendations for spirometry equipment (Miller *et al.* 2005; Townsend 2011; Redlich *et al.* 2014). OSHA's publication, *Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals*, provides helpful guidance (*See* Section 5 of this Appendix). Abnormal spirometry results may warrant further clinical evaluation and possible recommendations for limitations on the employee's exposure to respirable crystalline silica.

2.5. Chest X-ray.

2.5.1. The respirable crystalline silica standard requires the following: A single posteroanterior (PA) radiographic projection or radiograph of the chest at full inspiration recorded on either film (no less than 14 x 17 inches and no more than 16 x 17 inches) or digital radiography systems. A chest X-ray must be performed on the initial examination and every three years thereafter. The chest X-ray must be interpreted and classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader.

Chest radiography is necessary to diagnose silicosis, monitor the progression of silicosis, and identify associated conditions such as TB. If the B reading indicates small opacities in a profusion of 1/0 or higher, the employee is to receive a recommendation for referral to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine.

2.5.2. Additional guidance and recommendations: Medical imaging has largely transitioned from conventional film-based radiography to digital radiography systems. The ILO Guidelines for the Classification of Pneumoconioses has historically provided film-based chest radiography as a referent standard for comparison to individual exams. However, in 2011, the ILO revised the guidelines to include a digital set of referent standards that were derived from the prior film-based standards. To assist in assuring that digitally-acquired radiographs are at least as safe and effective as film radiographs, NIOSH has prepared guidelines, based upon accepted contemporary professional recommendations (*See* Section 5 of this Appendix). Current research from Laney *et al.* 2011 and Halldin *et al.* 2014 validate the use of the ILO digital referent images. Both studies conclude that the results of pneumoconiosis classification using digital references are comparable to film-based ILO classifications. Current ILO guidance on radiography for pneumoconioses and B-reading should be reviewed by the PLHCP periodically, as needed, on the ILO or NIOSH Web sites (*See* Section 5 of this Appendix).

2.6. Other Testing. Under the respirable crystalline silica standards, the PLHCP has the option of ordering additional testing he or she deems appropriate. Additional tests can be ordered on a case-by-case basis depending on individual signs or symptoms and clinical judgment. For example, if an

employee reports a history of abnormal kidney function tests, the PLHCP may want to order a baseline renal function tests (*e.g.*, serum creatinine and urinalysis). As indicated above, the PLHCP may order annual TB testing for silica-exposed employees who are at high risk of developing active TB infections. Additional tests that PLHCPs may order based on findings of medical examinations include, but is not limited to, chest computerized tomography (CT) scan for lung cancer or COPD, testing for immunologic diseases, and cardiac testing for pulmonary-related heart disease, such as cor pulmonale.

3. Roles and Responsibilities

3.1. PLHCP. The PLHCP designation refers to ''an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required'' by the respirable crystalline silica standard. The legally permitted scope of practice for the PLHCP is determined by each State. PLHCPs who perform clinical services for a silica medical surveillance program should have a thorough knowledge of respirable crystalline silica-related diseases and symptoms. Suspected cases of silicosis, advanced COPD, or other respiratory conditions causing impairment should be promptly referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine.

Once the medical surveillance examination is completed, the employer must ensure that the PLHCP explains to the employee the results of the medical examination and provides the employee with a written medical report within 30 days of the examination. The written medical report must contain a statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment. In addition, the PLHCP's written medical report must include any recommended limitations on the employee's use of respirators, any recommended limitations on the employee's exposure to respirable crystalline silica, and a statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational medicine if the chest X-ray is classified as 1/0 or higher by the B Reader, or if referral to a Specialist is otherwise deemed appropriate by the PLHCP.

The PLHCP should discuss all findings and test results and any recommendations regarding the employee's health, worksite safety and health practices, and medical referrals for further evaluation, if indicated. In addition, it is suggested that the PLHCP offer to provide the employee with a complete copy of their examination and test results, as some employees may want this information for their own records or to provide to their personal physician or a future PLHCP. Employees are entitled to access their medical records.

Under the respirable crystalline silica standard, the employer must ensure that the PLHCP provides the employer with a written medical opinion within 30 days of the employee examination, and that the employee also gets a copy of the written medical opinion for the employer within 30 days. The PLHCP may choose to directly provide the employee a copy of the written medical opinion. This can be particularly helpful to employees, such as construction employees, who may change employers frequently. The written medical opinion can be used by the employee as proof of up-to-date medical surveillance. The following lists the elements of the written medical report for the employee and written medical opinion for the employer. (Sample forms for the written medical report for the employee, the written medical opinion for the employer, and the written authorization are provided in Section 7 of this Appendix.)

3.1.1. The written medical report for the employee must include the following information:

3.1.1.1. A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment;

3.1.1.2. Any recommended limitations upon the employee's use of a respirator;

3.1.1.3. Any recommended limitations on the employee's exposure to respirable crystalline silica; and

3.1.1.4. A statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine, where the standard requires or where the PLHCP has determined such a referral is necessary. The standard requires referral to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for a chest X-ray B reading indicating small opacities in a profusion of 1/0 or higher, or if the PHLCP determines that referral to a Specialist is necessary for other silica-related findings.

3.1.2. The PLHCP's written medical opinion for the employer must include only the following information:

3.1.2.1. The date of the examination;

3.1.2.2. A statement that the examination has met the requirements of this section; and

3.1.2.3. Any recommended limitations on the employee's use of respirators.

3.1.2.4. If the employee provides the PLHCP with written authorization, the written opinion for the employer shall also contain either or both of the following:

(1) Any recommended limitations on the employee's exposure to respirable crystalline silica; and

(2) A statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a Specialist is otherwise deemed appropriate.

3.1.2.5. In addition to the above referral for abnormal chest X-ray, the PLHCP may refer an employee to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for other findings of concern during the medical surveillance examination if these findings are potentially related to silica exposure.

3.1.2.6. Although the respirable crystalline silica standard requires the employer to ensure that the PLHCP explains the results of the medical examination to the employee, the standard does not mandate how this should be done. The written medical opinion for the employer could contain a statement that the PLHCP has explained the results of the medical examination to the employee.

3.2. Medical Specialists. The silica standard requires that all employees with chest X-ray B readings of 1/0 or higher be referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine. If the employee has given written authorization for the employer to be informed, then the employer shall make available a medical examination by a Specialist within 30 days after receiving the PLHCP's written medical opinion.

3.2.1. The employer must provide the following information to the Board Certified Specialist in Pulmonary Disease or Occupational Medicine:

3.2.1.1. A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

3.2.1.2. The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

3.2.1.3. A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

3.2.1.4. Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

3.2.2. The PLHCP should make certain that, with written authorization from the employee, the Board Certified Specialist in Pulmonary Disease or Occupational Medicine has any other pertinent medical and occupational information necessary for the specialist's evaluation of the employee's condition.

3.2.3. Once the Board Certified Specialist in Pulmonary Disease or Occupational Medicine has evaluated the employee, the employer must ensure that the Specialist explains to the employee the results of the medical examination and provides the employee with a written medical report within 30 days of the examination. The employer must also ensure that the Specialist provides the employer with a written medical opinion within 30 days of the employee examination. (Sample forms for the written medical report for the employee, the written medical opinion for the employer and the written authorization are provided in Section 7 of this Appendix.)

3.2.4. The Specialist's written medical report for the employee must include the following information:

3.2.4.1. A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to

respirable crystalline silica and any medical conditions that require further evaluation or treatment;

3.2.4.2. Any recommended limitations upon the employee's use of a respirator; and

3.2.4.3. Any recommended limitations on the employee's exposure to respirable crystalline silica.

3.2.5. The Specialist's written medical opinion for the employer must include the following information:

3.2.5.1. The date of the examination; and

3.2.5.2. Any recommended limitations on the employee's use of respirators.

3.2.5.3. If the employee provides the Board Certified Specialist in Pulmonary Disease or Occupational Medicine with written authorization, the written medical opinion for the employer shall also contain any recommended limitations on the employee's exposure to respirable crystalline silica.

3.2.5.4. Although the respirable crystalline silica standard requires the employer to ensure that the Board Certified Specialist in Pulmonary Disease or Occupational Medicine explains the results of the medical examination to the employee, the standard does not mandate how this should be done. The written medical opinion for the employer could contain a statement that the Specialist has explained the results of the medical examination to the employee.

3.2.6. After evaluating the employee, the Board Certified Specialist in Pulmonary Disease or Occupational Medicine should provide feedback to the PLHCP as appropriate, depending on the reason for the referral. OSHA believes that because the PLHCP has the primary relationship with the employer and employee, the Specialist may want to communicate his or her findings to the PLHCP and have the PLHCP simply update the original medical report for the employee and medical opinion for the employer. This is permitted under the standard, so long as all requirements and time deadlines are met.

3.3. Public Health Professionals. PLHCPs might refer employees or consult with public health professionals as a result of silica medical surveillance. For instance, if individual cases of active TB are identified, public health professionals from state or local health departments may assist in diagnosis and treatment of individual cases and may evaluate other potentially affected persons, including coworkers. Because silica-exposed employees are at increased risk of progression from latent to active TB, treatment of latent infection is recommended. The diagnosis of active TB, acute or accelerated silicosis, or other silica-related diseases and infections should serve as sentinel events suggesting high levels of exposure to silica and may require consultation with the appropriate public health agencies to investigate potentially similarly exposed coworkers to assess for disease clusters. These agencies include local or state health departments or OSHA. In addition, NIOSH can provide assistance upon request through their Health Hazard Evaluation program. (*See* Section 5 of this Appendix)

4. Confidentiality and Other Considerations

The information that is provided from the PLHCP to the employee and employer under the medical surveillance section of OSHA's respirable crystalline silica standard differs from that of medical surveillance requirements in previous OSHA standards. The standard requires two separate written communications, a written medical report for the employee and a written medical opinion for the employer. The confidentiality requirements for the written medical opinion are more stringent than in past standards. For example, the information the PLHCP can (and must) include in his or her written medical opinion for the employer is limited to: The date of the examination, a statement that the examination has met the requirements of this section, and any recommended limitations on the employee's use of respirators. If the employee provides written authorization for the disclosure of any limitations on the employee's exposure to respirable crystalline silica, then the PLHCP can (and must) include that information in the written medical opinion for the employer as well. Likewise, with the employee's written authorization, the PLHCP can (and must) disclose the PLHCP's referral recommendation (if any) as part of the written medical opinion for the employer. However, the opinion to the employer must not include information regarding recommended limitations on the employee's exposure to respirable crystalline silica or any referral recommendations without the employee's written authorization.

The standard also places limitations on the information that the Board Certified Specialist in Pulmonary Disease or Occupational Medicine can provide to the employer without the employee's written authorization. The Specialist's written medical opinion for the employer, like the PLHCP's opinion, is limited to (and must contain): The date of the examination and any recommended limitations on the employee's use of respirators. If the employee provides written authorization, the written medical opinion can (and must) also contain any limitations on the employee's exposure to respirable crystalline silica.

The PLHCP should discuss the implication of signing or not signing the authorization with the employee (in a manner and language that he or she understands) so that the employee can make an informed decision regarding the written authorization and its consequences. The discussion should include the risk of ongoing silica exposure, personal risk factors, risk of disease progression, and possible health and economic consequences. For instance, written authorization is required for a PLHCP to advise an employer that an employee should be referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for evaluation of an abnormal chest X-ray (B-reading 1/0 or greater). If an employee does not sign an authorization, then the employer will not know and cannot facilitate the referral to a Specialist and is not required to pay for the Specialist's examination. In the rare case where an employee is diagnosed with acute or accelerated silicosis, co-workers are likely to be at significant risk of developing those diseases as a result of inadequate controls in the workplace. In this case, the PLHCP and/or Specialist should explain this concern to the affected employee and make a determined effort to obtain written authorization from the employee so that the PLHCP and/or Specialist can contact the employer.

Finally, without written authorization from the employee, the PLHCP and/or Board Certified Specialist in Pulmonary Disease or Occupational Medicine cannot provide feedback to an employer regarding control of workplace silica exposure, at least in relation to an individual employee. However, the regulation does not prohibit a PLHCP and/or Specialist from providing an employer with general recommendations regarding exposure controls and prevention programs in relation to silica exposure and silica-related illnesses, based on the information that the PLHCP receives from the employer such as employees' duties and exposure levels. Recommendations may include increased frequency of medical surveillance examinations, additional medical surveillance components, engineering and work practice controls, exposure monitoring and personal protective equipment. For instance, more frequent medical surveillance examinations may be a recommendation to employers for employees who do abrasive blasting with silica because of the high exposures associated with that operation.

ACOEM's Code of Ethics and discussion is a good resource to guide PLHCPs regarding the issues discussed in this section (*See* Section 5 of this Appendix).

5. Resources

5.1. American College of Occupational and Environmental Medicine (ACOEM):

ACOEM Code of Ethics. Accessed at: *http://www.acoem.org/codeofconduct.aspx*

Raymond, L.W. and Wintermeyer, S. (2006) ACOEM evidenced-based statement on medical surveillance of silica-exposed workers: Medical surveillance of workers exposed to crystalline silica. *J Occup Environ Med*, 48, 95–101.

5.2. Center for Disease Control and Prevention (CDC)

Tuberculosis Web page: *http://www.cdc.gov/tb/default.htm*

State TB Control Offices Web page: *http://www.cdc.gov/tb/links/tboffices.htm*

Tuberculosis Laws and Policies Web page: *http://www.cdc.gov/tb/programs/laws/default.htm*

CDC. (2013). Latent Tuberculosis Infection: A Guide for Primary Health Care Providers. Accessed at: *http://www.cdc.gov/tb/publications/ltbi/pdf/targetedltbi.pdf*

5.3. International Labour Organization

International Labour Office (ILO). (2011) Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses, Revised edition 2011. Occupational Safety and Health Series No. 22: *http://www.ilo.org/safework/info/publications/WCMS_168260/lang-en/index.htm*

5.4. National Institute of Occupational Safety and Health (NIOSH)

NIOSH B Reader Program Web page. (Information on interpretation of X-rays for silicosis and a list of certified B-readers). Accessed at: *http://www.cdc.gov/niosh/topics/chestradiography/breader-info.html*

NIOSH Guideline (2011). Application of Digital Radiography for the Detection and Classification of Pneumoconiosis. NIOSH publication number 2011–198. Accessed at: *http://www.cdc.gov/niosh/docs/2011-198/*

NIOSH Hazard Review (2002), Health Effects of Occupational Exposure to Respirable Crystalline Silica. NIOSH publication number 2002–129: Accessed at *http://www.cdc.gov/niosh/docs/2002-129/*

NIOSH Health Hazard Evaluations Programs. (Information on the NIOSH Health Hazard Evaluation (HHE) program, how to request an HHE and how to look up an HHE report). Accessed at: *http://www.cdc.gov/niosh/hhe/*

5.5. National Industrial Sand Association:

Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry. National Industrial Sand Association, 2nd ed. 2010. Can be ordered at: *http://www.sand.org/silica-occupational-health-program*

5.6. Occupational Safety and Health Administration (OSHA)

Contacting OSHA: *http://www.osha.gov/html/Feed_Back.html*

OSHA's Clinicians Web page. (OSHA resources, regulations and links to help clinicians navigate OSHA's Web site and aid clinicians in caring for workers.) Accessed at: *http://www.osha.gov/dts/oom/clinicians/index.html*

OSHA's Safety and Health Topics Web page on Silica. Accessed at: *http://www.osha.gov/dsg/topics/silicacrystalline/index.html*

OSHA (2013). Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals. (OSHA 3637–03 2013). Accessed at: *http://www.osha.gov/Publications/OSHA3637.pdf*

OSHA/NIOSH (2011). Spirometry: OSHA/NIOSH Spirometry InfoSheet (OSHA 3415–1–11). (Provides guidance to employers). Accessed at *http://www.osha.gov/Publications/osha3415.pdf*

OSHA/NIOSH (2011) Spirometry: OSHA/NIOSH Spirometry Worker Info. (OSHA 3418–3–11). Accessed at *http://www.osha.gov/Publications/osha3418.pdf*

5.7. Other

Steenland, K. and Ward E. (2014). Silica: A lung carcinogen. *CA Cancer J Clin*, 64, 63–69. (This article reviews not only silica and lung cancer but also all the known silica-related health effects. Further, the authors provide guidance to clinicians on medical surveillance of silica-exposed workers and worker counselling on safety practices to minimize silica exposure.)

6. References

American Thoracic Society (ATS). Medical Section of the American Lung Association (1997). Adverse effects of crystalline silica exposure. *Am J Respir Crit Care Med*, 155, 761–765.

American Thoracic Society (ATS), Centers for Disease Control (CDC), Infectious Diseases Society of America (IDSA) (2005). Controlling Tuberculosis in the United States. *Morbidity and Mortality Weekly Report (MMWR)*, 54(RR12), 1–81. Accessed at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm*

Brown, T. (2009). Silica exposure, smoking, silicosis and lung cancer—complex interactions. *Occupational Medicine*, 59, 89–95.

Halldin, C.N., Petsonk, E.L., and Laney, A.S. (2014). Validation of the International Labour Office digitized standard images for recognition and classification of radiographs of pneumoconiosis. *Acad Radiol*, 21, 305–311.

International Agency for Research on Cancer. (2012). Monographs on the evaluation of carcinogenic risks to humans: Arsenic, Metals, Fibers, and Dusts Silica Dust, Crystalline, in the Form of Quartz or Cristobalite. A Review of Human Carcinogens. Volume 100 C. Geneva, Switzerland: World Health Organization.

Jalloul, A.S. and Banks D.E. (2007). Chapter 23. The health effects of silica exposure. In: Rom, W.N. and Markowitz, S.B. (Eds). Environmental and Occupational Medicine, 4th edition. Lippincott, Williams and Wilkins, Philadelphia, 365–387.

Kramer, M.R., Blanc, P.D., Fireman, E., Amital, A., Guber, A., Rahman, N.A., and Shitrit, D. (2012). Artifical stone silicosis: Disease resurgence among artificial stone workers. *Chest*, 142, 419–424.

Laney, A.S., Petsonk, E.L., and Attfield, M.D. (2011). Intramodality and intermodality comparisons of storage phosphor computed radiography and conventional film-screen radiography in the recognition of small pneumonconiotic opacities. *Chest*, 140, 1574–1580.

Liu, Y., Steenland, K., Rong, Y., Hnizdo, E., Huang, X., Zhang, H., Shi, T., Sun, Y., Wu, T., and Chen, W. (2013). Exposure-response analysis and risk assessment for lung cancer in relationship to silica exposure: A 44-year cohort study of 34,018 workers. *Am J Epi*, 178, 1424–1433.

Liu, Y., Rong, Y., Steenland, K., Christiani, D.C., Huang, X., Wu, T., and Chen, W. (2014). Long-term exposure to crystalline silica and risk of heart disease mortality. *Epidemiology*, 25, 689–696.

Mazurek, G.H., Jereb, J., Vernon, A., LoBue, P., Goldberg, S., Castro, K. (2010). Updated guidelines for using interferon gamma release assays to detect Mycobacterium tuberculosis infection—United States. *Morbidity and Mortality Weekly Report (MMWR)*, 59(RR05), 1–25.

Miller, M.R., Hankinson, J., Brusasco, V., Burgos, F., Casaburi, R., Coates, A., Crapo, R., Enright, P., van der Grinten, C.P., Gustafsson, P., Jensen, R., Johnson, D.C., MacIntyre, N., McKay, R., Navajas, D., Pedersen, O.F., Pellegrino, R., Viegi, G., and Wanger, J. (2005). American Thoracic Society/European Respiratory Society (ATS/ERS) Task Force: Standardisation of Spirometry. *Eur Respir J*, 26, 319–338.

National Toxicology Program (NTP) (2014). Report on Carcinogens, Thirteenth Edition. Silica, Crystalline (respirable Size). Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. *http://ntp.niehs.nih.gov/ntp/roc/content/profiles/silica.pdf*

Occupational Safety and Health Administration/National Institute for Occupational Safety and Health (OSHA/NIOSH) (2012). Hazard Alert. Worker exposure to silica during hydraulic fracturing.

Occupational Safety and Health Administration/National Institute for Occupational Safety and Health (OSHA/NIOSH) (2015). Hazard alert. Worker exposure to silica during countertop manufacturing, finishing, and installation. (OSHA–HA–3768–2015).

Redlich, C.A., Tarlo, S.M., Hankinson, J.L., Townsend, M.C, Eschenbacher, W.L., Von Essen, S.G., Sigsgaard, T., Weissman, D.N. (2014). Official American Thoracic Society technical standards: Spirometry in the occupational setting. *Am J Respir Crit Care Med*; 189, 984–994.

Rees, D. and Murray, J. (2007). Silica, silicosis and tuberculosis. *Int J Tuberc Lung Dis*, 11(5), 474–484.

Shtraichman, O., Blanc, P.D., Ollech, J.E., Fridel, L., Fuks, L., Fireman, E., and Kramer, M.R. (2015). Outbreak of autoimmune disease in silicosis linked to artificial stone. *Occup Med*, 65, 444–450.

Slater, M.L., Welland, G., Pai, M., Parsonnet, J., and Banaei, N. (2013). Challenges with QuantiFERON–TB gold assay for large-scale, routine screening of U.S. healthcare workers. *Am J Respir Crit Care Med,* 188,1005–1010.

Steenland, K., Mannetje, A., Boffetta, P., Stayner, L., Attfield, M., Chen, J., Dosemeci, M., DeKlerk, N., Hnizdo, E., Koskela, R., and Checkoway, H. (2001). International Agency for Research on Cancer. Pooled exposure-response analyses and risk assessment for lung cancer in 10 cohorts of silica-exposed workers: An IARC multicentre study. *Cancer Causes Control,* 12(9): 773–84.

Steenland, K. and Ward E. (2014). Silica: A lung carcinogen. *CA Cancer J Clin,* 64, 63–69.

Townsend, M.C. ACOEM Guidance Statement. (2011). Spirometry in the occupational health setting—2011 Update. *J Occup Environ Med,* 53, 569–584.

7. Sample Forms

Three sample forms are provided. The first is a sample written medical report for the employee. The second is a sample written medical opinion for the employer. And the third is a sample written authorization form that employees sign to clarify what information the employee is authorizing to be released to the employer.

BILLING CODE 4510–26–P

WRITTEN MEDICAL REPORT FOR EMPLOYEE

EMPLOYEE NAME: _____ **DATE OF EXAMINATION**: _____

TYPE OF EXAMINATION:
[ ] Initial examination [ ] Periodic examination [ ] Specialist examination
[ ] Other: _____

RESULTS OF MEDICAL EXAMINATION:

Physical Examination –	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed
Chest X-Ray –	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed
Breathing Test (Spirometry) –	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed
Test for Tuberculosis –	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed
Other:_____	[ ] Normal	[ ] Abnormal (see below)	[ ] Not performed

Results reported as abnormal: _____
_____

[ ] Your health may be at increased risk from exposure to respirable crystalline silica due to the following:
_____

RECOMMENDATIONS:
[ ] No limitations on respirator use
[ ] Recommended limitations on use of respirator: _____
[ ] Recommended limitations on exposure to respirable crystalline silica: _____
_____

Dates for recommended limitations, if applicable: _____ to _____
MM/DD/YYYY MM/DD/YYYY

[ ] I recommend that you be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine

[ ] Other recommendations*:
_____
_____

Your next periodic examination for silica exposure should be in: [ ] 3 years [ ] Other: _____
MM/DD/YYYY

Examining Provider: _____ Date: _____
(signature)

Provider Name: _____
Office Address: _____ Office Phone: _____

*These findings may not be related to respirable crystalline silica exposure or may not be work-related, and therefore may not be covered by the employer. These findings may necessitate follow-up and treatment by your personal physician.

Respirable Crystalline Silica standard (§ 1910.1053 or 1926.1153)

WRITTEN MEDICAL OPINION FOR EMPLOYER

EMPLOYER: _____

EMPLOYEE NAME: _____ **DATE OF EXAMINATION:** _____

TYPE OF EXAMINATION:
[ ] Initial examination [ ] Periodic examination [ ] Specialist examination
[ ] Other: _____

USE OF RESPIRATOR:
[ ] No limitations on respirator use
[ ] Recommended limitations on use of respirator:_____

Dates for recommended limitations, if applicable: _____ to _____
MM/DD/YYYY MM/DD/YYYY

The employee has provided written authorization for disclosure of the following to the employer (if applicable):

[ ] This employee should be examined by an American Board Certified Specialist in Pulmonary Disease or Occupational Medicine
[ ] Recommended limitations on exposure to respirable crystalline silica:_____
_____

Dates for exposure limitations noted above: _____ to _____
MM/DD/YYYY MM/DD/YYYY

NEXT PERIODIC EVALUATION: [ ] 3 years [ ] Other: _____
MM/DD/YYYY

Examining Provider: _____ Date: _____
(signature)
Provider Name: _____ Provider's specialty:_____

Office Address: _____ Office Phone: _____

[ ] I attest that the results have been explained to the employee.

The following is required to be checked by the Physician or other Licensed Health Care Professional (PLHCP):
[ ] I attest that this medical examination has met the requirements of the medical surveillance section of the OSHA Respirable Crystalline Silica standard (§ 1910.1053(h) or 1926.1153(h)).

AUTHORIZATION FOR CRYSTALLINE SILICA OPINION TO EMPLOYER

This medical examination for exposure to crystalline silica could reveal a medical condition that results in recommendations for (1) limitations on respirator use, (2) limitations on exposure to crystalline silica, or (3) examination by a specialist in pulmonary disease or occupational medicine. Recommended limitations on respirator use will be included in the written opinion to the employer. If you want your employer to know about limitations on crystalline silica exposure or recommendations for a specialist examination, you will need to give authorization for the written opinion to the employer to include one or both of those recommendations.

I hereby authorize the opinion to the employer to contain the following information, if relevant (please check all that apply):

☐ Recommendations for limitations on crystalline silica exposure

☐ Recommendation for a specialist examination

OR

☐ I do not authorize the opinion to the employer to contain anything other than recommended limitations on respirator use.

Please read and initial:

___ I understand that if I do not authorize my employer to receive the recommendation for specialist examination, the employer will not be responsible for arranging and covering costs of a specialist examination.

_____
Name (printed)

_____ _____
Signature Date

[FR Doc. 2016–04800 Filed 3–24–16; 8:45 am]
BILLING CODE 4510–26–C

FEDERAL REGISTER

Vol. 81 Friday,

No. 58 March 25, 2016

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Part III

Department of Justice

Drug Enforcement Administration

Exempt Chemical Preparations Under the Controlled Substances Act; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–372]

Exempt Chemical Preparations Under the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of order with opportunity for comment.

SUMMARY: The applications for exempt chemical preparations received by the Drug Enforcement Administration (DEA) between April 1, 2013, and December 31, 2015, as listed below, were accepted for filing and have been approved or denied as indicated.

DATES: Interested persons may file written comments on this order in accordance with 21 CFR 1308.23(e). Electronic comments must be submitted, and written comments must be postmarked, on or before May 24, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–372'' on all correspondence, including any attachments. The Drug Enforcement Administration (DEA) encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a comment tracking number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for purpose of this action. 21 U.S.C. 801–971. The DEA published the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 201 of the CSA (21 U.S.C. 811) authorizes the Attorney General, by regulation, to exempt from certain provisions of the CSA certain compounds, mixtures, or preparations containing a controlled substance, if she finds that such compounds, mixtures, or preparations meet the requirements detailed in 21 U.S.C. 811(g)(3)(B).[1] DEA regulations 21 CFR 1308.23 and 1308.24 further detail the criteria by which the DEA Deputy Assistant Administrator may exempt a chemical preparation or mixture from certain provisions of the CSA. The Deputy Assistant Administrator may, pursuant to 21 CFR 1308.23(f), modify or revoke the criteria by which exemptions are granted and modify the scope of exemptions at any time.

Exempt Chemical Preparation Applications Submitted Between April 1, 2013, and September 17, 2015

The Deputy Assistant Administrator received applications between April 1, 2013, and September 17, 2015, requesting exempt chemical preparation status detailed in 21 CFR 1308.23. Pursuant to the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23, the Deputy Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart I below is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or animal and either: (1) Contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged

[1] This authority has been delegated from the Attorney General to the Administrator of the DEA by 28 CFR 0.100, and subsequently redelegated to the Deputy Assistant Administrator pursuant to section 7 of 28 CFR 0.104, appendix to subpart R.

quantity does not present any significant potential for abuse; or (2) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration that the preparation or mixture does not present any potential for abuse; if the preparation or mixture contains a narcotic controlled substance, it must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects if abused, and so that the narcotic substance cannot in practice be removed.

Accordingly, pursuant to 21 U.S.C. 811(g)(3)(B), and in accordance with 21 CFR 1308.23 and 21 CFR 1308.24, the Deputy Assistant Administrator has determined that each of the chemical preparations or mixtures generally described in Chart I below and specifically described in the application materials received by the DEA, are exempt, to the extent described in 21 CFR 1308.24, from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003, and 1004 (21 U.S.C. 822–823, 825–829, and 952–954) of the CSA, and 21 CFR 1301.74, as of the date that was provided in the approval letters to the individual requesters.

BILLING CODE 4410–09–P

Chart I

Supplier	Product Name	Form	Application Date
Aalto Scientific, Ltd.	Control FD Immunoassay	Kit: 6 vials; 3 mL each	10/22/2015
Aalto Scientific, Ltd.	Control FD TDM	Kit: 6 vials; 5 mL each	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Fertility Siemens Centaur	Kit: 10 vials; 3 mL each	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Immunoassay	Kit: 10 vials; 5 mL each	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Immunoassay Abbott Architect i Series K831M-5	Kit: 10 vials; 5 mL each	11/23/2015
Aalto Scientific, Ltd.	Linearity FD Immunoassay Abbott Architect i Series K833M-5	Kit: 5 vials; 5 mL each	11/23/2015
Aalto Scientific, Ltd.	Linearity FD TDM	Kit: 5 vials; 5 mL each	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM Siemens Centaur	Kit: 5 vials; 5 mL each	10/22/2015
Absolute Standards, Inc.	(-)-11-Nor-Δ9-THC-carboxylic acid Suitable for immunoassay (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(-)-11-Nor-Δ9-THC-carboxylic acid Suitable for immunoassay (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(-)-Δ8-THC (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(-)-Δ8-THC (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(-)-Δ9-THC – Calibration Standard (1000 µg/mL in methanol)	Glass ampule: 1 mL	11/20/2015
Absolute Standards, Inc.	(-)-Δ9-THC – Performance Test HPLC-GC (500 µg/mL in methanol)	Glass ampule: 1 mL	11/20/2015
Absolute Standards, Inc.	(-)-Δ9-THC (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(-)-Δ9-THC (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(-)-Δ9-THC-D3 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(-)-Δ9-THC-D3 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(-)-Δ9-THC-D3 (1000 µg/mL in methanol)	Glass ampule: 1 mL	11/20/2015
Absolute Standards, Inc.	(+/-) Amphetamine [(+/-)-1-Phenylpropan-2-amine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(+/-) Amphetamine-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014

Absolute Standards, Inc.	(+/-)-Amphetamine (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(+/-)Amphetamine-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(+/-)-Methamphetamine (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(+/-)-Methamphetamine (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(+/-)-Methamphetamine as free base [d-Methamphetamine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(+/-)Methamphetamine-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(+/-)Methamphetamine-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-11-nor-Δ9-THC carboxylic acid-D3 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-11-nor-Δ9-THC carboxylic acid-D3 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-MDA [3,4-Methylenedioxyamphetamine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-MDA 3,4-Methylenedioxyamphetamine (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-MDA-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-MDMA [d,l-3,4-Methylenedioxymethamphetamine; Ecstasy] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-MDMA 3,4-Methylenedioxymethamphetamine(Ecstasy) (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-MDMA-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	(±)-MDMA-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	17α-Methyltestosterone (100 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	17α-Methyltestosterone (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Alprazolam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Alprazolam-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Carisoprodol (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Carisoprodol (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Carisoprodol (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014

Absolute Standards, Inc.	Chloral hydrate (100 µg/mL) in MTBE	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Chloral hydrate (1000 µg/mL in MTBE)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Chloral hydrate Level 1 (5.0 µg/mL in MTBE)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Chloral hydrate Level 2 (2.5 µg/mL in MTBE)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Chloral hydrate Level 3 (1.0 µg/mL in MTBE)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Chloral hydrate Level 4 (0.5 µg/mL in MTBE)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Chlordiazepoxide (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Chlordiazepoxide (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	cis-Tramadol HCl (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Clonazepam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Clonazepam (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Clonazepam-D4 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Clonazepam-D4 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Cocaine (100 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Cocaine (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Cocaine (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Cocaine-D3 (100 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Cocaine-D3 (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Codeine [3-Methylmorphine] (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Codeine [3-Methylmorphine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Codeine-6-β-D-glucuronide (100 µg/mL in MeOH:H2O (80:20))	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Codeine-6-β-D-glucuronide (1000 µg/mL in MeOH:H2O (80:20))	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Codeine-D3 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014

Absolute Standards, Inc.	Codeine-D3 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	d-Cathine (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	d-Cathine (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Diazepam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Diazepam [Valium] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Diazepam-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Diazepam-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Estazolam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Estazolam (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Fentanyl-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Flunitrazepam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Flunitrazepam (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Flunitrazepam-D7 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Flunitrazepam-D7 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	GHB-D6 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	GHB-D6 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Heroin (100 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Heroin (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Lorazepam (100 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Lorazepam (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Meprobamate (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Meprobamate (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Methaqualone (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014

Absolute Standards, Inc.	Methaqualone (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Methaqualone-D4 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Methaqualone-D4 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Methcathinone (100 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Methcathinone (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Midazolam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Midazolam (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Nordiazepam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Nordiazepam (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Oxazepam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Oxazepam (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Oxazepam-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Oxazepam-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Pentobarbital.sodium salt (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Pentobarbital.sodium salt (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Pentobarbital-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Pentobarbital-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Phenobarbital (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Phenobarbital (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Phentermine (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Phentermine [2-Methyl-1-phenylpropan-2-amine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Prazepam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Prazepam (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014

Absolute Standards, Inc.	R(-)-Amphetamine [l-Amphetamine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	R(-)-Amphetamine l-Amphetamine (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	R(-)-Methamphetamine [l-Methamphetamine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	R(-)-Methamphetamine hydrochloride l-Methamphetamine HCl (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	S(+)-Amphetamine [d-Amphetamine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	S(+)-Amphetamine HCl d-Amphetamine HCl (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	S(+)-Methamphetamine [d-Methamphetamine] (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	S(+)-Methamphetamine d-Methamphetamine (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Secobarbital (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Secobarbital (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Secobarbital-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Secobarbital-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Sodium g-hydroxybutyrate (GHB) (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Sodium g-hydroxybutyrate (GHB) (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Temazepam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Temazepam (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Temazepam-D5 (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Temazepam-D5 (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Testosterone (100 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Testosterone (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Testosterone (1000 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Testosterone (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Testosterone-2,3,4-13C3 (100 µg/mL in Acetonitrile)	Glass ampoule: 1 mL	7/11/2014

Absolute Standards, Inc.	Testosterone-2,3,4-13C3 (1000 ng/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Total THC – Calibration Standard GC (100 µg/mL in methanol)	Glass ampule: 1 mL	11/20/2015
Absolute Standards, Inc.	Total THC – Calibration Standard HPLC (100 µg/mL in methanol)	Glass ampule: 1 mL	11/20/2015
Absolute Standards, Inc.	Total THC – Performance Test GC (500 µg/mL in methanol)	Glass ampule: 1 mL	11/20/2015
Absolute Standards, Inc.	Total THC – Performance Test HPLC (500 µg/mL in methanol)	Glass ampule: 1 mL	11/20/2015
Absolute Standards, Inc.	Tramadol (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Triazolam (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Triazolam (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Zolpidem (100 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Zolpidem (1000 µg/mL in Methanol)	Glass ampoule: 1 mL	7/11/2014
AccuStandard, Inc.	Custom Method 551 Standard, S-6861G-R8	Amber ampule: 1 mL	4/6/2015
AccuStandard, Inc.	Custom Method 551 Standard, S-6861G-R8-10X	Amber ampule: 1 mL	5/6/2013
AccuStandard, Inc.	Custom Organic Standard, S-16085A	Amber ampule: 1 mL	4/6/2015
AccuStandard, Inc.	Custom Standard, S-6861G-R10-5X	Amber ampule: 1 mL	5/27/2015
AccuStandard, Inc.	Custom Volatile Standard, S-11728-R3-0.25X	Amber ampule: 1 mL	4/6/2015
AccuStandard, Inc.	Korean Drinking Water Standard, KDWR-004	Amber ampule: 1 mL	5/6/2013
Agilent Technologies	Forensic Toxicology Comprehensive Mix – Submix 10A	Amber ampule: 1 mL	4/2/2013
Agilent Technologies	Forensic Toxicology Comprehensive Mix – Submix 10B	Amber ampule: 1 mL	4/2/2013
Agilent Technologies	Forensic Toxicology Comprehensive Mix – Submix 9A	Amber ampule: 1 mL	4/2/2013
Agilent Technologies	Forensic Toxicology Comprehensive Mix – Submix 9B	Amber ampule: 1 mL	4/2/2013
Agilent Technologies	Forensic Toxicology Comprehensive Mix – Submix 9C	Amber ampule: 1 mL	4/2/2013
Alltech Associates, Inc.	2C-C Quik-Chek, 1.0 mg/mL in Methanol	Glass ampule: 1 mL	5/14/2013

Alltech Associates, Inc.	2C-I, 1.0 mg/mL in Methanol	Glass ampule: 1 mL	5/14/2013
Alltech Associates, Inc.	2C-T-2, 1.0 mg/mL in Methanol	Glass ampule: 1 mL	5/14/2013
Alltech Associates, Inc.	2C-T-4 Quik-Chek, 1.0 mg/mL in Methanol	Glass ampule: 1 mL	9/12/2013
Alltech Associates, Inc.	Allobarbital Quik-Chek, 1.0 mg/mL in Methanol	Glass ampule: 1 mL	9/12/2013
Alltech Associates, Inc.	Tramadol Quik-Chek, 1.0 mg/mL in Methanol	Amber ampoule: 1 mL	8/19/2014
American Proficiency Institute (API)	PCAPTT-QQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCCAPTT-AQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCJACT-AQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCJACT-NQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCJCPT-AQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCJCPT-NQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCJLR-AQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCJLR-NQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCJPT-AQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCJPT-NQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
American Proficiency Institute (API)	PCPRO-AQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013

American Proficiency Institute (API)	PCPRO-NQ	Bag: 250-750 tubes; 0.5 mL each	9/12/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Oral Fluid, OF26	Glass vials: 1 mL- 100 mL	7/8/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Oral Fluid, OF27	Glass vials: 1 mL - 100 mL	8/20/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Plasma, P1	Glass vials: 1 mL- 200 mL	4/10/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine MC191	Glass vials: 1 mL- 200 mL	6/19/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine MC194	Glass vials: 1 mL- 200 mL	6/28/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine MC195	Glass vials: 1 mL- 200 mL	7/11/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC182	Glass vials: 1 mL- 200 mL	4/22/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC185	Glass vials: 1 mL- 200 mL	9/3/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC186	Glass vials: 1 mL- 200 mL	9/3/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC187	Glass vials: 1 mL- 200 mL	9/3/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC188	Glass vials: 1 mL- 200 mL	9/3/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC189	Glass vials: 1 mL- 200 mL	4/16/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC190	Glass vials: 1 mL- 200 mL	5/10/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC197	Glass vials: 1 mL- 200 mL	8/28/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC198	Glass vials: 1 mL- 200 mL	9/5/2013

Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC199	Glass vials: 1 mL- 200 mL	9/11/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC200	Glass vials: 1 mL- 200 mL	9/17/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC202	Glass vials: 1 mL- 200 mL	10/28/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC203	Glass vials: 1 mL- 200 mL	11/21/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC204	Glass vials: 1 mL- 200 mL	11/21/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC205	Glass vials: 1 mL- 200 mL	12/6/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC206	Glass vials: 1 mL- 200 mL	12/30/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC207	Glass vials: 1 mL- 20 mL	5/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC208	Glass vials: 1 mL- 200 mL	1/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC209	Glass vials: 1 mL- 200 mL	1/29/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC210	Glass vials: 1 mL- 200 mL	1/29/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC211	Glass vials: 1 mL- 200 mL	1/29/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC212	Glass vials: 1 mL- 200 mL	2/14/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC213	Glass vials: 1 mL- 200 mL	2/14/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC214	Glass vials: 1 mL- 200 mL	2/14/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC215	Glass vials: 1 mL- 200 mL	2/14/2014

Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC216	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC217	Glass vial: 100 mL	10/30/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC218	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC219	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC220	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC221	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC222	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC223	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC224	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC225	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC226	Glass vials: 1 ml - 100 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC227	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC228	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC229	Glass vials: 1 mL- 200 mL	4/11/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC230	Glass vials: 1 ml - 100 mL	4/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC231	Glass vials: 1 mL- 20 mL	5/16/2014

Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC232	Glass vials: 1 mL- 20 mL	5/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC233	Glass vials: 1 mL- 25 mL	5/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC234	Glass vials: 1 ml - 100 mL	4/25/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC235	Glass vials: 1 mL- 25 mL	5/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC236	Glass vials: 1 mL- 20 mL	5/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC237	Glass vials: 1 mL- 35 mL	5/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC238	Glass vials: 1 mL- 35 mL	5/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC239	Glass vials: 1 mL - 100 mL	6/2/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC240	Glass vials: 1 mL- 100 mL	7/8/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC241	Glass vials: 1 mL - 100 mL	8/14/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC242	Glass vials: 1 mL - 100 mL	8/14/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC243	Glass vials: 1 mL - 100 mL	8/20/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC244	Glass vials: 1 ml - 100 mL	9/9/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC245	Glass vials: 1 ml - 100 mL	9/14/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC246	Glass vials: 1 ml - 100 mL	10/29/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC247	Glass vials: 1 ml - 100 mL	12/3/2014

Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC248	Glass vials: 1 ml - 100 mL	12/5/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC249	Glass vials: 1 ml - 100 mL	1/28/2015
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, SC19	Glass vials: 1 mL- 200 mL	11/21/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, SD18	Glass vials: 1 mL- 2 L	4/11/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, SD20	Glass vials: 1 mL- 200 mL	1/15/2014
Biochemical Diagnostics, Inc.	Tapentadol Bulk Solution	Bulk container: 1 mL- 1 L	8/27/2013
Bionostics, Inc.	HEMOCHRON ACT Whole Blood Quality Control (QCACT)	Box: 20 vials; 2.0 mL (dried)	4/11/2014
Bionostics, Inc.	HEMOCHRON HiTTRx Whole Blood Quality Control (RQCHRT)	Box: 20 vials; 2.0 mL (dried)	4/11/2014
Bionostics, Inc.	HEMOCHRON HiTTRx Whole Blood Quality Control (RQCPRT)	Box: 20 vials; 2.0 mL (dried)	4/11/2014
Bionostics, Inc.	IN PROCESS MATERIAL DC PRO Whole Blood Control	Ampule: 0.5 mL	9/12/2013
Bionostics, Inc.	IN PROCESS MATERIAL DC Whole Blood Control	Ampule: 0.5 mL	9/12/2013
Bionostics, Inc.	IN PROCESS MATERIAL Whole Blood Control	Glass vial: 2 mL lyophilized	4/11/2014
Bio-Rad Laboratories	EQAS Immunoassay (Monthly) Program	Box 12 vials; 5 mL each	5/22/2013
Bio-Rad Laboratories	Liquichek Immunoassay Premium Control Levels 1-3	Box of 6 vials, 5 mL each	9/25/2013
Bio-Rad Laboratories	Liquichek Immunoassay Premium Control Trilevel	Box of 6 vials, 5 mL each	9/25/2013
Bio-Rad Laboratories	Liquichek Immunoassay Premium Control Trilevel MiniPak	Box of 3 vials, 5 mL each	9/25/2013
Bio-Rad Laboratories	Liquichek Netherlands Unassayed Chemistry Plus Control, Levels 1	Box: 25 vials, 5 mL each	6/30/2015
Bio-Rad Laboratories	Liquichek Netherlands Unassayed Chemistry Plus Control, Levels 2	Box: 25 vials, 5 mL each	6/30/2015
Bio-Rad Laboratories	Liquichek Netherlands Unassayed Chemistry Plus Control, Levels 3	Box: 25 vials, 5 mL each	6/30/2015
Cambridge Isotope Laboratories, Inc.	LABELED STEROID CAH SET S NSK-S-CAH-1	Plastic vial: 63 ng	2/7/2014

Cambridge Isotope Laboratories, Inc.	Testosterone (3,4-13C2,99%; 17-18O, 98%), 100 ug/mL in Methylene Chloride	Glass vial: 1.2 mL	1/21/2014
Cayman Chemical Company	(-)-(S)-Cathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(-)-(S)-Cathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(-)-(S)-Cathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(-)-(S)-Cathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(-)-(S)-Cathinone (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(-)-(S)-Cathinone (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(-)-(S)-Cathinone (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(-)-11-nor-9-carboxy-Δ9-THC CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(-)-11-nor-9-carboxy-Δ9-THC CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(-)-11-nor-9-carboxy-Δ9-THC CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(-)-11-nor-9-carboxy-Δ9-THC CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(-)-11-nor-9-carboxy-Δ9-THC-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(-)-11-nor-9-carboxy-Δ9-THC-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(-)-11-nor-9-carboxy-Δ9-THC-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	(-)-11-nor-9-carboxy-Δ9-THC-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(+)- Propoxyphene; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(+)- Propoxyphene; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(+)- Propoxyphene; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(+)-11-nor-Δ9-THC carboxylic acid CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(+)-11-nor-Δ9-THC carboxylic acid CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(+)-11-nor-Δ9-THC carboxylic acid CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(+)-11-nor-Δ9-THC carboxylic acid CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(+)-11-nor-Δ9-THC carboxylic acid; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(+)-11-nor-Δ9-THC carboxylic acid; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(+)-11-nor-Δ9-THC carboxylic acid; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(+)-Propoxyphene CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(+)-Propoxyphene CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(+)-Propoxyphene CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(+)-Propoxyphene CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±) Methcathinone CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	(±) Methcathinone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±) Methcathinone CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±) Methcathinone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)- Propoxyphene; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)- Propoxyphene; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)- Propoxyphene; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-11-nor-Δ9-THC carboxylic acid CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-11-nor-Δ9-THC carboxylic acid CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-11-nor-Δ9-THC carboxylic acid CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-11-nor-Δ9-THC carboxylic acid CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-11-nor-Δ9-THC carboxylic acid; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-11-nor-Δ9-THC carboxylic acid; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-11-nor-Δ9-THC carboxylic acid; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Cannabichromene-d9 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	(±)-Cannabichromene-d9 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	(±)-Cannabichromene-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	(±)-Cannabichromene-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	(±)-Cannabichromene-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	(±)-Cannabichromene-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	(±)-CP 47,497 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-CP 47,497 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-CP 47,497 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-CP 47,497 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-CP 47,497-C8-homolog CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-CP 47,497-C8-homolog CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-CP 47,497-C8-homolog CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-CP 47,497-C8-homolog CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-Methadone CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-Methadone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-Methadone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-Methadone CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-Methadone; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	(±)-Methadone; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Methadone; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Methadone-d3 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	(±)-Methadone-d3 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	(±)-Methadone-d3 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	(±)-Methadone-d3 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	(±)-Methamphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-Methamphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-Methamphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-Methamphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-Methamphetamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Methamphetamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Methamphetamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Methamphetamine-d5 (HCl) (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	(±)-Methamphetamine-d5 (HCl) (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	(±)-Methamphetamine-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	(±)-Methamphetamine-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	(±)-Methamphetamine-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	(±)-Methamphetamine-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	(±)-Methcathinone; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Methcathinone; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Methcathinone; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	(±)-Propoxyphene CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	(±)-Propoxyphene CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-Propoxyphene CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	(±)-Propoxyphene CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	11-hydroxy-Δ9-THC CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	11-hydroxy-Δ9-THC CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	11-hydroxy-Δ9-THC CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	11-hydroxy-Δ9-THC CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	11-hydroxy-Δ9-THC; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	11-hydroxy-Δ9-THC; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	11-hydroxy-Δ9-THC; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2,3-MDA-d3(HCl) (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	2,3-MDA-d3(HCl) (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	2,5-Dimethoxy-4-ethylamphetamine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2,5-Dimethoxy-4-ethylamphetamine; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2,5-Dimethoxy-4-ethylamphetamine; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2,5-Dimethoxy-4-ethylamphetamine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2,5-Dimethoxy-4-ethylamphetamine; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2,5-Dimethoxy-4-ethylamphetamine; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2,5-Dimethoxy-4-ethylamphetamine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2,5-Dimethoxyamphetamine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2,5-Dimethoxyamphetamine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2,5-Dimethoxyamphetamine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2,5-Dimethoxyamphetamine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2,5-Dimethoxyamphetamine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2,5-Dimethoxyamphetamine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	2,5-Dimethoxyamphetamine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25B-NBOMe (hydrochloride) CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	25B-NBOMe (hydrochloride) CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	25B-NBOMe (hydrochloride) CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	25B-NBOMe (hydrochloride) CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	25B-NBOMe (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25B-NBOMe (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25B-NBOMe (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25B-NBOMe CRM; 1 mg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	25B-NBOMe CRM; 1 mg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	25B-NBOMe CRM; 100 µg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	25B-NBOMe CRM; 100 µg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	25C-NBOMe (hydrochloride) CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	25C-NBOMe (hydrochloride) CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	25C-NBOMe (hydrochloride) CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	25C-NBOMe (hydrochloride) CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	25C-NBOMe (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25C-NBOMe (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25C-NBOMe (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25C-NBOMe CRM; 1 mg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	25C-NBOMe CRM; 1 mg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	25C-NBOMe CRM; 100 µg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	25C-NBOMe CRM; 100 µg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	25I-NBOMe (hydrochloride) CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	25I-NBOMe (hydrochloride) CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	25I-NBOMe (hydrochloride) CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	25I-NBOMe (hydrochloride) CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	25I-NBOMe (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25I-NBOMe (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25I-NBOMe (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	25I-NBOMe CRM; 1 mg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	25I-NBOMe CRM; 1 mg/mL Methanol	Glass ampule: 2 mL	5/2/2014

Cayman Chemical Company	25I-NBOMe CRM; 100 µg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	25I-NBOMe CRM; 100 µg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	2C-B (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-B (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-B (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-B (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-B (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-B (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-B (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-C CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-C CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-C CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-C CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-C; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-C; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-C; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	2C-D CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-D CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-D CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-D CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-D; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-D; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-D; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-E (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-E (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-E (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-E (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-E (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-E (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-E (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-H CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-H CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	2C-H CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-H CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-H; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-H; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-H; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-I (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-I (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-I (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-I (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-I (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-I (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-I (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-N CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-N CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-N CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-N CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	2C-N; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-N; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-N; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-P CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-P CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-P CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-P CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-P; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-P; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-P; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-T-2 CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-T-2 CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-T-2 CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-T-2 CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-T-2; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-T-2; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	2C-T-2; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-T-4 CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-T-4 CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-T-4 CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-T-4 CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-T-4; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-T-4; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-T-4; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-T-7 CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-T-7 CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-T-7 CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	2C-T-7 CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	2C-T-7; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-T-7; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	2C-T-7; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4,5-Trimethoxyamphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	3,4,5-Trimethoxyamphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	3,4,5-Trimethoxyamphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	3,4,5-Trimethoxyamphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	3,4,5-Trimethoxyamphetamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4,5-Trimethoxyamphetamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4,5-Trimethoxyamphetamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4-MDEA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	3,4-MDEA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	3,4-MDEA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	3,4-MDEA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	3,4-MDEA (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4-MDEA (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4-MDEA (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4-MDEA-d5 (HCl) (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	3,4-MDEA-d5 (HCl) (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	3,4-MDEA-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	3,4-MDEA-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	3,4-MDEA-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	3,4-MDEA-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	3,4-MDMA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	3,4-MDMA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	3,4-MDMA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	3,4-MDMA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	3,4-MDMA (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4-MDMA (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4-MDMA (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	3,4-MDMA-d3 (HCl) (exempt perparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	3,4-MDMA-d3 (HCl) (exempt perparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	3,4-MDMA-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	3,4-MDMA-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	3,4-MDMA-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	3,4-MDMA-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	3-Fluoromethcathinone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	3-Fluoromethcathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	3-FMC (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	3-FMC (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	3-FMC (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	4-Bromo-2,5-DMA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	4-Bromo-2,5-DMA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	4-Bromo-2,5-DMA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	4-Bromo-2,5-DMA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	4-Bromo-2,5-DMA (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Bromo-2,5-DMA (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Bromo-2,5-DMA (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Fluoromethcathinone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	4-Fluoromethcathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	4-FMC (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	4-FMC (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014

Cayman Chemical Company	4-FMC (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	4-MEC (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	4-MEC (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	4-MEC (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	4-MePPP (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	4-MePPP (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	4-MePPP (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	4-Methyl-2,5-dimethoxyamphetamine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	4-Methyl-2,5-dimethoxyamphetamine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	4-Methyl-2,5-dimethoxyamphetamine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	4-Methyl-2,5-dimethoxyamphetamine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	4-Methyl-2,5-dimethoxyamphetamine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Methyl-2,5-dimethoxyamphetamine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Methyl-2,5-dimethoxyamphetamine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Methylaminorex CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	4-Methylaminorex CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	4-Methylaminorex CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	4-Methylaminorex CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	4-Methylaminorex; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Methylaminorex; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Methylaminorex; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	4-Methylethcathinone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	4-Methylethcathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	4'-Methyl-α-pyrrolidinopropiophenone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	4'-Methyl-α-pyrrolidinopropiophenone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	5-fluoro PB-22 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	5-fluoro PB-22 (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	5-fluoro PB-22 (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	5-fluoro PB-22 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	5-hydroxy DMT CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	5-hydroxy DMT CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	5-hydroxy DMT CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	5-hydroxy DMT CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	5-hydroxy DMT; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	5-hydroxy DMT; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	5-hydroxy DMT; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	5-Methoxy DIPT CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	5-Methoxy DIPT CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	5-Methoxy DIPT CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	5-Methoxy DIPT CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	5-Methoxy DiPT; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	5-Methoxy DiPT; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	5-Methoxy DiPT; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	5-Methoxy-DMT CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	5-Methoxy-DMT CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	5-Methoxy-DMT CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	5-Methoxy-DMT CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	5-Methoxy-DMT; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	5-Methoxy-DMT; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	5-Methoxy-DMT; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	AB-FUBINACA (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	AB-FUBINACA (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	AB-FUBINACA (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	AB-FUBINACA CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	4/30/2015
Cayman Chemical Company	AB-FUBINACA CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	3/21/2014
Cayman Chemical Company	AB-FUBINACA CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	ADB-PINACA (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	ADB-PINACA (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	ADB-PINACA (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	ADB-PINACA CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	4/30/2015
Cayman Chemical Company	ADB-PINACA CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	3/21/2014
Cayman Chemical Company	ADB-PINACA CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	AKB48 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	AKB48 (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014

Cayman Chemical Company	AKB48 (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	AKB48 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	AKB48 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	AKB48 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	AKB48 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Alprazolam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Alprazolam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Alprazolam-d5 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Alprazolam-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Alprazolam-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	AM2201 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	AM2201 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	AM2201 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	AM2201 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	AM2201; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	AM2201; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	AM2201; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	AM694 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	AM694 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	AM694 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	AM694 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	AM694; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	AM694; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	AM694; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Aminorex CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Aminorex CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Aminorex CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Aminorex CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Aminorex; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Aminorex; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Aminorex; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Amphetamine-d5 (HCl)(exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014

Cayman Chemical Company	Amphetamine-d5 (HCl)(exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Amphetamine-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Amphetamine-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Amphetamine-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Amphetamine-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Androstenedione CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	6/13/2014
Cayman Chemical Company	Androstenedione CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	6/13/2014
Cayman Chemical Company	Androstenedione CRM; 100 ug/mL in Methanol	Glass ampule: 1 mL	6/13/2014
Cayman Chemical Company	Androstenedione CRM; 100 ug/mL in Methanol	Glass ampule: 1 mL	6/13/2014
Cayman Chemical Company	Benzoylecgonine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Benzoylecgonine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Benzoylecgonine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Benzoylecgonine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Benzoylecgonine-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Benzoylecgonine-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Benzoylecgonine-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	Benzoylecgonine-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Buprenorphine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Buprenorphine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Buprenorphine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Buprenorphine-d4 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Buprenorphine-d4 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Buprenorphine-d4 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Buprenorphine-d4 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Buprenorphine-d4 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Butylone (exempt preparation); 1 mg in 1 mL	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	Butylone (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	Butylone (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	Butylone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	Butylone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	BZP (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	BZP (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	BZP (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	BZP (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	BZP (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	BZP (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	BZP (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Cannabichromene CRM; 1 mg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	Cannabichromene CRM; 1 mg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	Cannabichromene CRM; 100 µg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	Cannabichromene CRM; 100 µg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	Cannabidiol CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Cannabidiol CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Cannabidiol CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Cannabidiol CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Cannabidiol-d9 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiol-d9 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiol-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Cannabidiol-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabidiol-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabidiol-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Cannabidiolic acid CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Cannabidiolic acid CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Cannabidiolic acid CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Cannabidiolic acid; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Cannabidiolic acid; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Cannabidiolic acid; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Cannabidiolic acid-d3 (exempt preparation); 1 mg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiolic acid-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiolic acid-d3 (exempt preparation); 100 µg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiolic acid-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiolic acid-d3 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d3 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Cannabidiolic acid-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d3 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d3 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d9 (exempt preparation); 1 mg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiolic acid-d9 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiolic acid-d9 (exempt preparation); 100 µg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiolic acid-d9 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabidiolic acid-d9 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d9 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d9 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d9 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	Cannabidiolic acid-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabidiolic acid-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabigerol CRM; 1 mg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	Cannabigerol CRM; 1 mg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	Cannabigerol CRM; 100 µg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	Cannabigerol CRM; 100 µg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	Cannabigerol-d9 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabigerol-d9 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabigerol-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabigerol-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabigerol-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabigerol-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabinol CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Cannabinol CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Cannabinol CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Cannabinol CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	Cannabinol; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Cannabinol; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Cannabinol; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Cannabinol-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabinol-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabinol-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabinol-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabinol-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabinol-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabinol-d9 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabinol-d9 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Cannabinol-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabinol-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Cannabinol-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Cannabinol-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Carisoprodol CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	Carisoprodol CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Carisoprodol CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Carisoprodol CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Carisoprodol-d7 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Carisoprodol-d7 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Carisoprodol-d7 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Carisoprodol-d7 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Carisoprodol-d7 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Carisoprodol-d7 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	cis-Tramadol (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	cis-Tramadol (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	cis-Tramadol (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	cis-Tramadol (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	cis-Tramadol-d6 (HCl) (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	cis-Tramadol-d6 (HCl) (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	cis-Tramadol-d6 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	cis-Tramadol-d6 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	cis-Tramadol-d6 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	cis-Tramadol-d6 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Clonazepam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Clonazepam-d4 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Clonazepam-d4 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Codeine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Codeine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Codeine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Codeine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Codeine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Codeine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Codeine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Codeine-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	8/7/2015
Cayman Chemical Company	Codeine-d6 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Codeine-d6 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014

Cayman Chemical Company	Codeine-d6 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Codeine-d6 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Codeine-d6 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Codeine-d6 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	D-Amphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	D-Amphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	D-Amphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	D-Amphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	D-Amphetamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	D-Amphetamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	D-Amphetamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Desomorphine CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Desomorphine CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Desomorphine CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Desomorphine CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Desomorphine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	Desomorphine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Desomorphine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Diazepam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Diazepam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Diazepam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Diazepam-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Diazepam-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Diazepam-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Diazepam-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Diazepam-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Diethyltryptamine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Diethyltryptamine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Diethyltryptamine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Diethyltryptamine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Diethyltryptamine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Diethyltryptamine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	Diethyltryptamine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Dihydrocodeine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Dihydrocodeine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Dihydrocodeine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Dihydrocodeine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Dihydrocodeine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Dihydrocodeine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Dihydrocodeine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Dihydrocodeine-d6 (HCl) (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Dihydrocodeine-d6 (HCl) (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Dihydrocodeine-d6 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Dihydrocodeine-d6 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Dihydrocodeine-d6 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Dihydrocodeine-d6 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Dihydrocodeine-d6 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Dihydrocodeine-d6 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	Dihydrocodeine-d6 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Dihydrocodeine-d6 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Dihydromorphine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Dihydromorphine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Dihydromorphine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Dihydromorphine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Dihydromorphine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Dihydromorphine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Dihydromorphine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Dihydrotestosterone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	6/13/2014
Cayman Chemical Company	Dihydrotestosterone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	6/13/2014
Cayman Chemical Company	Dihydrotestosterone CRM; 100 ug/mL in Methanol	Glass ampule: 1 mL	6/13/2014
Cayman Chemical Company	Dihydrotestosterone CRM; 100 ug/mL in Methanol	Glass ampule: 1 mL	6/13/2014
Cayman Chemical Company	DL-Amphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	DL-Amphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	DL-Amphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	DL-Amphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	DL-Amphetamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	DL-Amphetamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	DL-Amphetamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	DL-Cathinone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	DL-Cathinone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	DL-Cathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	DL-Cathinone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	DL-Cathinone (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	DL-Cathinone (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	DL-Cathinone (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Fentanyl (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Fentanyl-d3 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Flunitrazepam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Flunitrazepam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Flunitrazepam-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014

Cayman Chemical Company	Flunitrazepam-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Flunitrazepam-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Flurazepam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Flurazepam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Flurazepam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Flurazepam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Flurazepam-d10 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Flurazepam-d10 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Flurazepam-d10 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Flurazepam-d10 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Flurazepam-d10 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Flurazepam-d10 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Heroin CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Heroin CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Heroin CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Heroin CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	Heroin; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Heroin; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Heroin; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Heroin-d3 (exempt preparation); 1 mg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Heroin-d3 (exempt preparation); 100 µg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Heroin-d3 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Heroin-d3 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Heroin-d3 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Heroin-d3 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	HU-210 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	HU-210 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	HU-210 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	HU-210 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Hydrocodone CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Hydrocodone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Hydrocodone CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	Hydrocodone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Hydrocodone; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Hydrocodone; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Hydrocodone; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Hydrocodone-d6 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Hydrocodone-d6 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Hydrocodone-d6 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Hydrocodone-d6 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Hydrocodone-d6 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Hydrocodone-d6 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Hydromorphone CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Hydromorphone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Hydromorphone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Hydromorphone CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Hydromorphone; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Hydromorphone; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	Hydromorphone; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Hydromorphone-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Hydromorphone-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Hydromorphone-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Hydromorphone-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Hydromorphone-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	JWH 018 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 018 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 018 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 018 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 019 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 019 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 019 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 019 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 019; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 019; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	JWH 019; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 073 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 073 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 073 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 073 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 081 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 081 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 081 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 081 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 081; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 081; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 081; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 122 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 122 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 122 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 122 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	JWH 122; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 122; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 122; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 200 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 200 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 200 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 200 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 203 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 203 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 203 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 203 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 203; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 203; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 203; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 250 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 250 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	JWH 250 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 250 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 250; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 250; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 250; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 398 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 398 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 398 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	JWH 398 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	JWH 398; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 398; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	JWH 398; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	L-Amphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	L-Amphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	L-Amphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	L-Amphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	L-Amphetamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	L-Amphetamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	L-Amphetamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Levomethorphan CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Levomethorphan CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Levomethorphan CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Levomethorphan CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Levomethorphan; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Levomethorphan; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Levomethorphan; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Lisdexamfetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Lisdexamfetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Lisdexamfetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Lisdexamfetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Lisdexamfetamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Lisdexamfetamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	Lisdexamfetamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Lorazepam CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Lorazepam CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Lorazepam-d4 (exempt preparation); 100 µg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Lorazepam-d4 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Lorazepam-d4 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Lorazepam-d4 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	MDA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	MDA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	MDA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	MDA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	MDA (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	MDA (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	MDA (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	MDA-d3 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	MDA-d3 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	MDA-d3 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	MDA-d3 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Meperidine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Meperidine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Meperidine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Meperidine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Meperidine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Meperidine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Meperidine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Meperidine-d4 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Meperidine-d4 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Meperidine-d4 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Meperidine-d4 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Meperidine-d4 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Meperidine-d4 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Mephedrone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	Mephedrone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Mephedrone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Mephedrone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Mephedrone (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Mephedrone (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Mephedrone (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Meprobamate CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Meprobamate CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Meprobamate CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Meprobamate CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Meprobamate-d7 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Meprobamate-d7 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Meprobamate-d7 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Meprobamate-d7 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Meprobamate-d7 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Meprobamate-d7 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Mescaline (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Mescaline (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Mescaline (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Mescaline (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Mescaline (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Mescaline (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Mescaline (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Methadone-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Methadone-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Methylenedioxy Pyrovalerone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Methylenedioxy Pyrovalerone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Methylenedioxy Pyrovalerone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Methylenedioxy Pyrovalerone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Methylenedioxy Pyrovalerone (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Methylenedioxy Pyrovalerone (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Methylenedioxy Pyrovalerone (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	Methylone (hydrochloride) CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Methylone (hydrochloride) CRM; 1 mg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Methylone (hydrochloride) CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Methylone (hydrochloride) CRM; 100 µg/mL in 10% H20/ACN	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Methylone (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Methylone (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Methylone (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Midazolam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Midazolam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Midazolam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Midazolam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Midazolam-d5 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Midazolam-d5 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Midazolam-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Midazolam-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Midazolam-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Midazolam-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	MMDA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	MMDA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	MMDA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	MMDA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	MMDA (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	MMDA (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	MMDA (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Morphine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Morphine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Morphine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Morphine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Morphine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Morphine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Morphine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Morphine-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014

Cayman Chemical Company	Morphine-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Morphine-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Morphine-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Morphine-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Morphine-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Morphine-N-oxide CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Morphine-N-oxide CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Morphine-N-oxide CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Morphine-N-oxide CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Morphine-N-oxide; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Morphine-N-oxide; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Morphine-N-oxide; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N,N-Dimethyltryptamine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	N,N-Dimethyltryptamine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	N,N-Dimethyltryptamine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	N,N-Dimethyltryptamine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	N,N-Dimethyltryptamine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N,N-Dimethyltryptamine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N,N-Dimethyltryptamine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N,N-DMA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	N,N-DMA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	N,N-DMA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	N,N-DMA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	N,N-DMA (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N,N-DMA (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N,N-DMA (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Naphyrone (exempt preparation); 1 mg in 1 mL	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	Naphyrone (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	Naphyrone (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	Naphyrone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	Naphyrone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	N-Ethylamphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	N-Ethylamphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	N-Ethylamphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	N-Ethylamphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	N-Ethylamphetamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N-Ethylamphetamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N-Ethylamphetamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N-hydroxy MDA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	N-hydroxy MDA (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	N-hydroxy MDA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	N-hydroxy MDA (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	N-Hydroxy-MDA (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N-Hydroxy-MDA (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	N-Hydroxy-MDA (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Nitrazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Nitrazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Nitrazepam CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Nitrazepam CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Nitrazepam-d4 (exempt preparation); 1 mg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Nitrazepam-d4 (exempt preparation); 100 µg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Nitrazepam-d5 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Nitrazepam-d5 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Nitrazepam-d5 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Nitrazepam-d5 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Nordiazepam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Nordiazepam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Nordiazepam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Nordiazepam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Nordiazepam-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Nordiazepam-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Nordiazepam-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Nordiazepam-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Nordiazepam-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Nordiazepam-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Normeperidine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Normeperidine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Normeperidine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Normeperidine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Normeperidine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Normeperidine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Normeperidine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Normeperidine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Normeperidine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Normeperidine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Normeperidine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Normeperidine-d4 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Normeperidine-d4 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Normeperidine-d4 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Normeperidine-d4 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Normeperidine-d4 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Normeperidine-d4 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Normorphine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Normorphine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Normorphine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Normorphine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Normorphine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Normorphine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Normorphine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Opiate Mixture CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Opiate Mixture CRM; 100 µg/mL in Methanol	Glass ampule: 1mL	1/27/2014
Cayman Chemical Company	Opiate Mixture CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Oxazepam CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	12/2/2014
Cayman Chemical Company	Oxazepam CRM; 1 mg/mL in Acetonitrile	Glass vial: 2 mL	12/2/2014
Cayman Chemical Company	Oxazepam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Oxazepam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	Oxazepam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Oxazepam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Oxazepam-d5 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Oxazepam-d5 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Oxazepam-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Oxazepam-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Oxazepam-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Oxazepam-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Oxycodone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Oxycodone CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Oxycodone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Oxycodone CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Oxycodone; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Oxycodone; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Oxycodone; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Oxycodone-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014

Cayman Chemical Company	Oxycodone-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Oxycodone-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Oxycodone-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Oxycodone-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Oxycodone-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Oxymorphone CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Oxymorphone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Oxymorphone CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Oxymorphone; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Oxymorphone; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Oxymorphone; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Oxymorphone-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Oxymorphone-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Oxymorphone-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	para-Methoxyamphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	para-Methoxyamphetamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	para-Methoxyamphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	para-Methoxyamphetamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	para-Methoxyamphetamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	para-Methoxyamphetamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	para-Methoxyamphetamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	PB-22 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	PB-22 (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	PB-22 (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	PB-22 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	8/7/2015
Cayman Chemical Company	PB-22 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	PCP-d5 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	PCP-d5 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Pentedrone (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	Pentedrone (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	Pentedrone (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	Pentedrone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014

Cayman Chemical Company	Pentedrone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	Pentobarbital CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Pentobarbital CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Pentobarbital CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Pentobarbital CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Pentobarbital; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Pentobarbital; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Pentobarbital; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Pentylone (exempt preparation); 1 mg in 1 mL Methanol	-	3/17/2014
Cayman Chemical Company	Pentylone (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	Pentylone (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	Pentylone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	Pentylone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	Phencyclidine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phencyclidine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phencyclidine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	Phencyclidine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phencyclidine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phencyclidine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phencyclidine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phencyclidine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phencyclidine-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phencyclidine-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phencyclidine-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phencyclidine-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phencyclidine-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phencyclidine-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phencyclidine-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phencyclidine-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phentermine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phentermine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phentermine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Phentermine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phentermine-d5 (HCl) (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Phentermine-d5 (HCl) (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Phentermine-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phentermine-d5 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phentermine-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Phentermine-d5 (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Phenylacetone CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Phenylacetone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Phenylacetone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Phenylacetone CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Phenylacetone; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Phenylacetone; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Phenylacetone; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Propoxyphene-d5 (exempt preparation); 1 mg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Propoxyphene-d5 (exempt preparation); 100 µg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014

Cayman Chemical Company	Propoxyphene-d5 (hydrochloride) CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Propoxyphene-d5 (hydrochloride) CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Propoxyphene-d5 (hydrochloride) CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Propoxyphene-d5 (hydrochloride) CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Psilocin CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Psilocin CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Psilocin CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Psilocin CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Psilocin; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Psilocin; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Psilocin; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Psilocybin CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Psilocybin CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Psilocybin CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Psilocybin CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Psilocybin; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	Psilocybin; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Psilocybin; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	RCS-4 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	RCS-4 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	RCS-4 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	RCS-4 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	RCS-4; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	RCS-4; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	RCS-4; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	RCS-8 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	RCS-8 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	RCS-8 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	RCS-8 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	RCS-8; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	RCS-8; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	RCS-8; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	Temazepam CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	12/2/2014
Cayman Chemical Company	Temazepam CRM; 1 mg/mL in Acetonitrile	Glass vial: 2 mL	12/2/2014
Cayman Chemical Company	Temazepam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Temazepam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Temazepam CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Temazepam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Temazepam-d5 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Temazepam-d5 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Temazepam-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Temazepam-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Temazepam-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Temazepam-d5 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Testosterone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	6/13/2014
Cayman Chemical Company	Testosterone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	6/13/2014
Cayman Chemical Company	Testosterone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	6/13/2014
Cayman Chemical Company	Testosterone CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	6/13/2014

Cayman Chemical Company	Tetrahydrocannabivarin CRM; 1 mg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	Tetrahydrocannabivarin CRM; 1 mg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	Tetrahydrocannabivarin CRM; 100 µg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	Tetrahydrocannabivarin CRM; 100 µg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	THCA-A CRM; 1 mg/mL in Acetonitrile	Glass vial: 2 mL	12/2/2014
Cayman Chemical Company	THCA-A CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	12/2/2014
Cayman Chemical Company	THCA-A CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	THCA-A CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	THCA-A CRM; 100 µg/mL in Acetonitrile	Glass vial: 1 mL	12/2/2014
Cayman Chemical Company	THCA-A CRM; 100 µg/mL in Acetonitrile	Glass vial: 2 mL	12/2/2014
Cayman Chemical Company	THCA-A CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	THCA-A CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	THCA-A; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	THCA-A; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	THCA-A; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	THCA-A-d3 (exempt preparation); 1 mg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014

Cayman Chemical Company	THCA-A-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	THCA-A-d3 (exempt preparation); 100 µg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	THCA-A-d3 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	THCA-A-d3 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	THCA-A-d3 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	THCA-A-d3 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	THCA-A-d3 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	THCA-A-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	THCA-A-d3 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	THCA-A-d9 (exempt preparation); 1 mg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	THCA-A-d9 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	THCA-A-d9 (exempt preparation); 100 µg in 1 mL Acetonitrile	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	THCA-A-d9 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	THCA-A-d9 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	THCA-A-d9 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	THCA-A-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	THCA-A-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	THCA-A-d9 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	THCA-A-d9 CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	THCA-A-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	THCA-A-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Thebaine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Thebaine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Thebaine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Thebaine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Thebaine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Thebaine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Thebaine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Tilidine (hydrochloride) CRM CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Tilidine (hydrochloride) CRM CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Tilidine (hydrochloride) CRM CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Tilidine (hydrochloride) CRM CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	Tilidine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Tilidine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Tilidine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	UR-144 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	UR-144 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	UR-144 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	UR-144 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	UR-144; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	UR-144; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	UR-144; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	XLR11 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	XLR11 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	XLR11 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	XLR11 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	XLR11; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	XLR11; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	XLR11; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	α-Ethyltryptamine CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	α-Ethyltryptamine CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	α-Ethyltryptamine CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	α-Ethyltryptamine CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	α-Ethyltryptamine; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	α-Ethyltryptamine; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	α-Ethyltryptamine; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	α-Methyltryptamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	α-Methyltryptamine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	α-Methyltryptamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	α-Methyltryptamine (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	α-Methyltryptamine (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	α-Methyltryptamine (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	α-Methyltryptamine (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	α-PBP (exempt preparation); 1 mg in 1 mL	Glass vial: 1 mL	3/17/2014

Cayman Chemical Company	α-PBP (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	α-PBP (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	α-PVP (exempt preparation); 1 mg in 1 mL	Glass vial: 1 mL	3/17/2014
Cayman Chemical Company	α-PVP (exempt preparation); 100 µg in 100 µL Methanol	Glass vial: 100 µL	3/17/2014
Cayman Chemical Company	α-PVP (exempt preparation); 500 µg in 500 µL Methanol	Glass vial: 500 µL	3/17/2014
Cayman Chemical Company	α-Pyrrolidinopentiophenone (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	α-Pyrrolidinopentiophenone (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	3/21/2014
Cayman Chemical Company	γ-Hydroxybutyric acid (sodium salt) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	γ-Hydroxybutyric acid (sodium salt) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	γ-Hydroxybutyric acid (sodium salt) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	γ-Hydroxybutyric acid (sodium salt) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	γ-Hydroxybutyric acid (sodium salt); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	γ-Hydroxybutyric acid (sodium salt); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	γ-Hydroxybutyric acid (sodium salt); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Δ8-THC CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Δ8-THC CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	Δ8-THC CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Δ8-THC CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Δ8-THC; 1 mg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Δ8-THC; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Δ8-THC; 500 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Δ8-THC-d9 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Δ8-THC-d9 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Δ8-THC-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Δ8-THC-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Δ8-THC-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Δ8-THC-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Δ9-Tetrahydrocannabinol CRM; 1 mg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	Δ9-Tetrahydrocannabinol CRM; 1 mg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	Δ9-Tetrahydrocannabinol CRM; 100 µg/mL Methanol	Glass ampule: 2 mL	5/2/2014
Cayman Chemical Company	Δ9-Tetrahydrocannabinol CRM; 100 µg/mL Methanol	Glass ampule: 1 mL	5/2/2014
Cayman Chemical Company	Δ9-THC CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014

Cayman Chemical Company	Δ9-THC CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Δ9-THC CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Δ9-THC CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Δ9-THC; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Δ9-THC; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Δ9-THC; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Δ9-THC-d9 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Δ9-THC-d9 (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Δ9-THC-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Δ9-THC-d9 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Δ9-THC-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Δ9-THC-d9 CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cerilliant Corporation	(±)-2,5-Dimethoxy-4-bromoamphetamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	6/21/2013
Cerilliant Corporation	(±)-2,5-Dimethoxy-4-bromoamphetamine-D5 HCl (0.1 mg/mL)	Glass ampule: 1 mL	6/9/2015
Cerilliant Corporation	(±)-Cathinone-D5 HCl (0.1 mg/mL)	Glass ampule: 1 mL	11/17/2015
Cerilliant Corporation	(±)-Methcathinone-D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	11/19/2014
Cerilliant Corporation	(±)-threo-Methylphenidate-D4 HCl (0.1 mg/mL)	Glass ampule: 1 mL	2/13/2015
Cerilliant Corporation	17alpha-Methyltestosterone (1.0 mg/mL)	Glass ampule: 1 mL	4/21/2014

Cerilliant Corporation	2,5-Dimethoxy-4-(n)-propylphenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	9/9/2013
Cerilliant Corporation	2,5-Dimethoxy-4-(n)-propylthiophenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	10/21/2013
Cerilliant Corporation	2,5-Dimethoxy-4-ethylphenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	9/9/2013
Cerilliant Corporation	2,5-Dimethoxy-4-ethylphenethylamine-13C,D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	4/3/2014
Cerilliant Corporation	2,5-Dimethoxy-4-ethylthiophenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	2,5-Dimethoxy-4-ethylthiophenethylamine-13C,D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	4/3/2014
Cerilliant Corporation	2,5-Dimethoxy-4-isopropylthiophenethylamine-13C, D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	2,5-Dimethoxy-4-isopropylthiophenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	2,5-Dimethoxy-4-methylphenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	9/9/2013
Cerilliant Corporation	2,5-Dimethoxy-4-methylphenethylamine-13C,D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	4/3/2014
Cerilliant Corporation	2,5-Dimethoxy-4-nitrophenethylamine- 13C, D3 HCl (0.1 mg/mL as free base)	Glass ampule: 1 mL	6/16/2014
Cerilliant Corporation	2,5-Dimethoxy-4-nitrophenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	10/21/2013
Cerilliant Corporation	25B-NBOMe HCl (1.0 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	25B-NBOMe-D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	25C-NBOMe HCl (1.0 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	25C-NBOMe-D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	25I-NBOMe HCl (1.0 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	25I-NBOMe-D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	3,4-Dimethylmethcathinone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	3-Fluoromethcathinone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	4-Chloro-2,5-Dimethoxymethylphenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	10/21/2013
Cerilliant Corporation	4-Ethylmethcathinone (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	4-Fluoromethcathinone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014

Cerilliant Corporation	4-Iodo-2,5-Dimethoxymethylphenethylamine HCl (1.0 mg/mL)	Glass ampule: 1 mL	10/21/2013
Cerilliant Corporation	4-Iodo-2,5-dimethoxyphenethylamine- 13C, D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	12/11/2013
Cerilliant Corporation	4-Methylethcathinone (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	5-Fluoro PB-22 (0.1 mg/mL)	Ampule: 1 mL	2/11/2014
Cerilliant Corporation	5-MeO-DiPT (1.0 mg/mL)	Glass ampule: 1 mL	8/6/2015
Cerilliant Corporation	5-MeO-DMT (1.0 mg/mL)	Glass ampule: 1 mL	10/7/2014
Cerilliant Corporation	6alpha-Naloxol (1.0 mg/mL)	Glass ampule: 1 mL	3/30/2015
Cerilliant Corporation	6-beta-Naltrexol-3-beta-D-glucuronide (1 mg/mL)	Glass ampule: 1 mL	6/1/2015
Cerilliant Corporation	AB-FUBINACA (0.1 mg/mL)	Ampule: 1 mL	2/11/2014
Cerilliant Corporation	AB-PINACA (0.1 mg/mL)	Glass ampule: 1 mL	8/6/2015
Cerilliant Corporation	Acetyl fentanyl (0.05 mg/mL)	Glass ampule: 1 mL	10/8/2015
Cerilliant Corporation	Acetyl fentanyl-13C6 (0.05 mg/mL)	Glass ampule: 1 mL	10/8/2015
Cerilliant Corporation	AKB48 (0.1 mg/mL)	Glass ampule: 1 mL	5/16/2013
Cerilliant Corporation	alpha-PVP HCl (alpha-Pyrrolidinovalerophenone HCl) (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	alpha-Pyrrolidinovalerophenone-D8 HCl (0.1 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	APINACA (0.1 mg/mL)	Glass ampule: 1 mL	10/8/2015
Cerilliant Corporation	Bromazepam-D4 (0.1 mg/mL)	Glass ampule: 1 mL	12/23/2014
Cerilliant Corporation	Buphedrone HCl (1.0 mg/mL)	Glass ampule: 1mL	5/8/2013
Cerilliant Corporation	Buprenorphine-3-beta-D-glucuronide (0.1 mg/mL)	Glass ampule: 1 mL	6/9/2015
Cerilliant Corporation	Buprenorphine-D4-3-beta-D-glucuronide (0.1 mg/mL)	Glass ampule: 1 mL	8/13/2015
Cerilliant Corporation	Butabarbital-D5 (0.1 mg/mL)	Glass ampule: 1 mL	8/6/2015
Cerilliant Corporation	Butylone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Butylone-D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	2/25/2014

Cerilliant Corporation	Cannabichromene [CBC] (1.0 mg/mL	Glass vial: 1 mL	6/3/2014
Cerilliant Corporation	Cannabidiolic acid [CBDA] (1.0 mg/mL)	Glass vial: 1 mL	6/3/2014
Cerilliant Corporation	Cannabidivarin [CBDV] (1.0 mg/mL)	Glass vial: 1 mL	6/3/2014
Cerilliant Corporation	Cannabidivarinic acid (1.0 mg/mL)	Glass ampule: 1 mL	9/15/2015
Cerilliant Corporation	Cannabigerol [CBG] (1.0 mg/mL)	Glass vial: 1 mL	6/3/2014
Cerilliant Corporation	Cannabigerolic acid [CBGA] (1.0 mg/mL)	Glass vial: 1 mL	6/3/2014
Cerilliant Corporation	Carisoprodol- 13C3 (0.1 mg/mL)	Glass ampule: 1 mL	6/16/2014
Cerilliant Corporation	cis-Tramadol HCl (1.0 mg/mL)	Glass ampule: 1 mL	7/7/2014
Cerilliant Corporation	Clobazam-13C6 (0.1 mg/mL)	Glass ampule: 1 mL	8/9/2013
Cerilliant Corporation	Codeine-6-beta-D-glucuronide-D3 (0.1 mg/mL)	Glass ampule: 1 mL	4/3/2014
Cerilliant Corporation	Delorazepam (0.1 mg/mL)	Glass ampule: 1 mL	12/11/2015
Cerilliant Corporation	Desomorphine-D3 (0.1 mg/mL)	Glass ampule: 1 mL	7/19/2013
Cerilliant Corporation	Dihydrocodeine-6-beta-D-glucuronide (1.0 mg/mL)	Glass ampule: 1 mL	3/16/2015
Cerilliant Corporation	Dihydrocodeine-6-beta-D-glucuronide (0.1 mg/mL)	Ampule: 1 mL	2/11/2014
Cerilliant Corporation	Dihydromorphine-3-beta-D-glucuronide (1.0 mg/mL)	Glass ampule: 1 mL	2/13/2015
Cerilliant Corporation	Dihydromorphine-6-beta-D-glucuronide (0.1 mg/mL)	Ampule: 1 mL	2/11/2014
Cerilliant Corporation	Ethylone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Ethylone-D5 HCl (0.1 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Eutylone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Eutylone-D5 HCl (0.1 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Flunitrazepam-13C6 (0.1 mg/mL)	Glass ampule: 1 mL	8/6/2015
Cerilliant Corporation	Flurazepam-D4 (0.1 mg/mL)	Glass ampule: 1 mL	12/11/2015
Cerilliant Corporation	GHB Sodium Salt (1.0 mg/mL)	Glass ampule: 1 mL	4/29/2014

Cerilliant Corporation	GHB Sodium Salt-D6 (0.1 mg/mL)	Glass ampule: 1 mL	4/29/2014
Cerilliant Corporation	GHB Sodium Salt-D6 (1.0 mg/mL)	Glass ampule: 1 mL	4/29/2014
Cerilliant Corporation	Interference Mix 1 (100-1000 µg/mL)	Glass ampule: 1 mL	1/29/2015
Cerilliant Corporation	Interference Mix 2 (100 µg/mL)	Glass ampule: 1 mL	1/29/2015
Cerilliant Corporation	Interference Mix 3 (50-1000 µg/mL)	Glass ampule: 1 mL	1/29/2015
Cerilliant Corporation	Interference Mix 4 (5-100 µg/mL)	Glass ampule: 1 mL	1/29/2015
Cerilliant Corporation	Interference Mix 5 (100 µg/mL)	Glass ampule: 1 mL	1/29/2015
Cerilliant Corporation	Ketamine-D4 HCl (1 mg/mL)	Glass ampule: 1 mL	4/14/2015
Cerilliant Corporation	Levorphanol tartrate (1 mg/mL)	Glass ampule: 1 mL	11/17/2015
Cerilliant Corporation	MBDB-D5 HCl (0.1 mg/mL)	Glass ampule: 1 mL	6/16/2014
Cerilliant Corporation	Mephobarbital (1.0 mg/mL)	Glass ampule: 1 mL	12/11/2015
Cerilliant Corporation	Meprobamate-13C3 (0.1 mg/mL)	Glass ampule: 1 mL	4/3/2014
Cerilliant Corporation	Meprobamate-D3 (0.1 mg/mL)	Glass ampule: 1 mL	7/19/2013
Cerilliant Corporation	Methylphenidate-D9 HCl	Glass ampule: 1 mL	12/23/2013
Cerilliant Corporation	N,N-Dimethyltryptamine (1.0 mg/mL)	Glass ampule: 1 mL	10/7/2014
Cerilliant Corporation	Naloxone-3-beta-D-glucuronide (0.1 mg/mL)	Ampule: 1 mL	2/11/2014
Cerilliant Corporation	Naphyrone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Naphyrone-D5 HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	N-Ethylcathinone HCl (1.0 mg/mL)	Glass ampule: 1mL	5/8/2013
Cerilliant Corporation	Norbuprenorphine glucuronide-D3 (0.1 mg/mL)	Glass vial: 1 mL	6/3/2014
Cerilliant Corporation	Normeperidine (1.0 mg/mL)	Glass ampule: 1mL	4/2/2013
Cerilliant Corporation	Oxycodone-D3 (N-methyl-D3) (0.1 mg/mL)	Glass ampule: 1 mL	9/9/2013
Cerilliant Corporation	Oxycodone-D3 (N-methyl-D3) (1.0 mg/mL)	Glass ampule: 1 mL	9/9/2013

Cerilliant Corporation	Pain Management Multi-component Opiate Mixture-13 (0.01 - 0.1 mg/mL)	Glass ampule: 1 mL	8/26/2014
Cerilliant Corporation	PB-22 (0.1 mg/mL)	Ampule: 1 mL	2/11/2014
Cerilliant Corporation	Pentedrone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Pentylone HCl (1.0 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Pentylone-D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	2/25/2014
Cerilliant Corporation	Pregabalin-13-C3 (0.1 mg/mL)	Glass ampule: 1 mL	9/9/2013
Cerilliant Corporation	Psilocybin-D3 (0.1 mg/mL)	Glass ampule: 1 mL	12/23/2014
Cerilliant Corporation	Testosterone Calibrator Level 1 (2 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 10 (2000 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 2 (4 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 3 (9 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 4 (17.5 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 5 (35 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 6 (52.5 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 7 (150 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 8 (500 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone Calibrator Level 9 (750 ng/dL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Testosterone-2,3,4-13C3 (10 µg/mL)	Glass ampule: 1 mL	8/7/2014
Cerilliant Corporation	Tetrahydrocannabinolic acid [THCA-A] (1.0 mg/mL)	Glass vial: 1 mL	6/3/2014
Cerilliant Corporation	Tetrahydrocannabivarin [THCV] (1.0 mg/mL)	Glass vial: 1 mL	6/3/2014
Cerilliant Corporation	THC Cannabinoids Mixture-3 (0.5 mg/mL each analyte)	Glass ampule: 1 mL	6/9/2015
Cerilliant Corporation	THC Cannabinoids Mixture-3 (1.0 mg/mL)	Glass ampule: 0.5 mL	8/13/2015
Cerilliant Corporation	Tramadol-13C, D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	7/7/2014

Cerilliant Corporation	Tramadol-13C, D3 HCl (1.0 mg/mL)	Glass ampule: 1 mL	7/7/2014
Cerilliant Corporation	UR-144 (0.1 mg/mL)	Glass ampule: 1 mL	5/16/2013
Cerilliant Corporation	XLR-11 (0.1 mg/mL)	Glass ampule: 1 mL	5/16/2013
Cliniqa Corporation	TDM Control Level 1	Plastic bottle: 1 Gallon	4/15/2014
Cliniqa Corporation	TDM Control Level 1	Plastic bottle: 500 ml	4/15/2014
Cliniqa Corporation	TDM Control Level 1, Part: 82809-M	Bottle: 5 mL	12/15/2014
Cliniqa Corporation	TDM Control Level 2	Plastic bottle: 500 ml	4/15/2014
Cliniqa Corporation	TDM Control Level 2, Part: 82810-M	Bottle: 5 mL	12/15/2014
Cliniqa Corporation	TDM Control Level 3	Plastic bottle: 500 ml	4/15/2014
Cliniqa Corporation	TDM Control Level 3, Part: 82811-M	Bottle: 5 mL	12/15/2014
College of American Pathologists	PCAPTT-QQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCCAPTT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCJACT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCJACT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCJCPT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCJCPT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCJLR-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCJLR-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCJPT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013

College of American Pathologists	PCJPT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCPRO-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
College of American Pathologists	PCPRO-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
Eli Lilly and Company	Testosterone Reference Standard	Glass ampule: 1 mL	11/26/2013
Honeywell Specialty Materials	LUMILUX Red CD 325	Plastic bottle: 5 g	9/16/2015
Immunalysis Corporation	6-Acetylmorphine Calibrator	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	6-Acetylmorphine High Control	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	6-Acetylmorphine Low Control	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Amphetamine Calibrator Level 1	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Amphetamine Calibrator Level 2	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Amphetamine Calibrator Level 3	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Amphetamine Calibrator Level 4	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Amphetamine High Control-A	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Amphetamine High Control-B	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Amphetamine Low Control-A	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Amphetamine Low Control-B	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Carisoprodol Calibrator Level 1	Glass vial: 10 mL	8/25/2014
Immunalysis Corporation	Carisoprodol Calibrator Level 2	Glass vial: 10 mL	8/25/2014
Immunalysis Corporation	Carisoprodol Calibrator Level 3	Glass vial: 10 mL	8/25/2014
Immunalysis Corporation	Carisoprodol Calibrator Level 4	Glass vial: 10 mL	8/25/2014
Immunalysis Corporation	Carisoprodol High Control-1	Glass vial: 10 mL	8/25/2014

Immunalysis Corporation	Carisoprodol High Control-2	Glass vial: 10 mL	8/25/2014
Immunalysis Corporation	Carisoprodol Low Control-1	Glass vial: 10 mL	8/25/2014
Immunalysis Corporation	Carisoprodol Low Control-2	Glass vial: 10 mL	8/25/2014
Immunalysis Corporation	Carisoprodol Positive Reference Control-1	Glass vial: 2 mL	8/25/2014
Immunalysis Corporation	Carisoprodol Positive Reference Control-2	Glass vial: 5 mL	8/25/2014
Immunalysis Corporation	cTHC Calibrator High Control	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	cTHC Calibrator Level 1	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	cTHC Calibrator Level 2	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	cTHC Calibrator Level 3	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	cTHC Calibrator Level 4	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	cTHC Calibrator Low Control	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Fentanyl Calibrator High Control	Glass vial: 10 mL	7/16/2014
Immunalysis Corporation	Fentanyl Calibrator Level 1	Glass vial: 10 mL	7/16/2014
Immunalysis Corporation	Fentanyl Calibrator Level 2	Glass vial: 10 mL	7/16/2014
Immunalysis Corporation	Fentanyl Calibrator Level 3	Glass vial: 10 mL	7/16/2014
Immunalysis Corporation	Fentanyl Calibrator Level 4	Glass vial: 10 mL	7/16/2014
Immunalysis Corporation	Fentanyl Calibrator Low Control	Glass vial: 10 mL	7/16/2014
Immunalysis Corporation	Morphine Calibrator Level 1	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Morphine Calibrator Level 2	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Morphine Calibrator Level 3	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Morphine Calibrator Level 4	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Oxazepam Calibrator Level 1	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Oxazepam Calibrator Level 2	Glass vial: 5 mL	7/16/2014

Immunalysis Corporation	Oxazepam Calibrator Level 3	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Oxazepam Calibrator Level 4	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Oxazepam High Control	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Oxazepam Low Control	Glass vial: 5 mL	7/16/2014
Immunalysis Corporation	Tramadol Calibrator Level 1	Glass vial: 10 mL	7/8/2014
Immunalysis Corporation	Tramadol Calibrator Level 2	Glass vial: 10 mL	7/8/2014
Immunalysis Corporation	Tramadol Calibrator Level 3	Glass vial: 10 mL	7/8/2014
Immunalysis Corporation	Tramadol Calibrator Level 4	Glass vial: 10 mL	7/8/2014
Immunalysis Corporation	Tramadol High Control	Glass vial: 10 mL	7/8/2014
Immunalysis Corporation	Tramadol Low Control	Glass vial: 10 mL	7/8/2014
Immunalysis Corporation	Tramadol Posititve Reference Control	Glass vial: 5 mL	7/8/2014
Immunalysis Corporation	Tramadol Positive Reference Control	Glass vial: 2 mL	7/8/2014
Instrumentation Laboratory	GEM Check Coag Abnormal (6260060100)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Abnormal (6260060200)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Abnormal (6260060300)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Abnormal (6260061400)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Citrate PT Abnormal (6260061600)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Citrate PT Normal (6260061100)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Normal (6260060400)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Normal (6260060500)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Normal (6260060600)	Box: 15 vials; 0.5 mL each	9/12/2013
Instrumentation Laboratory	GEM Check Coag Normal (6260061700)	Box: 15 vials; 0.5 mL each	9/12/2013
Irvine Scientific	Chang Amnio Ref: 99473	100 mL; 500 mL	1/29/2015
Irvine Scientific	Chang Medium C Frozen Supplement Ref: C106	14 mL	1/29/2015
Irvine Scientific	Chang Medium C Frozen Supplement Ref:	10 mL	1/29/2015

	C107		
Irvine Scientific	Chang Medium C Frozen Supplement Ref: C108	70 mL	1/29/2015
Irvine Scientific	Chang Medium C Frozen Supplement Ref: C109	50 mL	1/29/2015
Irvine Scientific	Chang Medium C Lyophilized Ref: T101-019	100 mL	1/29/2015
Irvine Scientific	Chang Medium C Lyophilized Ref: T101-059	500 mL	1/29/2015
Irvine Scientific	Chang Medium C Lyophilized with Gentamicin Ref: 99419	100 mL; 500 mL	1/29/2015
Irvine Scientific	Chang Medium D Ref: 99404	100 mL; 500 mL	1/29/2015
Irvine Scientific	Chang Medium D Ref: T105	100 mL; 500 mL	1/29/2015
Irvine Scientific	Chang Medium In Situ Ref: T104	100 mL; 500 mL	1/29/2015
Irvine Scientific	IS 293 Catalog # 91101	Plastic bottle: 1 L	1/29/2015
Irvine Scientific	IS 293-V Catalog # 91107	Plastic bottle: 1 L	1/29/2015
Irvine Scientific	IS GRO Catalog # 91105	Plastic bottle: 1 L	1/29/2015
Irvine Scientific	IS PRO Catalog # 91103	Plastic bottle: 1 L	1/29/2015
Irvine Scientific	Prime VX ASFC Catalog # 91133	Plastic bottle: 250 mL	9/30/2014
Irvine Scientific	W.I.P. Catalog #: CC.IP	1 L	1/29/2015
IsoSciences, LLC	1,4-Androstadiene-3,17-dione (Boldione), 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	1,4-Androstadiene-3,17-dione (Boldione), 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	11β-Hydroxytestosterone, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	11β-Hydroxytestosterone, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5-Androsten-3β,17β-diol, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5-Androsten-3β,17β-diol, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5-Androsten-3β,17β-diol-[2H3], 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5-Androsten-3β,17β-diol-[2H3], 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3,17-dione, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3,17-dione, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3α,17β-diol, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3α,17β-diol, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015

IsoSciences, LLC	5α-Androstan-3α,17β-diol-[2H3], 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3α,17β-diol-[2H3], 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol-[2H3], 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol-[2H3], 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol-[2H4], 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol-[2H4], 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol-[2H4]-17-sulfate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol-[2H4]-17-sulfate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol-[2H4]-3-sulfate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	5α-Androstan-3β,17β-diol-[2H4]-3-sulfate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Androst-4-ene-3,17-dione, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Androst-4-ene-3,17-dione, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Androst-4-ene-3,17-dione-[13C3], 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Androst-4-ene-3,17-dione-[13C3], 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Androst-4-ene-3,17-dione-[2H7], 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Androst-4-ene-3,17-dione-[2H7], 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Boldenone sulfate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Boldenone sulfate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Boldenone, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Boldenone, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Dihydrotestosterone, 100 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015

IsoSciences, LLC	Dihydrotestosterone, 1000 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Dihydrotestosterone-[13C3], 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Dihydrotestosterone-[13C3], 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Methandriol, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Methandriol, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Methandrostenolone, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Methandrostenolone, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Nandrolone Laurate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Nandrolone Laurate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Stanozolol, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Stanozolol, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Decanoate, 100 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Decanoate, 1000 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Glucuronide, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Glucuronide, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Heptanoate, 100 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Heptanoate, 1000 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Isocaproate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Isocaproate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Phenylpropionate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Phenylpropionate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Propionate, 100 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Propionate, 1000 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015

IsoSciences, LLC	Testosterone Undecanoate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone Undecanoate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone, 100 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone, 1000 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[13C3], 100 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[13C3], 1000 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Decanoate, 100 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Decanoate, 1000 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Glucuronide, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Glucuronide, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Heptanoate, 100 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Heptanoate, 1000 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Isocaproate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Isocaproate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Phenylpropionate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Phenylpropionate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Propionate, 100 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Propionate, 1000 µg /mL in 1,2-dimethoxyethane	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Undecanoate, 100 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3] Undecanoate, 1000 µg /mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3], 100 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H3], 1000 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Testosterone-[2H5], 100 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015

IsoSciences, LLC	Testosterone-[2H5], 1000 µg/mL in methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Unlabeled Steroid Standard Mix SMU001, methanol	Amber Ampule: 1 mL	9/17/2015
IsoSciences, LLC	Unlabeled Steroid Standard Mix SMU002, methanol	Amber Ampule: 1 mL	9/17/2015
ITC	directCHECK Whole Blood Control (DCJACT-A)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJACT-N)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJAPTT-A)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJAPTT-N)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJCAPTT-A CITRATE)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJCPT-A CITRATE)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJCPT-N CITRATE)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJLR-A)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJLR-N)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJPT-A)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCJPT-N)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCPRO-A)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCPRO-N)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCRHY-L1)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	directCHECK Whole Blood Control (DCRHY-L2)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	HepCheck Whole Blood Control (DCP214-A)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	HepCheck Whole Blood Control (DCP214-N)	Box: 15 vials; 0.5 mL each	9/12/2013
ITC	PCAPTT-QQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCCAPTT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013

ITC	PCJACT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCJACT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCJCPT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCJCPT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCJLR-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCJLR-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCJPT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCJPT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCPRO-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
ITC	PCPRO-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
LGC Limited	(S)-(+)-Amphetamine (Dextroamphetamine) 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Alprazolam 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Amobarbital 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Chlordiazepoxide 0.1 mg/ml in Acetonitrile	Glass vial: 1 mL	6/23/2014
LGC Limited	Chlordiazepoxide 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Chlordiazepoxide 1.0 mg/ml in Acetonitrile	Glass vial: 1 mL	6/23/2014
LGC Limited	Chlordiazepoxide-D5 0.1 mg/ml in Acetonitrile	Glass vial: 1 mL	6/23/2014
LGC Limited	Clobazam 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Clonazepam 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014

LGC Limited	Ecgonine Ethyl Ester 0.1 mg/ml in Acetonitrile	Glass vial: 1 mL	6/23/2014
LGC Limited	Estazolam 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Fluoxymesterone 1.0 mg/ml in 1,2-Dimethoxyethane	Glass vial: 1 mL	6/23/2014
LGC Limited	Lormetazepam 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Meprobamate 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Meprobamate-D7 (2-methyl-1,3-propanediol-D7) 0.1 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Methamphetamine ((S)-(+)-Methamphetamine) 0.1 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Methandieone 1.0 mg/ml in 1,2-Dimethoxyethane	Glass vial: 1 mL	6/23/2014
LGC Limited	Methaqualone 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Methenolone 1.0 mg/ml in Acetonitrile	Glass vial: 1 mL	6/23/2014
LGC Limited	Methyltestosterone (17alpha-Methyltestosterone) 1.0 mg/ml in 1,2-Dimethoxyethane	Glass vial: 1 mL	6/23/2014
LGC Limited	Norethandrolone 1.0 mg/ml in 1,2-Dimethoxyethane	Glass vial: 1 mL	6/23/2014
LGC Limited	Oxazepam 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Pentobarbital 0.1 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Phencyclidine (PCP) 0.01 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Phenobarbital 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Phentermine 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Pipradrol Hydrochloride 0.01 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Prazepam 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	rac-Amphetamine-D10 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Secobarbital 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Secobarbital-D5 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Stanozolol-D3 1.0 mg/ml in 1,2-Dimethoxyethane	Glass vial: 1 mL	6/23/2014

LGC Limited	Triazolam 0.1 mg/ml in Methanol	Glass vial: 1 mL	6/23/2014
LGC Standards	1-Naphyrone Hydrochloride (1-Naphthalen-1-yl-2-pyrrolidin-1-ylpentan-1-one Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	2-Fluoromethcathinone Hydrochloride (1-(2-Fluorophenyl)-2-(methylamino)propan-1-one Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	2-MMC HCl (2-Methylmethcathinone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	3,4-Dichloromethylphenidate Hydrochloride (3,4-CTMP HCl; Methyl (2RS)-3,4-Dichlorophenyl[(2RS)-piperidin-2-yl]acetate Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	3',4'-Methylenedioxy-alpha-pyrrolidinobutiophenone Hydrochloride (MDPBP HCl) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	3,4-Methylenedioxycathinone Hydrochloride (MDC HCl, bk-MDA HCl) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	3-Acetylmorphine 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	3-Acetylmorphine 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	3-Fluoromethcathinone Hydrochloride (1-(3-Fluorophenyl)-2-(methylamino)propan-1-one Hydrochloride) 1.0 mg/ml in Dimethyl Sulfoxide (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	4-EMC HCl (4-Ethylmethcathinone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	4-MePPP HCl (4-Methyl-alpha-pyrrolidinopropiophenone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	5-F-AKB-48 (5-F-APINACA; N-(1-Adamantyl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	5-F-AKB-48 (5-F-APINACA; N-(1-Adamantyl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	AKB-48 (APINACA; N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	AKB-48 (APINACA; N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015

LGC Standards	Allobarbital 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Allobarbital 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	AM-2201 ((1-(5-Fluoropentyl)indol-3-yl)(naphthalen-1-yl)methanone) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	AM-2201 ((1-(5-Fluoropentyl)indol-3-yl)(naphthalen-1-yl)methanone) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Anhydroecgonine Hydrochloride 1.0 mg/ml in Water (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Benzoylecgonine 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Benzylpiperazine Dihydrochloride (BZP Dihydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	beta-Ethylmethcathinone Hydrochloride (Pentedrone Hydrochloride)1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	bk-2C-B HCl (2-Amino-1-(4-bromo-2,5-dimethoxyphenyl)ethanone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Buprenorphine 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Buprenorphine 3-beta-D-Glucuronide 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Butylone Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Cocaethylene (Benzoylethylecgonine) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Cocaine 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Cocaine-D8 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Cocaine-D8 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Desomorphine (Dihydrodesoxymorphine, Krokodil) 0.01 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Desomorphine (Dihydrodesoxymorphine, Krokodil) 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Dibutylone Hydrochloride (bk-MMBDB HCl) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Dihydromorphine 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Embutramide 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015

LGC Standards	Epitestosterone 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Ethcathinone Hydrochloride (N-Ethylcathinone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Ethylmorphine 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Ethylmorphine 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Ethylmorphine-D5 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Ethylmorphine-D5 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Ethylone Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Ethylone-D5 Hydrochloride 0.1 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Eutylone Hydrochloride (1-(3,4-Methylenedioxyphenyl)-2-ethylamino-butan-1-one Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Flephedrone Hydrochloride (4-Fluoromethcathinone Hydrochloride) 1.0 mg/ml in Dimethyl Sulfoxide (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Flephedrone Hydrochloride (4-Fluoromethcathinone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Fluoxymesterone 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Heroin (Diacetylmorphine) 0.01 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Heroin-D3 (Diacetylmorphine-D3) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Heroin-D3 (Diacetylmorphine-D3) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Hexobarbital 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Hydrocodone 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Hydromorphone 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Isomethadone ((5RS)-6-(Dimethylamino)-5-methyl-4,4-diphenylhexan-3-one) 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	JWH-018 ((Naphthalen-1-yl)(1-pentylindol-3-yl)methanone) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	JWH-081 ((4-Methoxynaphthalen-1-yl)(1-pentylindol-3-yl)methanone) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015

LGC Standards	JWH-122 ((4-Methylnaphthalen-1-yl)(1-pentylindol-3-yl)methanone) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	JWH-203 (2-(2-Chlorophenyl)-1-(1-pentylindol-3-yl)ethanone) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	JWH-250 (2-(2-Methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	JWH-250 (2-(2-Methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	JWH-398 ((4-Chloronaphthalen-1-yl)(1-pentylindol-3-yl)methanone) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Lorazepam-D4 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Mephedrone Hydrochloride (4-MMC HCl, 4-Methylmethcathinone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Mephedrone-D3 Hydrochloride (4-MMC-D3 HCl, 4-Methylmethcathinone-D3 Hydrochloride) 0.1 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Methamphetamine Hydrochloride ((S)-(+)-Methamphetamine Hydrochloride) 0.1 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Methamphetamine Hydrochloride ((S)-(+)-Methamphetamine Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Methylenedioxypyrovalerone Hydrochloride (MDPV HCl) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Methylethcathinone Hydrochloride (4-Methyl-N-ethylcathinone Hydrochloride, 4-MEC HCl) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Midazolam 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Modafinil 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Morphine N-Oxide 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Morphine-D3 3-beta-D-Glucuronide 0.1 mg/ml in Methanol with 0.05 percent Sodium Hydroxide (w/v)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Morphine-D3 6-beta-Glucuronide 0.1 mg/ml in Methanol/Water (1/1)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Morphine-D6 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Morphine-D6 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015

LGC Standards	Nalorphine Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Naphyrone Hydrochloride (1-Naphthalen-2-yl-2-pyrrolidin-1-ylpentan-1-one Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	N-Desmethyldextromethorphan Hydrochloride (ent-3-Methoxymorphinan Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	N-Ethylbuphedrone Hydrochloride (NEB HCl, alpha-Ethylaminobutyrophenone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Normorphine 0.01 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Noroxymorphone Hydrochloride 1.0 mg/ml in Dimethyl Sulfoxide (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Norpethidine (Normeperidine) 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Norpethidine-D4 (Normeperidine-D4) 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Oripavine 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Oxycodone 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Oxymorphone 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Pentylone Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Pethidine (Meperidine) 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Pethidine Acid (Meperidine Acid, 1-Methyl-4-phenylpiperidine-4-carboxylic Acid) 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Pethidine Acid Methyl Ester (Meperidine Acid Methyl Ester, Methyl 1-Methyl-4-phenylpiperidine-4-carboxylate) 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Pholcodine-D3 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Pholcodine-D3 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	PMEA HCl (p-Methoxyethylamphetamine Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	PPP HCl (alpha-Pyrrolidinopropiophenone Hydrochloride) 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Properidine (1-Methylethyl 1-Methyl-4-phenyl-piperidine-4-carboxylate) 0.01 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015

LGC Standards	Properidine (1-Methylethyl 1-Methyl-4-phenyl-piperidine-4-carboxylate) 1.0 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Amphetamine-D11 Hydrochloride 0.1 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Amphetamine-D11 Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Amphetamine-D6 Hydrochloride 0.1 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Amphetamine-D6 Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Amphetamine-D8 Hydrochloride 0.1 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Amphetamine-D8 Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Cathinone Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-MDA (rac-3,4-Methylenedioxyamphetamine) 0.01 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-MDEA (rac-3,4-Methylenedioxy-N-ethylamphetamine) 0.01 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-MDEA-D6 (rac-3,4-Methylenedioxy-N-ethylamphetamine-D6) 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-MDMA (rac-3,4-Methylenedioxymethamphetamine) 0.01 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Methamphetamine-D11 Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Methamphetamine-D14 Hydrochloride 0.1 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	rac-Methamphetamine-D14 Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	RCS-4 (DD-001, (4-Methoxyphenyl)(1-pentylindol-3-yl)methanone) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	RCS-8 (1-(1-(2-Cyclohexylethyl)indol-3-yl)-2-(2-methoxyphenyl)ethanone) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	Thebaine 0.1 mg/ml in Methanol	Glass ampule: 1 mL	6/8/2015
LGC Standards	Tilidine Hydrochloride Hemihydrate 1.0 mg/ml in Methanol (as anhydrous free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Tramadol Hydrochloride 1.0 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015
LGC Standards	Tramadol-13C-D3 Hydrochloride 0.1 mg/ml in Methanol (as free base)	Glass ampule: 1 mL	6/8/2015

LGC Standards	UR-144 ((1-Pentylindol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, KM X-1) 0.1 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
LGC Standards	UR-144 ((1-Pentylindol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, KM X-1) 1.0 mg/ml in Acetonitrile	Glass ampule: 1 mL	6/8/2015
Lipomed Inc.	1-Benzylpiperazine.2HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	2C-B-D6-HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-B-D6-HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-C.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-C-D6.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-C-D6.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-D.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-E.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	2C-H.HCl(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	2C-I.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	2C-I-D6-HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-I-D6-HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-N.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-P.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	2C-T-2.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	2C-T-4.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	3,4-Methylendioxypyrovalerone.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	4-Methylmethcathinone.HCl; Mephedrone.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	6-Acetylmorphine-D6.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	AM-2201 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015

Lipomed Inc.	AM-2201 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Amfepramone.HCl (1 mg/1 mL ethanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Benzodiazepines mixture 8 (0.25 mg/1 mL acetronitrile)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Boldenone (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Bromazepam-D4 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Bromazepam-D4 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Bufotenine.oxalate.monohydrate (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Buphedrone.HCl (MABP.HCl)(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Butabarbital(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Butalbital(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Carisoprodol(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Clonazepam-D4 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Codeine-D6(0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Codeine-D6(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-2,5-DMA.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-3,4,5-TMA.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-3,4-Dimethoxyamphetamine.HCl d,l-3,4-DMA.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-4-Methylmethcathinone-D3.HCl; Mephedrone-D3.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-4-Methylmethcathinone-D3.HCl; Mephedrone-D3.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Amphetamine-D11.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Amphetamine-D3.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Amphetamine-D3.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Amphetamine-D5.HCl (side chain) (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013

Lipomed Inc.	d,l-Amphetamine-D5.HCl (side chain) (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Cathinone.HCl(1 mg/1 mL Acetonitrile)/water (1/1)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Fenfluramine.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-HMMA.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Metamfepramone.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	d,l-Methylphenidate.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-N,N-Dimethylamphetamine.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Pentobarbital-D5 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-Pentobarbital-D5 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-trans-Tilidine.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-trans-Tilidine.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Desmethyldiazepam(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Desmethyldiazepam-D5 (Nordazepam-D5) (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Desmethyldiazepam-D5 (Nordazepam-D5) (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Desomorphine (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Dihydrocodeine-D6.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Dihydrocodeine-D6.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Estazolam(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Ethcathinone.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Fenethylline.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Fenethylline-D3.HCl (0.1 mg/1 mL Methanol))	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Fenethylline-D3.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Heroin-D9 (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	4/8/2013

Lipomed Inc.	Heroin-D9(0.1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Hexobarbital(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Hydrocodone-D6(0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Hydrocodone-D6(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-018 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-018 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-018-D11 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-018-D11 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-019 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-019 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-073 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-073 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-081 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-081 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-122 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-122 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-200 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-200 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-250 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	JWH-250 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	l-Methamphetamine.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Loprazolam (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Lorazepam-D4 (0.1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	4/8/2013

Lipomed Inc.	Lorazepam-D4 (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Mazindol (1 mg/1 mL dimethylformamide)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Mazindol (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Meperidine-D4.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Meperidine-D4.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Meperidine-D4.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Meperidine-D4.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Meprobamate (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Meprobamate-D7 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Meprobamate-D7 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Mescaline-NB2OMe.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Methylone.HCl; bk-MDMA.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Methylone-D3.HCl; bk-MDMA-D3.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Methylone-D3.HCl; bk-MDMA-D3.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Methylone-D3.HCl; bk-MDMA-D3.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Methylone-D3.HCl; bk-MDMA-D3.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Morphine-D3 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Morphine-D3 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Nandrolone (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Nimetazepam (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Norbuprenorphine (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Norbuprenorphine (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Norbuprenorphine-D3 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013

Lipomed Inc.	Norbuprenorphine-D3 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Normeperidine.HCl ; Norpethidine.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Normeperidine-D4.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Normeperidine-D4.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Noroxycodone.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Oxycodone-D6.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Oxycodone-D6.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Oxymorphone (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Oxymorphone-D3 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Oxymorphone-D3 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Pregabalin (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Propoxyphen-D5.HCl (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Propoxyphen-D5.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Pyrovalerone.HCl (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	RCS-4 (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	RCS-4 (1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	S(-)-Cathinone.HCl (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Stanozolol (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Temazepam-glucuronide (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Thiopental(1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Trenbolone (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Trenbolone (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Trenbolone acetate (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	1/5/2015

Lipomed Inc.	Trenbolone acetate (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Zolpidem-D6.tartrate (0.1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Zolpidem-D6.tartrate (1 mg/1 mL Methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Zopiclone (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Zopiclone-D4 (0.1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Zopiclone-D4 (1 mg/1 mL Acetonitrile)	Glass ampule: 1 mL	4/8/2013
Microgenics Corporation	Abbott Phenobarbital Catalog Number : 5P07-21	Box: 6 bottles; 23 mL or 8mL each	9/3/2013
Microgenics Corporation	Cascadion SM Total Testosterone Calibrator Set	Box: 6 vials, 5 mL each	6/2/2014
Microgenics Corporation	Cascadion SM Total Testosterone Control 1	Box: 6 vials, 10 mL each	6/2/2014
Microgenics Corporation	Cascadion SM Total Testosterone Control 2	Box: 6 vials, 10 mL each	6/2/2014
Microgenics Corporation	Cascadion SM Total Testosterone Control 3	Box: 6 vials, 10 mL each	6/2/2014
Microgenics Corporation	Cascadion SM Total Testosterone Internal Standard Reagent	Box: 8 bottles, 29 mL each	8/26/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Calibrator 100 ng/mL, Catalog Number: 10019837	Box: 1 bottle, 10 mL	8/18/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Calibrator 100 ng/mL, Part Number: 10018079	Box: 1 Bottle, 10 mL	9/11/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Calibrator 1000 ng/mL, Part Number: 10018082	Box: 1 Bottle, 10 mL	9/11/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Calibrator 1000 ng/mL, Part Number: 10019840	Box: 1 Bottle, 10 mL	8/18/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Calibrator 300 ng/mL, Catalog Number: 10019838	Box: 1 bottle, 10 mL	8/18/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Calibrator 300 ng/mL, Part Number: 10018080	Box: 1 Bottle, 10 mL	9/11/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Calibrator 500 ng/mL, Part Number: 10018081	Box: 1 Bottle, 10 mL	9/11/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Calibrator 500 ng/mL, Part Number: 10019839	Box: 1 Bottle, 10 mL	8/18/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Controls (High and Low), Catalog Number: 10019841	Box: 2 bottles, 10 mL each	8/18/2014
Microgenics Corporation	DRI Hydrocodone/Hydromorphone Assay Controls (High and Low), Part Number: 10018149	Box: 2 Bottles, 10 mL each	9/11/2014

Microgenics Corporation	Thermo Scientific CEDIA Cocaine Assay Catalog Number: 10016413	Glass vial: 17 mL, Box: 3 vials	8/23/2013
Microgenics Corporation	Thermo Scientific CEDIA Opiate Assay Catalog Number: 10016429	Glass vial: 17 mL, Box: 3 vials	8/23/2013
Microgenics Corporation	Thermo Scientific Intercept i2he Methamphetamine Oral Fluid Control Set (High and Low), Catalog Number : 10010391 Catalog Number : 10010391	Box: 2 vial; 10 mL each	7/29/2014
Microgenics Corporation	Thermo Scientific Intercept i2he Methamphetamine Oral Fluid Cutoff Calibrator, Catalog Number : 10010392	Box: 1 vial; 5 mL	7/29/2014
Microgenics Corporation	Thermo Scientific Intercept i2he Multi-Drug Oral Fluid Control Set A (High and Low), Catalog Number : 10010394	Box: 2 vial; 15 mL each	7/29/2014
Microgenics Corporation	Thermo Scientific Intercept i2he Multi-Drug Oral Fluid Cutoff Calibrator Set A, Catalog Number: 10010395	Box: 1 vial; 10 mL	7/29/2014
Microgenics Corporation	Thermo Scientific Intercept i2he THC Oral Fluid Control Set (High and Low), Catalog Number : 10010397	Box: 2 vial; 10 mL each	7/29/2014
Microgenics Corporation	Thermo Scientific Intercept i2he THC Oral Fluid Cutoff Calibrator, Catalog Number : 10010398	Box: 1 vial; 5 mL	7/29/2014
Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostics Products Total T4 Reagent Pack	Chamber: 18.3 mL	7/29/2014
PerkinElmer, Inc.	AlphaLISA Testosterone (100 µM) AL324S 100% DMSO	Screw-cap Vial: 210 µL	5/28/2015
Pierce Biotechnology, Inc.	Cascadion SM Total Testosterone Internal Standard Reagent, Bulk Solution	Glass bottle: 8-10 L	3/25/2015
Pierce Biotechnology, Inc.	Gold Standard, Cascadion SM Total Testosterone Internal Standard Reagent	Amber vial: 30 mL	3/25/2015
Pierce Biotechnology, Inc.	Testosterone Stock Solution (500 ng/g) in Methanol	Glass bottle: 2 L	3/25/2015
Restek Corporation	(+/-)-11-nor-9-carboxy-delta-9-THC Standard	Ampule: 1.3 mL	2/11/2014
Restek Corporation	Cannabidiolic Acid (CBDA) Standard	Ampule: 1.3 mL	1/28/2014
Restek Corporation	Custom Pesticides Standard #1	Glass vial: 1.3 mL	5/22/2013
Restek Corporation	Custom Rev Appendix IX Kit/ Ampule 2	Ampule: 5.4 mL	7/1/2013
Restek Corporation	Delta-9-THC Standard	Ampule: 1.3 mL	2/11/2014

Restek Corporation	Endoctrine Disruptors Standard #3	Ampule: 1.3 mL	4/9/2014
Restek Corporation	Morphine and Hydromorphone Standard	Ampule: 1.3 mL	11/15/2013
Siemens Healthcare Diagnostics, Inc.	BK Emit Specialty Drug Calibrator/Control LVL 1	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	BK Emit Specialty Drug Calibrator/Control LVL 2	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	BK Emit Specialty Drug Calibrator/Control LVL 3	Bulk Container: 10 L – 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	BK Emit Specialty Drug Calibrator/Control LVL 4	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	BK Emit Specialty Drug Control Negative	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	BK Emit Specialty Drug Control Positive	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Dimension Vista TSTP CAL	Box of 12 vials, 1 mL each	6/6/2013
Siemens Healthcare Diagnostics, Inc.	Dimension Vista TTST CAL	Box of 12 vials, 1 mL each	6/6/2013
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Drug Calibrator/Control Level 1	Vial: 10 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Drug Calibrator/Control Level 2	Vial: 10 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Drug Calibrator/Control Level 3	Vial: 10 mL	6/7/2013

Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Drug Calibrator/Control Level 4	Vial: 10 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Drug Control Negative	Vial: 10 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Drug Control Positive	Vial: 10 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP BK Emit Specialty Drug Calibrator/Control LVL 1	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP BK Emit Specialty Drug Calibrator/Control LVL 2	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP BK Emit Specialty Drug Calibrator/Control LVL 3	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP BK Emit Specialty Drug Calibrator/Control LVL 4	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP BK Emit Specialty Drug Control Negative	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP BK Emit Specialty Drug Control Positive	Bulk Container: 10 L- 50 L	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Drug Calibrator/Control LVL 1	Vial: 15 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Drug Calibrator/Control LVL 2	Vial: 15 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Drug Calibrator/Control LVL 3	Vial: 15 mL	6/7/2013

Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Drug Calibrator/Control LVL 4	Vial: 15 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Drug Control Negative	Vial: 15 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Drug Control Positive	Vial: 15 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP Pilot Emit Specialty Drug Calibrator/Control LVL 1	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP Pilot Emit Specialty Drug Calibrator/Control LVL 2	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP Pilot Emit Specialty Drug Calibrator/Control LVL 3	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP Pilot Emit Specialty Drug Calibrator/Control LVL 4	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP Pilot Emit Specialty Drug Control Negative	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	MP Pilot Emit Specialty Drug Control Positive	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Pilot Emit Specialty Drug Calibrator/Control LVL 1	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Pilot Emit Specialty Drug Calibrator/Control LVL 2	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Pilot Emit Specialty Drug Calibrator/Control LVL 3	Pilot Container: 4 mL- 200 mL	6/7/2013

Siemens Healthcare Diagnostics, Inc.	Pilot Emit Specialty Drug Calibrator/Control LVL 4	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Pilot Emit Specialty Drug Control Negative	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	Pilot Emit Specialty Drug Control Positive	Pilot Container: 4 mL- 200 mL	6/7/2013
Siemens Healthcare Diagnostics, Inc.	VS TSTP CAL Vial Level A	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TSTP CAL Vial Level B	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TSTP CAL Vial Level C	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TSTP CAL Vial Level D	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TSTP CAL Vial Level E	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TSTP CAL Vial Level F	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TTST CAL Vial Level A	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TTST CAL Vial Level B	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TTST CAL Vial Level C	Vial: 1 mL	6/6/2013

Siemens Healthcare Diagnostics, Inc.	VS TTST CAL Vial Level D	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TTST CAL Vial Level E	Vial: 1 mL	6/6/2013
Siemens Healthcare Diagnostics, Inc.	VS TTST CAL Vial Level F	Vial: 1 mL	6/6/2013
Sigma-Aldrich, Co.	4-Androstene-3,17-dione-2,3,4-13C3 solution (0.1 mg/mL in methanol)	Glass ampule: 2 mL	5/28/2015
Sigma-Aldrich, Co.	Dihydrotestosterone-2,3,4-13C3 solution (0.1 mg/mL in methanol)	Glass ampule: 2 mL	5/28/2015
Sigma-Aldrich, Co.	Testosterone-2,3,4-13C3 solution (0.1 mg/mL in methanol)	Glass ampule: 2 mL	5/28/2015
Supelco, Inc.	a,a-Dimethylphenethylamine 2000 µg/mL in methylene chloride	Glass vial: 1 mL	8/15/2013
Supelco, Inc.	Chloral Hydrate 1000 µg/mL in Acetonitrile	Glass ampule: 1 mL	4/8/2013
Supelco, Inc.	LS4434-Mix 1_15, 0.019- 2.375 µg/mL in Methanol	Glass ampule: 1 mL	4/2/2015
Toronto Research Chemicals Inc.	Δ1-Testosterone (1.0/mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	10-Oxo Morphine (100 µg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	17α-Methyl Testosterone (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	1-Butyl-3-(1-naphthoyl)indole JWH-073 (100 µg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	1-Pentyl-3-(1-naphthoyl)indole JWH 018 (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	2-(Methylamino)-3',4'-(methylenedioxy)valerophenone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	2-Methyl Methcathinone Hydrochloride (1 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	2-Naphthyl Pyrovalerone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014

Toronto Research Chemicals Inc.	3,4,5-Trimethoxyphenethylamine, Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	3-Fluoroephedrone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	4-Fluoroephedrone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	6-Acetyl Morphine (100 µ /mL in Acetonitrile)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	6-Acetyl Morphine-d3 (100 µg/mL in Acetonitrile)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	6β-Naltrexol (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	6β-Naltrexol-d4 (1.0 mg/ml in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Aminorex (1 mg/mL in Acetonitrile)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Amobarbital (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Androstanolone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Androstanolone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Androstenedione (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Benzoyl Ecgonine (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Benzoyl Ecgonine (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Benzoyl Ecgonine-d3 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Boldenone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014

Toronto Research Chemicals Inc.	Bromazepam (1 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Bromazepam (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Buprenorphine β-D-Glucuronide (100 ug/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Butabarbital (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Butalbital (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Chlordiazepoxide-d5 (100 ug/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Clonazepam-d4 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Cocaine-d3 (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Cocaine-d3 (100 µg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Codeine (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Codeine-d3 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Delorazepam (100 ug/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Desmethyl Diazepam (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Desmethyl Diazepam-d5 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Desmethyl Pyrovalerone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Desmethyl Pyrovalerone-d8 Hydrochloride (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014

Toronto Research Chemicals Inc.	Desomorphine (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Desomorphine (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Desomorphine-d3 (100 µg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Diazepam (1 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Diethylpropion Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Dihydromorphine-d3 (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Drostanolone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Ethyl Morphine (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Ethylone (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Ethylone-d5 (100 µg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Furazabol (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Heroin (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	HU 210 (100µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Hydrocodone (1.0 mg/ml in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Hydrocodone-d6 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Ketamine Hydrochloride (1.0 mg/ml in Methanol)	Glass vial: 1 mL	6/26/2014

Toronto Research Chemicals Inc.	Ketamine-d4 (100 µg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Meperidine Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Mephedrone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Mephedrone-d3 Hydrochloride (100 µg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Meprobamate (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Meprobamate-d3 (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Methcathinone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Methylenedioxy Pyrovalerone Hydrochloride (1 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Methylenedioxy Pyrovalerone-d8 Hydrochloride (0.5 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Methylenedioxy Pyrovalerone-d8 Hydrochloride (0.5 mg/mL in Methanol)	Glass vial: 1 mL	8/29/2014
Toronto Research Chemicals Inc.	Methylone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Methylone-d3 Hydrochloride (100 µg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Methylphenidate Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Mibolerone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Midazolam (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014

Toronto Research Chemicals Inc.	Morphine 3-β-D-Glucuronide (0.1 mg/mL in Methanol/Water 1:1)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine 3-β-D-Glucuronide (1.0 mg/mL in Methanol w/ 0.05% NaOH)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine 6-β-D-Glucuronide (1.0 mg/mL in Water:Methanol 80:20)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine 6-β-D-Glucuronide (100 µg/mL in Methanol:Water)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine N-Oxide (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine-d3 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine-d3 (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine-d3 3-β-D-Glucuronide (100 µg/mL in Methanol w/0.05% NaOH)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Morphine-d3 6-β-D-Glucuronide (100 µg/mL Methanol:Water 1:1)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Morphine-d6 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Nabilone (1.0 mg/ml in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Naloxone N-Oxide (100 µg/mL in 1:1 Acetonitrile and water solution)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Naloxone N-Oxide (100 µg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Nandrolone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	N-Benzylpiperazine Dihydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Nimetazepam (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014

Toronto Research Chemicals Inc.	Nitrazepam (1.0 mg/ml in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Nitrazepam (100 µg/ml in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Nitrazepam-d5 (100µg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Norbuprenorphine (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Norclostebol (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Norcocaine Hydrochloride (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Norcocaine-d3 Hydrochloride (100 µg/mL in Acetonitrile)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	nor-Flurazepam (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Noroxycodone-d3 (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Oxandrolone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Oxazepam (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Oxazepam (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Oxazepam-d5 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Oxazepam-d5 (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Oxymorphone-d3 (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Phencyclidine Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014

Toronto Research Chemicals Inc.	Phencyclidine-d5 Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Phencyclidine-d5 Hydrochloride (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Phenobarbital (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Phenobarbital-d5 (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Phenobarbital-d5 (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Pipradrol Hydrochloride (1.0 mg/ml in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Propoxyphene Hydrochloride (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Propoxyphene Hydrochloride (100 µg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Pyrovalerone Hydrochloride (1mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	rac Amphetamine Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	rac Amphetamine Hydrochloride (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	rac Diethypropion-d10 Hydrochloride (100 µg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	rac Methadone Hydrochloride (1 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	rac Methadone-d3 Hydrochloride (100 ug/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	rac-Amphetamine-d6 Hydrochloride (100 µg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	rac-N-Ethyl-4-methyl-Cathinone Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014

Toronto Research Chemicals Inc.	Stanozolol (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Synthetic Cannabinoid Mixture 2 (mixture of AM2201, JWH 019, JWH 081, and JWH 122, 100 µg/mL of each component in Acetonitrile)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Temazepam (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Temazepam (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Testosterone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Testosterone Benzoate (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Testosterone-d3 (100 µg/mL in 1,2-Dimethoxyethane)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Thebaine-N-(methyl-d3) (1.0 mg/ml in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Tilidine Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	7/11/2014
Toronto Research Chemicals Inc.	Tilidine-d6 Hydrochloride (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Trenbolone (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Zolpidem (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Zolpidem-d6 (100 ug/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Δ1-Androstenedione (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals, Inc.	Buphedrone (1 mg/mL in Methanol, as free base)	Glass vial: 1 mL	7/11/2014
USP	USP Levomethorphan Reference Standard	Amber ampule: 1.2 mL	1/19/2015

WSLH Proficiency Testing	PCAPTT-QQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCCAPTT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCJACT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCJACT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCJCPT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCJCPT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCJLR-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCJLR-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCJPT-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCJPT-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCPRO-AQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013
WSLH Proficiency Testing	PCPRO-NQ	Bag: 250- 750 tubes; 0.5 mL each	9/12/2013

The Deputy Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart II below is not consistent with the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23. Accordingly, the Deputy Assistant Administrator has determined that the chemical preparations or mixtures generally described in Chart II below and specifically described in the application materials received by the DEA, are not exempt from application of any part of the CSA or from application of any part of the CFR, with regard to the requested exemption pursuant to 21 CFR 1308.23, as of the date that was provided in the determination letters to the individual requesters.

Chart II

Supplier	Product Name	Form	Application Date
Aalto Scientific, Ltd.	Control FD Immunoassay, Level 1	Glass vial: 3 mL	10/22/2015
Aalto Scientific, Ltd.	Control FD Immunoassay, Level 2	Glass vial: 3 mL	10/22/2015
Aalto Scientific, Ltd.	Control FD Immunoassay, Level 3	Glass vial: 3 mL	10/22/2015
Aalto Scientific, Ltd.	Control FD TDM, Level 1	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Control FD TDM, Level 2	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Control FD TDM, Level 3	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Fertility Siemens Centaur, Level A	Glass vial: 3 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Fertility Siemens Centaur, Level B	Glass vial: 3 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Fertility Siemens Centaur, Level C	Glass vial: 3 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Fertility Siemens Centaur, Level D	Glass vial: 3 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Fertility Siemens Centaur, Level E	Glass vial: 3 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Immunoassay, Level A	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Immunoassay, Level B	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Immunoassay, Level C	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Immunoassay, Level D	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD Immunoassay, Level E	Glass vial: 5 mL	10/22/2015

Aalto Scientific, Ltd.	Linearity FD TDM Siemens Centaur, Level A	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM Siemens Centaur, Level B	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM Siemens Centaur, Level C	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM Siemens Centaur, Level D	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM Siemens Centaur, Level E	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM, Level A	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM, Level B	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM, Level C	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM, Level D	Glass vial: 5 mL	10/22/2015
Aalto Scientific, Ltd.	Linearity FD TDM, Level E	Glass vial: 5 mL	10/22/2015
Absolute Standards, Inc.	(-)-Δ9-THC (Varied µg/mL in methanol)	Glass ampoule: 1 mL	6/18/2015
Absolute Standards, Inc.	Alprazolam (1000 µg/mL in methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Alprazolam-D5 (1000 µg/mL in methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Chloral hydrate (2000 µg/mL in acetone)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Fentanyl (1000 µg/mL in methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Fentanyl-D5 (1000 µg/mL in methanol)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Lysergic acid diethylamide (LSD) (100 µg/mL in acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Lysergic acid diethylamide (LSD) (1000 µg/mL in acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Lysergic acid diethylamide-d3 (LSD) (100 µg/mL in acetonitrile)	Glass ampoule: 1 mL	7/11/2014

Absolute Standards, Inc.	Lysergic acid diethylamide-d3 (LSD) (1000 µg/mL in acetonitrile)	Glass ampoule: 1 mL	7/11/2014
Absolute Standards, Inc.	Medicinal Cannabis PT (Varied µg/mL in methanol)	Glass ampoule: 1 mL	6/18/2015
Absolute Standards, Inc.	Total THC (100 µg/mL in methanol)	Glass ampoule: 1 mL	6/18/2015
Absolute Standards, Inc.	Total THC Medicinal Cannabis Calibration (100 µg/mL in methanol)	Glass ampoule: 1 mL	6/18/2015
Absolute Standards, Inc.	Total THC Medicinal Cannabis PT (Varied µg/mL in methanol)	Glass ampoule: 1 mL	6/18/2015
Biochemical Diagnostics, Inc.	1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (UR-144/XLR11) Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144) Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	3,4-Methylendioxy-N-Methylcathinone (Methylone) Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	3,4-Methylenedioxy-N-Methylcathinone (Methylone) Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	4-Methyl-N-Methycathinone (Mephedrone) Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	4-Methyl-N-Methycathinone (Mephedrone) Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Benzoylecgonine Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Butylone Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	Carisoprodol Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Cocaine Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Codeine Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014

Biochemical Diagnostics, Inc.	d-Amphetamine Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC182	Glass vials: 500 mL- 2 L	4/22/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC207	Glass vials: 1 mL- 200 mL	12/30/2013
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC207	Glass vials: 1 mL- 200 mL	2/24/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC207	Glass vials: 1 mL- 100 mL	4/14/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC231	Glass vials: 1 mL- 100 mL	4/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC232	Glass vials: 1 mL- 100 mL	4/16/2014
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC233	Glass vials: 1 mL- 100 mL	4/25/2014
Biochemical Diagnostics, Inc.	d-Methamphetamine Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	d-Propoxyphene Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Fentanyl Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Heroin Bulk Solution (1 mL - 1L)	Glass bottle or polypropylene and polyethylene container: 1 mL - 100 mL	8/12/2014
Biochemical Diagnostics, Inc.	Heroin Bulk Solution (1 mL- 1 L)	Glass bottle or polypropylene and polyethylene container: 1 mL - 100 mL	7/3/2014
Biochemical Diagnostics, Inc.	Hydrocodone Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Hydromorphone Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014

Biochemical Diagnostics, Inc.	Ketamine Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	l-Benzylpiperazine Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	MDA Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	MDEA Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	MDMA Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Mescaline Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	Methadone Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Methaqualone Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Methcathinone Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	Morphine Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Oxazepam Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Pentylone Bulk Solution	Bottle: 1 mL- 500 mL	8/29/2014
Biochemical Diagnostics, Inc.	Phencyclidine Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Secobarbital Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Biochemical Diagnostics, Inc.	Tapentadol Bulk Solution	Glass/plastic bottle: 1 mL- 1 L	5/6/2013
Biochemical Diagnostics, Inc.	Tapentadol Bulk Solution	Glass/plastic bottle: 1 mL- 1 L	5/31/2013

Biochemical Diagnostics, Inc.	Tramadol Bulk Solution	Bottle: 1 mL- 500 mL	9/2/2014
Bionostics, Inc.	IN PROCESS MATERIAL DC PRO Whole Blood Control	Plastic bottle: 1 L	9/12/2013
Bionostics, Inc.	IN PROCESS MATERIAL DC Whole Blood Control	Plastic bottle: 1 L	9/12/2013
Bio-Rad Laboratories	Benzoylecgonine Anhydrous [Spike Solution]	Flask: 10 mL	5/19/2013
Bio-Rad Laboratories	Dextropropoxyphene HCl [Spike Solution]	Flask: 50 mL	5/19/2013
Bio-Rad Laboratories	d-Methamphetamine HCl [Spike Solution]	Flask: 50 mL	5/19/2013
Bio-Rad Laboratories	Methadone HCl [Spike Solution]	Flask: 50 mL	5/19/2013
Bio-Rad Laboratories	Methaqualone [Spike Solution]	Flask: 50 mL	5/19/2013
Bio-Rad Laboratories	Morphine HCl [Spike Solution]	Flask: 50 mL	5/19/2013
Bio-Rad Laboratories	Oxazepam [Spike Solution]	Flask: 50 mL	5/19/2013
Bio-Rad Laboratories	Secobarbital [Spike Solution]	Flask: 10 mL	5/19/2013
Cayman Chemical Company	Alprazolam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Alprazolam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Alprazolam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	4/30/2015
Cayman Chemical Company	Alprazolam-d5 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Alprazolam-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Alprazolam-d5 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Buprenorphine (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Buprenorphine-d4 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014

Cayman Chemical Company	Cannabichromene (exempt preparation); 10 mg in 400 µL Methanol	Glass vial: 400 µL	5/2/2014
Cayman Chemical Company	Cannabichromene (exempt preparation); 25 mg in 1 mL Methanol	Glass vial: 1 mL	5/2/2014
Cayman Chemical Company	Cannabichromene (exempt preparation); 5 mg in 200 µL Methanol	Glass vial: 200 µL	5/2/2014
Cayman Chemical Company	Cannabigerol (exempt preparation); 10 mg in 400 µL Methanol	Glass vial: 400 µL	5/2/2014
Cayman Chemical Company	Cannabigerol (exempt preparation); 25 mg in 1 mL Methanol	Glass vial: 1 mL	5/2/2014
Cayman Chemical Company	Cannabigerol (exempt preparation); 5 mg in 200 µL Methanol	Glass vial: 200 µL	5/2/2014
Cayman Chemical Company	Cannabinol (exempt preparation); 10 mg in 400 µL Methanol	Glass vial: 400 µL	5/2/2014
Cayman Chemical Company	Cannabinol (exempt preparation); 25 mg in 1 mL Methanol	Glass vial: 1 mL	5/2/2014
Cayman Chemical Company	Cannabinol (exempt preparation); 5 mg in 200 µL Methanol	Glass vial: 200 µL	5/2/2014
Cayman Chemical Company	Clonazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	12/2/2014
Cayman Chemical Company	Clonazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	12/2/2014
Cayman Chemical Company	Clonazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	4/30/2015
Cayman Chemical Company	Clonazepam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Clonazepam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Clonazepam CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Clonazepam-d4 (exempt preparation); 1 mg in 1 mL Methanol	Glass ampule: 1 mL	9/22/2014

Cayman Chemical Company	Clonazepam-d4 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Clonazepam-d4 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Clonazepam-d4 CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Diazepam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Diazepam-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Fentanyl (hydrochloride) CRM CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Fentanyl (hydrochloride) CRM CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Fentanyl (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	4/30/2015
Cayman Chemical Company	Fentanyl (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Fentanyl (hydrochloride); 1 mg in 1 mL Methanol-	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Fentanyl (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Fentanyl (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Fentanyl-d3 (HCl) (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Fentanyl-d3 (HCl) (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Fentanyl-d3 (hydrochloride) CRM CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Fentanyl-d3 (hydrochloride) CRM CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014

Cayman Chemical Company	Fentanyl-d3 (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Fentanyl-d3 (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Fentanyl-d3 (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Fentanyl-d3 (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Flunitrazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	12/2/2014
Cayman Chemical Company	Flunitrazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	12/2/2014
Cayman Chemical Company	Flunitrazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	4/30/2015
Cayman Chemical Company	Flunitrazepam CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Flunitrazepam CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Flunitrazepam-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass ampule: 1 mL	9/22/2014
Cayman Chemical Company	Flunitrazepam-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Flunitrazepam-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Hydromorphone-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Lorazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Lorazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Lorazepam CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	4/30/2015

Cayman Chemical Company	Lorazepam-d4 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Lorazepam-d4 CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Lysergic acid diethylamide CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Lysergic acid diethylamide CRM; 1 mg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Lysergic acid diethylamide CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Lysergic acid diethylamide CRM; 100 µg/mL in Acetonitrile	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Lysergic acid diethylamide; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Lysergic acid diethylamide; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Lysergic acid diethylamide; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Opiate Mixture CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Oxymorphone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Oxymorphone CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Oxymorphone-d3 (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Oxymorphone-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Oxymorphone-d3 CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Sufentanil (citrate) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014

Cayman Chemical Company	Sufentanil (citrate) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Sufentanil (citrate) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Sufentanil (citrate) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Sufentanil (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Sufentanil (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Sufentanil (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Sufentanil (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Sufentanil (hydrochloride); 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Sufentanil (hydrochloride); 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Sufentanil (hydrochloride); 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Sufentanil citrate CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Sufentanil citrate CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Sufentanil citrate CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Sufentanil citrate CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Sufentanil citrate; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Sufentanil citrate; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013

Cayman Chemical Company	Sufentanil citrate; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Sufentanil CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Sufentanil CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Sufentanil CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	1/27/2014
Cayman Chemical Company	Sufentanil CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	1/27/2014
Cayman Chemical Company	Sufentanil; 1 mg in 1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Sufentanil; 100 µg in 0.1 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Sufentanil; 500 µg in 0.5 mL Methanol	Glass vial: 3 mL	12/20/2013
Cayman Chemical Company	Sufentanil-d3 (citrate) CRM; 1 mg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Sufentanil-d3 (citrate) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Sufentanil-d3 (citrate) CRM; 100 µg/mL in Methanol	Glass ampule: 2 mL	9/19/2014
Cayman Chemical Company	Sufentanil-d3 (citrate) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	9/19/2014
Cayman Chemical Company	Sufentanil-d3 citrate (exempt preparation); 1 mg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Sufentanil-d3 citrate (exempt preparation); 100 µg in 1 mL Methanol	Glass vial: 1 mL	9/22/2014
Cayman Chemical Company	Tetrahydrocannabivarin (exempt preparation); 10 mg in 400 µL Methanol	Glass vial: 400 µL	5/2/2014
Cayman Chemical Company	Tetrahydrocannabivarin (exempt preparation); 25 mg in 1 mL Methanol	Glass vial: 1 mL	5/2/2014

Cayman Chemical Company	Tetrahydrocannabivarin (exempt preparation); 5 mg in 200 µL Methanol	Glass vial: 200 µL	5/2/2014
Cayman Chemical Company	Δ9-Tetrahydrocannabinol (exempt preparation); 10 mg in 400 µL Methanol	Glass vial: 400 µL	5/2/2014
Cayman Chemical Company	Δ9-Tetrahydrocannabinol (exempt preparation); 25 mg in 1 mL Methanol	Glass vial: 1 mL	5/2/2014
Cayman Chemical Company	Δ9-Tetrahydrocannabinol (exempt preparation); 5 mg in 200 µL Methanol	Glass vial: 200 µL	5/2/2014
Celanese Ltd.	Acetaldehyde	Truck: 85 tons	5/20/2013
Cerilliant Corporation	6-beta-Naltrexol-3-beta-D-glucuronide (1 mg/mL)	Glass ampule: 1 mL	4/14/2015
Cerilliant Corporation	Acetyl fentanyl (1.0 mg/mL)	Glass ampule: 1 mL	7/17/2015
Cerilliant Corporation	Acetyl fentanyl- 13C6 (0.1 mg/mL)	Glass ampule: 1 mL	7/17/2015
Cerilliant Corporation	Remifentanil HCl (1.0 mg/mL)	Glass ampule: 1 mL	4/3/2014
Cerilliant Corporation	THC Cannabinoids Mixture-3 (1.0 mg/mL)	Glass ampule: 1 mL	10/7/2014
Cliniqa Corporation	TDM Control Level 2	Plastic jug: 1 Gallon	4/15/2014
Cliniqa Corporation	TDM Control Level 3	Plastic jug: 1 Gallon	4/15/2014
Helena Laboratories	HDL Cholesterol Gel	Kit: 48 gels	9/10/2014
Honeywell Specialty Materials	LUMILUX Red CD 325	Plastic bottle: 5 g	9/16/2015
IsoSciences, LLC	Testosterone-[2H5], 5000 µg/mL in methanol	Amber ampule: 1 mL	9/17/2015
LGC Limited	(-)-delta-9-Tetrahydrocannabinol-C3 (THCV) 1.0 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	(-)-delta9-THC (Dronabinol) 0.1 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	(-)-Delta-9-THC (Dronabinol) 5.0 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Cannabidiol carboxylic acid (CBDA) 1.0 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	Cannabigerol (CBG) 1.0 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Limited	LSD (Lysergic Acid Diethylamide) 0.01 mg/mL in Acetonitrile	Glass vial: 1 mL	6/23/2014
LGC Limited	THCA-A (Tetrahydrocannabinolic acid A) 1.0 mg/mL in Methanol	Glass vial: 1 mL	6/23/2014
LGC Standards	LAMPA (Lysergic Acid N-Methyl-N-propylamide) 1.0 mg/mL in Acetonitrile	Glass ampule: 1 mL	6/8/2015

LGC Standards	Lorazepam-D4 1.0 mg/mL in Acetonitrile	Glass ampule: 1 mL	6/8/2015
Lipomed Inc.	(-)-11-Nor-D9-THC-carboxylic acid (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	(±)-11-Nor- Δ9-THC-carboxylic acid (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Cannabidiol-D3 (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Cannabidiol-D3 (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	Cannabinol-D3 (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Cannabinol-D3 (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Clonazepam-D4 (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/5/2015
Lipomed Inc.	d,l-11-Hydroxy-D9-THC-CD3 (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-11-Hydroxy-D9-THC-CD3 (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-11-Nor-Δ9-THC-carboxylic acid-D9 (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-11-Nor-Δ9-THC-carboxylic acid-D9 (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-11-Nor-Δ9-THC-carboxylic acid-D3 (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	d,l-11-Nor-Δ9-THC-carboxylic acid-D3 (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Fentanyl.citrate (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Fentanyl.citrate (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Fentanyl-D5 (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	Fentanyl-D5 (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Lipomed Inc.	THCA-A [(-)-trans- Δ9-THC acid A] (1 mg/1 mL methanol)	Glass ampule: 1 mL	4/8/2013
Microgenics Corporation	Sodium Plus Buffer pH 8.6	Glass container: 22.4 g	7/27/2015
Toronto Research Chemicals Inc.	Alfentanil Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Alfentanil-d3 Hydrochloride (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Alprazolam (1 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014

Toronto Research Chemicals Inc.	Fentanyl (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Fentanyl-d5 (100 µg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Lorazepam (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Lysergide (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Midazolam-d6 (1.0 mg/mL in Acetonitrile)	Glass vial: 1 mL	8/29/2014
Toronto Research Chemicals Inc.	Oxymorphone (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014
Toronto Research Chemicals Inc.	Triazolam (1.0 mg/mL in Methanol)	Glass vial: 1 mL	6/26/2014

BILLING CODE 4410–09–C

Scope of Approval

The exemptions are applicable only to the precise preparation or mixture described in the application submitted to DEA in the form(s) listed in this order and only for those sections of the CSA and the CFR that are specifically identified. In accordance with 21 CFR 1308.24(h), any change in the quantitative or qualitative composition of the preparation or mixture, or change in the trade name or other designation of the preparation or mixture after the date of application requires a new application. In accordance with 21 CFR 1308.24(g), the DEA may prescribe requirements other than those set forth in 21 CFR 1308.24 (b) through (e) on a case-by-case basis for materials exempted in bulk quantities. Accordingly, in order to limit opportunity for diversion from the larger bulk quantities, the DEA has determined that each of the exempted bulk products listed in this order may only be used in-house by the manufacturer, and may not be distributed for any purpose, or transported to other facilities.

Additional exempt chemical preparation requests received between April 1, 2013, and December 31, 2015, and not otherwise referenced in this order may remain under consideration until the DEA receives additional information required, in accordance with 21 CFR 1308.23(d), as detailed in separate correspondence to individual requesters. The DEA's order on such requests will be communicated to the public in a future **Federal Register** publication.

The DEA also notes that these exemptions are limited to exemption from only those sections of the CSA and the CFR that are specifically identified in 21 CFR 1308.24(a). All other requirements of the CSA and the CFR apply, including registration as an importer as required by 21 U.S.C. 957.

Chemical Preparations Containing Newly Controlled Substances

The statutory authority for exempt chemical preparations is based on the control status of substances contained within a preparation, the intended administration of a preparation, and the packaged form of a preparation. The DEA conducts a case-by-case analysis of each application for exemption to determine whether exemption of a preparation from certain provisions of the CSA is appropriate pursuant to the specified statutory and regulatory requirements.

Most exempt chemical preparations have remained effective until the holder of a specific exempt chemical preparation specifically requested that the exemption be terminated. The CSA allows for modifications to the controlled substances schedules to add, remove, or change the schedule of substances thus resulting in periodic modifications to the control status of various substances. 21 U.S.C. 811(a). Since the CSA was enacted in 1970, the DEA has on several occasions added to, removed from, or modified the schedules of controlled substances in accordance with the CSA. Such changes may result in the non-compliance of exempt chemical preparations with current statutes or regulations if chemical preparations that have already obtained exempt status contain newly controlled substances. For example, although an exempt chemical preparation may continue to be packaged in the same manner as when it was approved, non-controlled substances in the preparation may become controlled, thus prompting the need for a new application for exemption of the chemical preparation to ensure continued compliance. Other preparations that previously contained no controlled substances may contain newly controlled substances and thus would require an application for exemption.

The DEA reviews applications for chemical preparation exemptions based on the statutes and regulations that are in place at the time of the application, including the control status of substances included in the preparation. The DEA must remain vigilant to ensure that exempt chemical preparations remain consistent with the standards set

forth in the CSA and its implementing regulations. As such, the DEA reminds the public that any chemical preparation, regardless of whether it was previously exempt, that contains a newly controlled substance will require a new application for exemption pursuant to 21 U.S.C. 811(g)(3)(B) and 21 CFR 1308.23–1308.24.

Opportunity for Comment

In accordance with 21 CFR 1308.23, any interested person may submit written comments on or objections to any chemical preparation in this order that has been approved or denied as exempt. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Deputy Assistant Administrator will immediately suspend the effectiveness of any applicable part of this order until he may reconsider the application in light of the comments and objections filed.

Approved Exempt Chemical Preparations Are Posted on DEA's Web Site

A list of all current exemptions, including those listed in this order, is available on the DEA's Web site at *http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf*. The dates of applications of all current exemptions are posted for easy reference.

Dated: March 16, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–06624 Filed 3–24–16; 8:45 am]

BILLING CODE 4410–09–P

FEDERAL REGISTER

Vol. 81 Friday,
No. 58 March 25, 2016

Part IV

Department of Defense

Defense Acquisition Regulations System
48 CFR Parts 211, 212, 216 et al.
Defense Acquisition Regulations; Rules, Proposed Rules, and Notice.

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 211, 212 and 252

[Docket DARS–2015–0054]

RIN 0750–AI39

Defense Federal Acquisition Regulation Supplement: Warranty Tracking of Serialized Items (DFARS Case 2014–D026)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to require use of the electronic contract attachments accessible via the Product Data Reporting and Evaluation Program to record and track warranty data and source of repair information for serialized items.

DATES: Effective March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Jo Ann Reilly, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 58671 on September 30, 2015, to require use of the electronic contract attachments accessible via the Product Data Reporting and Evaluation Program to record and track warranty data and source of repair information for serialized items. No public comments were submitted in response to the proposed rule.

II. Discussion and Analysis

There are two editorial changes from the proposed rule made in the final rule. The title ''International Standards Organization/International Electrotechnical Commission'' is spelled out in lieu of the acronym ISO/IEC in the definition of ''issuing agency'' at DFARS 246.701 and 252.246–7006(a). In addition, the list of examples of organizations that are responsible for assigning globally unique identifiers to an enterprise is removed from the definition of ''issuing agency'' at DFARS 246.701, 252.211–7003(a), and 252.246–7006(a), because a full list is available in the Register of Issuing Agency Codes for ISO/IEC 15459, the link for which is already provided in the definition.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

The provision at DFARS 252.246–7005, Notice of Warranty Tracking and Serialized Items, and the clause at DFARS 252.246–7006, Warranty Tracking of Serialized Items, are prescribed for use when the solicitation includes the clause at 252.211–7003, Item Unique Identification and Valuation, and it is anticipated that the resulting contract will include a warranty for serialized items. The clause at 252.211–7003 is applicable to acquisitions valued at or below at or below the simplified acquisition threshold and for commercial items, including commercially available off-the-shelf items, involving the furnishing of supplies, unless the conditions in DFARS 211.274–2(b) apply. This rule does not change prescriptions for the provision at 252.246–7005 and the clause at 252.246–7006; rather, this rule merely require use of the electronic contract attachments to record and track warranty data and source of repair information for serialized items.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD has prepared a final regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act 5.U.S.C. 601, *et seq.* The FRFA is summarized as follows:

The objective of the rule is to improve the process of collecting and sharing data on warranties provided by contractors on serialized items procured by DoD. Use of the electronic formats available via the Product Data Reporting and Evaluation Program (PDREP) ensures the data elements for warranty terms are effectively transmitted through various systems, such as Electronic Document Access, Wide Area WorkFlow, the Invoice, Receipt, Acceptance and Property Transfer module, and the PDREP Warranty Tracking database.

The final rule requires the use of the electronic formats for the ''Warranty Tracking Information'' and ''Source of Repair Instructions'' attachments, which are used to track the warranties of serialized items in accordance with the provision at DFARS 252.246–7005, Notice of Warranty Tracking of Serialized Items, and the clause at DFARS 252.246–7006, Warranty Tracking of Serialized Items. This rule is also necessary to provide clear guidance on the requirements for completion and submission of the warranty attachments.

There were no issues raised by the public in response to the initial regulatory flexibility analysis provided in the proposed rule.

According to data available in the Federal Procurement Data System, in fiscal year (FY) 2014 DoD awarded 5,807 contracts that contain one or more warranty clauses. Subject matter experts within DoD estimate that almost twice as many solicitations (11,500) issued by DoD in FY 2014 may have contained a warranty clause. It is also estimated that an average of four offers may have been received in response those solicitations, or 46,000 total offers. Of those responses, approximately 85 percent, or 39,100 responses, are estimated to be received from small businesses.

It is estimated that fifty percent of the time (for approximately 5,750 solicitations) the Government will specify the desired warranty terms, in which case the contractor provides the remaining data elements on the ''Warranty Tracking Information'' attachment and the ''Source of Repair Instructions'' attachment with its proposal, at contract award, or at the point of delivery. The other fifty percent of the time, the contractor will be required to specify all the warranty terms on the ''Warranty Tracking Information'' attachment and the ''Source of Repair Instructions'' attachment.

This rule does not create any new reporting or recordkeeping requirements. Offerors and contractors are already required to complete the attachments in accordance with the provision at DFARS 252.246–7005, Notice of Warranty Tracking of Serialized Items, and the clause at DFARS 252.246–7006, Warranty Tracking of Serialized Items. This rule merely requires contractors and offerors

to complete the existing warranty attachments using the specified electronic formats.

No known alternatives to the rule have been identified that would achieve the stated objectives.

VI. Paperwork Reduction Act

The rule contains information collection requirements that require the approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. chapter 35); however, these changes to the DFARS do not impose additional information collection requirement to the paperwork burden previously approved under OMB Control Number 0704–0481, entitled ''Warranty Tracking of Serialized Items.'' The rule clarifies existing requirements for completion and submission of warranty attachments and requires electronic submission of those attachments by using the formats available in the Product Data Reporting and Evaluation Program.

List of Subjects in 48 CFR Parts 246 and 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 246 and 252 are amended as follows:

■ 1. The authority citation for parts 246 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 246—QUALITY ASSURANCE

■ 2. Amend section 246.701 by—

■ a. Revising the heading and adding introductory text;

■ c. Removing the last paragraph; and

■ d. Adding, in alphabetical order, definitions of ''Enterprise,'' ''Enterprise identifier,'' ''Issuing agency,'' ''Serialized item,'' ''Unique item identifier,'' and ''Warranty tracking''. The revision and additions read as follows:

246.701 Definitions.

As used in this subpart—

* * * * *

Enterprise means the entity (*e.g.,* a manufacturer or vendor) responsible for granting the warranty and/or assigning unique item identifiers to serialized warranty items.

Enterprise identifier means a code that is uniquely assigned to an enterprise by an issuing agency.

Issuing agency means an organization responsible for assigning a globally unique identifier to an enterprise, as indicated in the Register of Issuing Agency Codes for International Standards Organization/International Electrotechnical Commission 15459, located at *http://www.aimglobal.org/?Reg_Authority15459.*

Serialized item means each item produced is assigned a serial number that is unique among all the collective tangible items produced by the enterprise, or each item of a particular part, lot, or batch number is assigned a unique serial number within that part, lot, or batch number assignment within the enterprise identifier. The enterprise is responsible for ensuring unique serialization within the enterprise identifier or within the part, lot, or batch numbers, and that serial numbers, once assigned, are never used again.

Unique item identifier means a set of data elements marked on an item that is globally unique and unambiguous.

Warranty tracking means the ability to trace a warranted item from delivery through completion of the effectivity of the warranty.

■ 3. Amend section 246.710 by revising paragraph (3) to read as follows:

246.710 Contract clauses.

* * * * *

(3) When the solicitation includes the clause at 252.211–7003, Item Unique Identification and Valuation, which is prescribed in 211.274–6(a), and it is anticipated that the resulting contract will include a warranty for serialized items—

(i) Use the provision at 252.246–7005, Notice of Warranty Tracking of Serialized Items, in the solicitation if the Government does not specify a warranty and offerors will be required to enter data with the offer;

(ii) Use the clause at 252.246–7006, Warranty Tracking of Serialized Items, in the solicitation and contract; and

(iii) Include the following warranty attachments, available at *https://www.pdrep.csd.disa.mil/pdrep_files/other/wsr.htm,* in the solicitation and contract and see 246.710–70:

(A) Warranty Tracking Information.

(B) Source of Repair Instructions.

■ 4. Revise section 246.710–70 to read as follows:

246.710–70 Warranty attachments.

Follow the procedures at PGI 246.710–70 regarding warranty attachments.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. Amend section 252.211–7003 by—

■ a. Removing the clause date ''(DEC 2013)'' and adding ''(MAR 2016)'' in its place; and

■ b. In paragraph (a), revising the definition of ''Issuing agency''.

The revision reads as follows:

252.211–7003 Item Unique Identification and Valuation.

* * * * *

(a) * * *

Issuing agency means an organization responsible for assigning a globally unique identifier to an enterprise, as indicated in the Register of Issuing Agency Codes for ISO/IEC 15459, located at *http://www.aimglobal.org/?Reg_Authority15459.*

* * * * *

■ 6. Amend section 252.246–7005 by—

■ a. Removing from the introductory text ''246.710(3)(i)(A)'' and adding ''246.710(3)(i)'' in its place;

■ b. Removing the clause date ''(JUN 2011)'' and adding ''(MAR 2016)'' in its place; and

■ c. Revising paragraphs (a) and (b).

The revisions read as follows:

252.246–7005 Notice of Warranty Tracking of Serialized Items.

* * * * *

(a) *Definitions. Duration, enterprise, enterprise identifier, fixed expiration, item type, serialized item, starting event, unique item identifier, usage, warranty administrator, warranty guarantor,* and *warranty tracking* are defined in the clause at 252.246–7006, Warranty Tracking of Serialized Items.

(b) *Reporting of data for warranty tracking and administration.* (1) The Offeror shall provide the information required by the attachment entitled ''Warranty Tracking Information'' on each contract line item number, subline item number, or exhibit line item number for warranted items with its offer. Information required in the warranty attachment for each warranted item shall include such information as duration, fixed expiration, item type, starting event, usage, warranty administrator enterprise identifier, and warranty guarantor enterprise identifier.

(2) The successful offeror will be required to provide the following information no later than when the warranted items are presented for receipt and/or acceptance, in accordance with the clause at 252.246–7006—

(i) The unique item identifier for each warranted item required by the attachment entitled ''Warranty Tracking Information;'' and

(ii) All information required by the attachment entitled ''Source of Repair Instructions'' for each warranted item.

(3) For additional information on warranty attachments, see the ''Warranty and Source of Repair'' training and ''Warranty and Source of Repair Tracking User Guide'' accessible on the Product Data Reporting and Evaluation Program (PDREP) Web site at *https://www.pdrep.csd.disa.mil/pdrep_files/other/wsr.htm.*

(End of provision)

■ 7. Amend section 252.246–7006 by—

■ a. Removing from the introductory text ''246.710(3)(i)(B)'' and adding ''246.710(3)(ii)'' in its place;

■ b. Removing the clause date ''(JUN 2011)'' and adding ''(MAR 2016)'' in its place;

■ c. Revising in paragraph (a) the definitions of ''Issuing agency'' and ''Starting event''; and

■ d. Revising paragraph (b).

The revision reads as follows:

252.246–7006 Warranty Tracking of Serialized Items.

* * * * *

(a) * * *

Issuing agency means an organization responsible for assigning a globally unique identifier to an enterprise, as indicated in the Register of Issuing Agency Codes for International Standards Organization/International Electrotechnical Commission 15459, located at *http://www.aimglobal.org/?Reg_Authority15459.*

* * * * *

Starting event means the event or action that initiates the warranty, such as first use or upon installation.

* * * * *

(b) *Reporting of data for warranty tracking and administration.* (1) The Contractor shall provide the information required by the attachment entitled ''Warranty Tracking Information'' on each contract line item number, subline item number, or exhibit line item number for warranted items no later than the time of award. Information required in the warranty attachment shall include such information as duration, fixed expiration, item type, starting event, usage, warranty administrator enterprise identifier, and warranty guarantor enterprise identifier.

(2) The Contractor shall provide the following information no later than when the warranted items are presented for receipt and/or acceptance—

(i) The unique item identifier for each warranted item required by the attachment entitled ''Warranty Tracking Information;'' and

(ii) The warranty repair source information and instructions for each warranted item required by the attachment entitled ''Source of Repair Instructions.''

(3) The Contractor shall submit the data for warranty tracking to the Contracting Officer with a copy to the requiring activity and the Contracting Officer Representative.

(4) For additional information on warranty attachments, see the ''Warranty and Source of Repair'' training and ''Warranty and Source of Repair Tracking User Guide'' accessible on the Product Data Reporting and Evaluation Program (PDREP) Web site at *https://www.pdrep.csd.disa.mil/pdrep_files/other/wsr.htm.*

* * * * *

[FR Doc. 2016–06720 Filed 3–24–16; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 217 and 234

[Docket DARS–2015–0042]

RIN 0750–AI62

Defense Federal Acquisition Regulation Supplement: Extension and Modification of Contract Authority for Advanced Component Development and Prototype Units (DFARS Case 2015–D008)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2015 that amended a section of the National Defense Authorization Act for Fiscal Year 2010, to extend and modify contract authority for advanced component development and prototype units.

DATES: Effective March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Janetta Brewer, telephone 571–372–6104.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 72671 on November 20, 2015, to revise the DFARS to implement section 811 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2015 (Pub. L. 113–291, enacted December 19, 2014), which amended paragraphs (a) and (b) of section 819 of the NDAA for FY 2010 (10 U.S.C. 2302 note). The rule proposed to amend DFARS 217.202(2) and 234.005–1(1) to add ''or initial production'' to the text, to allow for inclusion of a contract line item (possibly an option) for advanced component development and prototype units to go to initial production without further competition. The rule also proposed to amend DFARS 234.005–1(2) to extend this authority to September 30, 2019. There were no public comments submitted in response to the proposed rule. There are no changes from the proposed rule made in the final rule.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This case does not add any new provisions or clauses or impact any existing provisions or clauses.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD has prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This rule is necessary to implement section 811 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2015 (Pub. L. 113–291). Section 811 amends paragraphs (a) and (b) of section 819 of the NDAA for FY 2010 (10 U.S.C. 2302 note). The objective of this rule is to provide authority for the inclusion of a contract line item (possibly an option) for advanced component development and prototype units to go to initial production without further competition.

There were no significant issues raised by the public in response to the initial regulatory flexibility analysis.

The rule will apply to DoD major defense acquisition program contractors and subcontractors. Most major defense acquisition programs are awarded to large concerns as they are of a scope too large for any small business to perform. As such, it is not expected that this rule will have a significant impact on a significant number of small entities.

This rule does not impose new recordkeeping or reporting requirements. There are no known significant alternative approaches to the rule that would meet the requirements of the statute.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 217 and 234

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 217 and 234 are amended as follows:

■ 1. The authority citation for 48 CFR parts 217 and 234 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 217—SPECIAL CONTRACTING METHODS

■ 2. Amend section 217.202 by revising paragraph (2) to read as follows:

217.202 Use of options.

* * * * *

(2) See 234.005–1 for limitations on the use of contract options for the provision of advanced component development, prototype, or initial production of technology developed under the contract or the delivery of initial or additional items.

PART 234—MAJOR SYSTEM ACQUISITION

234.005–1 [Amended]

■ 3. Amend section 234.005–1—

■ a. In paragraph (1) introductory text, by removing ''component development or prototype of technology'' and adding ''component development, prototype, or initial production of technology'' in its place, and removing ''additional prototype items'' and adding ''additional items'' in its place; and

■ b. In paragraph (2) by removing ''September 30, 2014'' and adding ''September 30, 2019'' in its place.

[FR Doc. 2016–06721 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 219, and 252

[Docket DARS–2015–0044]

RIN 0750–AI68

Defense Federal Acquisition Regulation Supplement: Clauses With Alternates—Small Business Programs (DFARS Case 2015–D017)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to clarify clauses and their prescriptions for small business programs and to create basic and alternate clauses structured in a manner to facilitate use of automated contract writing systems.

DATES: Effective March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Johnson, telephone 571–372–6100.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 58669 on September 30, 2015, to clarify, in the small business programs' clause prescriptions, the appropriate use of the basic clause and its alternate clause. This final rule provides the basic clause at 252.219–7003, Small Business Subcontracting Plan (DoD Contracts), in full text as well as the alternate to the basic clause in full text, instead of only reflecting the paragraphs that are different. The clause at DFARS 252.219–7010, now titled ''Notification of Competition Limited to Eligible 8(a) Concerns—Partnership Agreement'' is modified to incorporate Federal Acquisition Regulation (FAR) clause 52.219–18 and its two alternates into the existing clause at DFARS 252.219–7010. No public comments were received in response to the proposed rule. Three editorial changes were made to the proposed rule to (1) correct a typographical error, (2) update how the basic clause and alternate clause for 252.219–7003 are displayed at 212.301, and (3) spell out the acronym ''eSRS'' in the DFARS basic and alternate clause 252.219–7003.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not change the prescription for DFAR clause 252.219–7003, Small Business Subcontracting Plan (DoD Contracts); rather, the rule merely clarifies the use of the clause and the way it is displayed in the regulations. DFARS clause 252.219–7003 is used in conjunction with FAR clause 52.219–9, Small Business Subcontracting Plan, and applies to solicitations and contracts for commercial items, including commercially available off-the-shelf items. The clause is not applicable to acquisitions valued at or below the simplified acquisition threshold, because the FAR clause is only used in acquisitions expected to exceed $700,000.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* and is summarized as follows:

This final rule clarifies: (1) DFARS clause, 252.219–7003, Small Business Subcontracting Plan (DoD Contracts), which has an alternate, and (2) DFARS clause 252.219–7010, now titled ''Notification of Competition Limited to Eligible 8(a) Concerns—Partnership Agreement,'' which is an alternate to a FAR clause. The basic and alternate clauses will be full, separate clauses for ease of use by the contracting officers. This rule also explains the appropriate

use of the affected basic and alternate clauses for the small business programs. No substantial changes are being made to the clauses.

The objective of this rule is to clarify the use of each clause by giving the basic and alternate clauses a separate prescription describing when to use the clause for the small business programs. This does not change the applicability of the basic or alternate clause. The basic and alternate clauses will each appear in full text, which will facilitate use of the automated contract writing systems.

No comments were received from the public in response to the initial regulatory flexibility analysis.

DFARS 252.219–7003, Small Business Subcontracting Plan (DoD Contracts), and its alternate are prescribed to be used with FAR 52.219–9 and its alternates. FAR 52.219–9 does not apply to small business concerns; therefore, there is no burden on any small business for this rule.

DFARS 252.219–7010, now titled ''Notification of Competition Limited to Eligible 8(a) Concerns—Partnership Agreement,'' is the alternate for FAR 52.219–18, Notification of Competition Limited to Eligible 8(a) Concerns. This clause only affects 8(a) concerns when competing for an 8(a) award. Currently, there are approximately 5,217 active concerns registered in SAM that are certified in the 8(a) program. Nothing substantive will change in solicitations or contracts for potential offerors; only the way the clause alternates are presented in solicitations and contracts will be changed. This rule will result in potential offerors, including small businesses, expending less time to review and understand the solicitation and contract. The rule anticipates saving contractors' time by making all paragraph substitutions from the basic clause and by not requiring offerors to read inapplicable paragraphs contained in the basic clauses where alternates are used in the solicitations and contracts.

The rule does not impose any additional reporting, recordkeeping, or other compliance requirements.

No alternatives were identified that will accomplish the objectives of the rule.

V. Paperwork Reduction Act

The rule contains information collection requirements that require the approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. chapter 35); however, these changes to the DFARS do not impose additional information collection requirement to the paperwork burden previously approved under OMB Control Number 0704–0386, entitled ''Small Business Programs and Associated Clauses in part 252.219.'' The rule merely clarifies the use of two DFARS clauses and the way the clauses are displayed in the regulation.

List of Subjects in 48 CFR Parts 212, 219, and 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 219, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 219, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. In section 212.301, revise paragraph (f)(vii)(A) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(f) * * *

(vii) *Part 219—Small Business Programs.* (A) Use the clause at 252.219–7003, Small Business Subcontracting Plan (DoD Contracts), to comply with 15 U.S.C. 637.

(*1*) Use the basic clause as prescribed in 219.708(b)(1)(A)(*1*).

(*2*) Use the alternate I clause as prescribed in 219.708(b)(1)(A)(*2*).

* * * * *

PART 219—SMALL BUSINESS PROGRAMS

■ 3. In section 219.708, revise paragraph (b)(1)(A) to read as follows:

219.708 Contract clauses.

(b)(1)(A) Use the basic or alternate clause at 252.219–7003, Small Business Subcontracting Plan (DoD Contracts), in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items, that contain the clause at FAR 52.219–9, Small Business Subcontracting Plan.

(*1*) Use the basic clause at 252.219–7003, when using the basic, alternate I, or alternate II of FAR 52.219–9.

(*2*) Use the alternate I clause at 252.219–7003, when using Alternate III of FAR 52.219–9.

* * * * *

■ 4. In section 219.811–3, revise paragraph (2) to read as follows:

219.811–3 Contract clauses.

* * * * *

(2) Use the clause at 252.219–7010, Notification of Competition Limited to Eligible 8(a) Concerns—Partnership Agreement, in lieu of the clause at FAR 52.219–18, Notification of Competition Limited to Eligible 8(a) Concerns, in competitive solicitations and contracts when the acquisition is accomplished using the procedures of FAR 19.805 and processed in accordance with the PA cited in 219.800.

* * * * *

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. Amend section 252.219–7003 by—

■ a. Revising the introductory text, clause title, and date;

■ b. Amending paragraph (a) by removing ''eSRS'' and adding ''the Electronic Subcontracting Reporting System (eSRS)'' in its place;

■ c. In paragraph (c)(2), removing ''Section'' and adding ''section'' in its place; and

■ c. Revising Alternate I.

The revisions read as follows:

252.219–7003 Small Business Subcontracting Plan (DoD Contracts).

Basic. As prescribed in 219.708(b)(1)(A) and (b)(1)(A)(*1*), use the following clause:

SMALL BUSINESS SUBCONTRACTING PLAN (DOD CONTRACTS)—BASIC (MAR 2016)

* * * * *

Alternate I. As prescribed in 219.708(b)(1)(A) and (b)(1)(A)(*2*), use the following clause, which uses a different paragraph (f) than the basic clause.

SMALL BUSINESS SUBCONTRACTING PLAN (DOD CONTRACTS)—ALTERNATE I (MAR 2016)

This clause supplements the Federal Acquisition Regulation 52.219–9, Small Business Subcontracting Plan, clause of this contract.

(a) *Definitions. Summary Subcontract Report (SSR) Coordinator,* as used in this clause, means the individual at the department or agency level who is registered in the Electronic Subcontracting Reporting System (eSRS) and is responsible for acknowledging receipt or rejecting SSRs in eSRS for the department or agency.

(b) Subcontracts awarded to workshops approved by the Committee for Purchase from People Who are Blind or Severely Disabled (41 U.S.C. 8502–8504), may be counted toward the Contractor's small business subcontracting goal.

(c) A mentor firm, under the Pilot Mentor-Protege Program established under section 831 of Public Law 101–510, as amended, may

count toward its small disadvantaged business goal, subcontracts awarded to—

(1) Protege firms which are qualified organizations employing the severely disabled; and

(2) Former protege firms that meet the criteria in section 831(g)(4) of Public Law 101–510.

(d) The master plan is approved by the Contractor's cognizant contract administration activity.

(e) In those subcontracting plans which specifically identify small businesses, the Contractor shall notify the Administrative Contracting Officer of any substitutions of firms that are not small business firms, for the small business firms specifically identified in the subcontracting plan. Notifications shall be in writing and shall occur within a reasonable period of time after award of the subcontract. Contractor-specified formats shall be acceptable.

(f)(1) For DoD, the Contractor shall submit reports in eSRS as follows:

(i) The Standard Form 294, Subcontracting Report for Individual Contracts, shall be submitted in accordance with the instructions on that form.

(ii) An SSR for other than a commercial subcontracting plan, or construction and related maintenance repair contracts, shall be submitted in eSRS to the department or agency within DoD that administers the majority of the Contractor's individual subcontracting plans. An example would be Defense Finance and Accounting Service or Missile Defense Agency.

(2) For DoD, the authority to acknowledge receipt or reject reports in eSRS is as follows:

(i) Except as provided in paragraph (f)(2)(ii) of this clause, the authority to acknowledge receipt or reject SSRs in eSRS resides with the SSR Coordinator at the department or agency that administers the majority of the Contractor's individual subcontracting plans.

(ii) The authority to acknowledge receipt or reject SSRs for construction and related maintenance and repair contracts resides with the SSR Coordinator for each department or agency.

(End of clause)

■ 6. Revise section 252.219–7010 to read as follows:

252.219–7010 Notification of Competition Limited to Eligible 8(a) Concerns—Partnership Agreement

As prescribed in 219.811–3(2), use the following clause:

NOTIFICATION OF COMPETITION LIMITED TO ELIGIBLE 8(A) CONCERNS—PARTNERSHIP AGREEMENT (MAR 2016)

(a) Offers are solicited only from small business concerns expressly certified by the Small Business Administration (SBA) for participation in the SBA's 8(a) Program and which meet the following criteria at the time of submission of offer:

(1) The Offeror is in conformance with the 8(a) support limitation set forth in its approved business plan.

(2) The Offeror is in conformance with the Business Activity Targets set forth in its approved business plan or any remedial action directed by the SBA.

(3) If the competition is to be limited to 8(a) concerns within one or more specific SBA regions or districts, then the offeror's approved business plan is on the file and serviced by _____. *[Contracting Officer completes by inserting the appropriate SBA District and/or Regional Office(s) as identified by the SBA.]*

(b) By submission of its offer, the Offeror represents that it meets all of the criteria set forth in paragraph (a) of this clause.

(c) Any award resulting from this solicitation will be made directly by the Contracting Officer to the successful 8(a) offeror selected through the evaluation criteria set forth in this solicitation.

(d)(1) *Agreement.* A small business concern submitting an offer in its own name shall furnish, in performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas, unless—

(i) The SBA has determined that there are no small business manufacturers or processors in the Federal market place in accordance with FAR 19.502–2(c);

(ii) The acquisition is processed under simplified acquisition procedures and the total amount of this contract does not exceed $25,000, in which case a small business concern may furnish the product of any domestic firm; or

(iii) The acquisition is a construction or service contract.

(2) The _____ *[insert name of SBA's contractor]* will notify the _____ *[insert name of contracting agency]* Contracting Officer in writing immediately upon entering an agreement (either oral or written) to transfer all or part of its stock or other ownership interest to any other party.

(End of clause)

[FR Doc. 2016–06722 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 225

[Docket DARS–2015–0053]

RIN 0750–AI77

Defense Federal Acquisition Regulation Supplement: Buy American and Balance of Payments Program—Clause Prescription (DFARS Case 2015–D037)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to clarify how the clause prescription addresses applicability when an exception to the Buy American statute or Balance of Payments Program applies.

DATES: Effective March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 72672 on November 20, 2015, to revise the DFARS to clarify when it is appropriate to omit DFARS clause 252.225–7001 with regard to exceptions to the Buy American statute and Balance of Payment Program. There were no public comments submitted in response to the proposed rule. There are no changes from the proposed rule made in the final rule.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

The clause at DFARS 252.225–7001, Buy American Act and Balance of Payments Program, applies to acquisitions at or below the simplified acquisition threshold and for commercial items, including commercially available off-the-shelf items. This rule merely clarifies when it is appropriate to omit DFARS clause 252.225–7001 in accordance with existing exceptions to the Buy American statute and Balance of Payment Program.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This rule is necessary to ensure that contracting officers do not mistakenly omit the clause at DFARS 252.225–7001, Buy American and Balance of Payments Program, when it is appropriate for inclusion in a solicitation and contract. The objective of the rule is to clarify the prescription for use of DFARS clause 252.225–7001 to state that the clause does not apply when the acquisition is for supplies for use either within the United States and an exception to the Buy American statute applies, or outside the United States and an exception to the Balance of Payments Program applies.

There were no significant issues raised by the public in response to the initial regulatory flexibility analysis.

This rule will apply to small entities that are awarded contracts that contain DFARS clause 252.225–7001; however, there is no impact on these small entities because the rule merely clarifies the clause prescription to correctly address applicability when an exception to the Buy American statute or Balance of Payments Program applies.

The rule does not impose any additional reporting, recordkeeping, or other compliance requirements.

No alternatives were identified that will accomplish the objectives of the rule.

IV. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 225

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 225 is amended as follows:

PART 225—FOREIGN ACQUISITION

■ 1. The authority citation for part 225 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

225.1100 [Amended]

■ 2. In section 225.1100, remove ''Subparts'' in two places and add ''subparts'' in their place.

■ 3. Amend section 225.1101 by—

■ a. Revising paragraph (2)(i)(C);

■ b. Redesignating paragraphs (2)(i)(D) and (E) as paragraphs (2)(i)(E) and (F); and

■ c. Adding a new paragraph (2)(i)(D).

The revision and addition read as follows:

225.1101 Acquisition of supplies.

* * * * *

(2)(i) * * *

(C) The acquisition is for supplies for use within the United States and an exception to the Buy American statute applies, *e.g.,* nonavailability or public interest (see FAR 25.103 and 225.103);

(D) The acquisition is for supplies for use outside the United States and an exception to the Balance of Payments Program applies (see 225.7501);

* * * * *

[FR Doc. 2016–06723 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 211 and 225

[Docket DARS–2016–0003]

RIN 0750–AI85

Defense Federal Acquisition Regulation Supplement: Prohibition on Requiring the Use of Fire-resistant Rayon Fiber (DFARS Case 2016–D012)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to delete obsolete text requiring the use of fire-resistant rayon fiber.

DATES: Effective March 25, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, at 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DFARS 225.7016 prohibits requiring the use of fire-resistant rayon fiber in any solicitation issued before January 1, 2015. This prohibition was implemented in accordance with section 821 of the National Defense Authorization Act for Fiscal Year 2011. Since the effective period imposed by the statute has passed, the DFARS text is now obsolete. Therefore, this final rule removes DFARS 225.7016 and the cross reference at 211.170.

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707 entitled ''Publication of proposed regulations.'' Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it merely removes obsolete text from the DFARS and affects only the internal operating procedures of the Government. As such, the change has no significant cost or administrative impact on contractors or offerors.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 211 and 225

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 211 and 225 are amended as follows:

■ 1. The authority citation for 48 CFR parts 211 and 225 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 211—DESCRIBING AGENCY NEEDS

211.170 [Removed]

■ 2. Remove section 211.170.

PART 225—FOREIGN ACQUISITION

225.7016 [Removed]

■ 3. Remove section 225.7016.

[FR Doc. 2016–06724 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 216 and 236

[Docket DARS–2016–0006]

RIN 0750–AI87

Defense Federal Acquisition Regulation Supplement: Prohibition on Use of Any Cost-Plus System of Contracting for Military Construction and Military Family Housing Projects (DFARS Case 2015–D040)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2012 that amended title 10 of the United States Code by prohibiting any form of cost-plus contracting for military construction projects or military family housing projects.

DATES: Comments on the proposed rule should be submitted in writing on or before May 24, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2015–D040, using any of the following methods:

- Regulations.gov: *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2015–D040'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2015–D040.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2015–D040'' on your attached document.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2015–D040 in the subject line of the message.
- *Fax:* 571–372–6094.
- *Mail:* Defense Acquisition Regulations System, Attn: Mr. Christopher Stiller, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 2801 of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81). Section 2801 entitled ''Prohibition on Use of Any Cost-Plus System of Contracting for Military Construction and Military Family Housing Projects'' amends section 2306 of title 10, United States Code (U.S.C.), by prohibiting any form of cost-plus contracting for military construction projects or military family housing projects.

II. Discussion and Analysis

The rule proposes to amend DFARS 216.301–3, Limitations, to prohibit the use of any form of cost-plus contract type for contracts in connection with a military construction project or military family housing project. The placement of the text aligns with general limitations provided at FAR 16.301–3 on cost-reimbursement contracts. Because 10 U.S.C. 2306(c) prohibits several distinct kinds of cost-plus type contracts, the prohibition does not align with any specific cost-plus type as implemented at FAR 16.301–3.

The prohibition at 10 U.S.C. 2306(c) is broader in scope than the prohibition currently implemented at DFARS 216.306; therefore, the language at DFARS 216.306 is revised to add a cross reference to the proposed revision at DFARS 216.301–3. The proposed rule adds a new section at DFARS 236.215 to align with FAR 36.215 and provide a cross reference to DFARS 216.301–3. Finally, a cross reference is also added at DFARS 236.271 to 216.301–3.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This case does not add any new provisions or clauses or impact any existing provisions or clauses.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows.

DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement section 2801 of the National Defense Authorization Act for Fiscal Year 2012, which amends 10 U.S.C. 2306, to prohibit any form of cost-plus contracting for military construction projects or military family housing projects.

There is an existing prohibition at DFARS 216.306 on using certain cost-plus-fixed-fee contracts funded by a military construction appropriations acts. This proposed rule expands this prohibition to all cost-plus contract types in connection with a military construction project or military family housing project.

There is minimal impact anticipated on small entities as a result of the proposed rule. Based on data available in the Federal Procurement Data System, there were only 19 cost-reimbursement type construction acquisitions awarded in fiscal year 2015, two of which were awarded to small businesses. There is already a general prohibition at DFARS 216.306 on certain cost-plus-fixed-fee contracts funded by a military construction appropriations act. The proposed rule expands this prohibition to all cost-plus contract types in connection with a military construction project or a military family housing project.

There are no new projected reporting, recordkeeping, and other compliance requirements of the rule.

The rule does not duplicate, overlap, or conflict with any other Federal rules. There are no known significant alternatives to this rule.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2015–D040), in correspondence.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 216 and 236

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 216 and 236 are proposed to be amended as follows:

■ 1. The authority citation for 48 CFR parts 216 and 236 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Add section 216.301–3 to read as follows:

PART 216—TYPES OF CONTRACTS

216.301–3 Limitations.

Contracts in connection with a military construction project or a military family housing project shall not use any form of a cost-plus contract type (10 U.S.C. 2306(c)). This applies notwithstanding a declaration of war or the declaration by the President of a national emergency under section 201 of the National Emergencies Act (50 U.S.C. 1621) that includes the use of the armed forces.

■ 3. Amend section 216.306 by adding introductory text to paragraph (c) to read as follows:

216.306 Cost-plus-fixed-fee contracts.

(c) *Limitations.* For contracts in connection with a military construction project or military family housing project, see the prohibition at 216.301–3.

* * * * *

PART 236—CONSTRUCTION AND ARCHITECT–ENGINEER CONTRACTS

■ 4. Add section 236.215 to read as follows:

236.215 Special procedures for cost-reimbursement contracts for construction.

See 216.301–3 for the prohibition on the use of any form of a cost-plus contract in connection with a military construction project or a military family housing project.

■ 5. Revise section 236.271 to read as follows:

236.271 Cost-plus-fixed-fee contracts.

Annual military construction appropriations acts restrict the use of cost-plus-fixed-fee contracts (see 216.306(c)). See also 216.301–3 regarding the prohibition against the use of any form of a cost-plus contract in connection with a military construction project or military family housing project.

[FR Doc. 2016–06725 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Chapter 2

[Docket DARS–2016–0001]

RIN 0750–AI83

Defense Federal Acquisition Regulation Supplement: Instructions for the Wide Area WorkFlow Reparable Receiving Report (DFARS Case 2016–D004)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to add instructions for utilizing the Wide Area WorkFlow Reparable Receiving Report.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before May 24, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2016–D004, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2016–D004'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2016–D004.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2016–D004'' on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2016–D004 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Jo Ann Reilly, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Jo Ann Reilly, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise Appendix F of the DFARS to add instructions for the use, preparation, and distribution of the Wide Area WorkFlow (WAWF) Reparable Receiving Report (RRR) that has been created to differentiate between deliveries of new Government assets (new procurements) and the return of Government property that has been repaired or overhauled. The WAWF RRR creates an acceptance transaction for use in paying for the repair service and property transfers, moving the asset back to the Government, and reporting the movement to the Item Unique Identification (IUID) registry. Without the RRR, the contractor would have to take multiple actions to comply with the DFARS clauses at 252.232–7003, Electronic Submission of Payment Requests and Receiving Reports; 252.211–7003, Item Unique Identification and Valuation; and 252.211–7007, Reporting of Government-Furnished Property. In addition, this proposed rule would improve reporting efficiency by eliminating manual intervention that is currently required to ensure accurate information flow between different Government reporting systems.

II. Discussion and Analysis

DoD is proposing to make the following changes to DFARS Appendix F to provide guidance on the use of the WAWF RRR as follows:

- F–101—states that the WAWF RRR is the electronic equivalent of the DD Form 250 for repair, maintenance, or overhaul of Government furnished property (GFP).
- F–103—adds new guidance on the use of the WAWF RRR as a multipurpose report. Adds a new paragraph (e)(3) to state that use of the

WAWF RRR, when the contract includes DFARS 252.211–7007, Reporting of Government-Furnished Property, will capture the shipment of GFP items after acceptance of repair services and forward the data to the IUID registry.

- F–104—adds paragraph (b) to permit use of the WAWF RRR or DD Form 250 for delivery of services for repair, overhaul, or maintenance.
- Part 3—adds WAWF RRR to the title of part 3.
- F–301—adds paragraphs (b)(15)(ii)(A) and (B), to provide WAWF RRR completion instructions.
- F–301(b)(18)—adds clarifying information for entering unit prices when using the WAWF RRR.
- F–303—adds use of the WAWF RRR for consolidated shipments.
- F–304—adds WAWF RRR correction instructions for contracts administered by the Defense Contract Management Agency and paid by the Mechanization of Contract Administration Services system.
- F–306—provides information on printing capability when using the WAWF RRR as a packing list.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This case does not add any new provisions or clauses or impact any existing provisions or clauses.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD does not expect this rule to have an economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

DoD is proposing to revise the Defense Federal Acquisition Regulation Supplement (DFARS), Appendix F, to add the instructions for utilizing the Wide Area WorkFlow (WAWF) Reparable Receiving Report (RRR).

The objective of this rule is to provide instructions for the use, preparation, and distribution of the electronic WAWF RRR that has been created to differentiate between deliveries of new Government assets (new procurements) and the return of Government property that has been repaired or overhauled. This rule proposes to improve reporting efficiency by eliminating manual intervention that is currently required to ensure accurate information flows between different Government property reporting systems.

The number of small entities affected is unknown. However, DoD expects this rule to have a positive economic impact on contractors, including small businesses, because the proposed rule would reduce the reporting burden for Government property repair or overhaul contracts. For example, DFARS clause 252.232–7003, Electronic Submission of Payment Requests and Receiving Reports, requires the use of WAWF by contactors in preparing and submitting receiving reports; 252.211–7003, Item Unique Identification and Valuation, requires all delivered items with an item unique identification (IUID) be reported to the IUID registry; and 252.211–7007, Reporting of Government-Furnished Property, requires Government furnished property be reported to the IUID registry, specifically the return to the Government of serially managed assets. With the proposed rule, contractors would only use the WAWF RRR system to meet the reporting requirements for Government property repair or overhaul contracts, instead of taking multiple actions to comply with the DFARS clauses above.

The projected recordkeeping and reporting is unchanged from current requirements, and only the method of submitting the reports for the return of Government property that has been repaired or overhauled has changed. Reporting and recordkeeping is limited to that required to properly record material inspection and receiving report information using the WAWF RRR under Government contracts. Preparation of these records requires clerical and analytical skills to create the electronic documents in the WAWF system.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no significant alternatives to the proposed rule that accomplish the stated objectives.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2016–D004), in correspondence.

VI. Paperwork Reduction Act

The rule contains information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). However, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 0704–0248 entitled ''Material Inspection and Receiving Report.'' The projected recordkeeping and reporting is unchanged from current requirements, and only the method of submitting the reports for the return of Government property that has been repaired or overhauled has changed.

List of Subjects in 48 CFR Appendix F to Chapter 2

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR chapter 2, subchapter I, is proposed to be amended in appendix F as follows:

CHAPTER 2—DEFENSE ACQUISITION REGULATIONS SYSTEM, DEPARTMENT OF DEFENSE

■ 1. The authority citation for appendix F to chapter 2 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend appendix F to chapter 2 by—

■ a. In section F–101, paragraph (a), removing ''(WAWF) Receiving Report'' and adding ''(WAWF) Receiving Report (RR), the WAWF Reparable Receiving Report (WAWF RRR)'' in its place, and adding a sentence at the end of paragraph (a);

■ b. In section F–103, paragraphs (a) introductory text, (a)(6), (b) introductory text, and (c) by removing ''WAWF RR'' and adding ''WAWF RR, WAWF RRR,'' in each place; in paragraph (e)

introductory text, removing ''WAWF RR'' and adding ''WAWF RR and WAWF RRR'' in its place; and adding paragraph (e)(3);
■ c. In section F–104, redesignating paragraph (b) as paragraph (c) and adding a new paragraph (b);
■ d. Revising the part 3 heading;
■ e. In section F–301, revising paragraphs (b)(15)(ii) and (b)(18);
■ f. In section F–303, by removing ''WAWF RR'' and adding ''WAWF RR or WAWF RRR'' in its place;
■ g. Revising section F–304; and
■ h. In section F–306, revising the introductory text and paragraph (a).

The revisions and additions read as follows:

APPENDIX F TO CHAPTER 2—MATERIAL INSPECTION AND RECEIVING REPORT

PART 1—INTRODUCTION

F—101 General.

(a) * * * The WAWF RRR is the electronic equivalent of the DD Form 250 for repair, maintenance, or overhaul of Government-furnished property.

* * * * *

F–103 Use.

* * * * *

(e) * * *

(3) Reporting of Government-Furnished Property, when the clause at DFARS 252.211–7007, Reporting of Government-Furnished Property, is used in the contract, use of the WAWF RRR will capture the shipment of Government-furnished property items after acceptance of repair services and forward the data to the IUID registry. WAWF is the only way a contractor can report the transfer of Government-furnished property items in the IUID registry.

F–104 Application.

(a) * * *

(b) *WAWF RRR or DD Form 250.* Use as in (a) above for delivery of services for repair, overhaul, or maintenance.

* * * * *

PART 3—PREPARATION OF THE WIDE AREA WORKFLOW (WAWF) RECEIVING REPORT (RR), THE WIDE AREA WORKFLOW REPARABLE RECEIVING REPORT (WAWF RRR), AND WAWF ENERGY RR

* * * * *

F–301 Preparation instructions.

* * * * *

(b) * * *

(15) * * *

(ii) For service line items, select SV for ''SERVICE'' in the type field followed by as short a description as is possible in the description field. Some examples of service line items are maintenance, repair, alteration, rehabilitation, engineering, research, development, training, and testing

(A) For RRRs, the ''Ship To'' code is the DoDAAC, MAPAC, or CAGE code from the contract or shipping instructions.

(B) For service line items not using a RRR, the ''Ship To'' code and the ''Unit'' shall be filled out. The ''Ship To'' code is the destination Service Acceptor Code for WAWF. If source inspected and accepted, enter the service performance location as the ''Ship To'' code.

* * * * *

(18) UNIT PRICE. The contractor shall enter unit prices on all WAWF RR copies. When using the WAWF RRR, the unit price is the price of the repair, overhaul, or maintenance service from the contract.

* * * * *

F–304 Correction instructions.

Functionality for correcting a WAWF RR or WAWF RRR is available for DCMA administered contracts paid using the Mechanization of Contract Administration Services (MOCAS) system with source acceptance. Preparation instructions and training for corrections is available at *https://wawftraining.eb.mil.* The instructions are part of the Vendor Training section.

* * * * *

F–306 Packing list instructions.

Contractors may also use a WAWF processed RR, including the WAWF RRR, as a packing list. WAWF provides options to print the RR. These printed RRs may also be used if a signed copy is required.

(a) WAWF provides a print capability for its RR. The WAWF printed RR can be identified by its distinctive format and by the text title at the top of each printed page ''Material Inspection and Receiving Report in accordance with DFARS Appendix F. Paper DD Form 250 is usable in lieu of this document on an exception basis.'' (See DFARS 252.232–7003(c).) This printed copy can be used as a packing list. If needed, the signature can be verified by reviewing the signed RR in WAWF.

* * * * *

[FR Doc. 2016–06726 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 225

[Docket DARS–2016–0007]

RIN 0750–AI88

Defense Federal Acquisition Regulation Supplement: Treatment of Interagency and State and Local Purchases (DFARS Case 2016–D009)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 to provide that contracts executed by DoD as a result of the transfer of contracts from the General Services Administration, or for which DoD serves as an item manager for products on behalf of the General Services Administration, shall not be subject to certain domestic source restrictions, to the extent that such contracts are for the purchase of products by other Federal agencies or State or local governments.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before May 24, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2016–D009, using any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2016–D009'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2016–D009.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2016–D009'' on your attached document.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2016–D009 in the subject line of the message.
- *Fax:* 571–372–6094.
- *Mail:* Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to amend the DFARS to implement section 897 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92). Section 897 entitled ''Treatment of Interagency and State and Local Purchases'' provides that contracts executed by DoD as a result of the

transfer of contracts from the General Services Administration (GSA) or for which DoD serves as an item manager for products on behalf of GSA shall not be subject to the requirements under 10 U.S.C. chapter 148 (National Defense Technology and Industrial Base, Defense Investment, and Defense Conversion), to the extent that such contracts are for the purchase of products by other Federal agencies or State or local governments.

10 U.S.C. chapter 148 includes domestic source restrictions at 10 U.S.C. 2533a (Berry Amendment), 10 U.S.C. 2533b (specialty metals), and 10 U.S.C. 2534 (miscellaneous domestic source restrictions), which are implemented in DFARS subpart 225.70 as follows:

- 225.7002 (Berry Amendment).
- 225.7003 (specialty metals purchased directly by DoD or aircraft, missile or space systems, ships, tank or automotive items, weapon systems, or ammunition containing specialty metals).
- 225.7004 (buses).
- 225.7005 (certain chemical weapons antidotes).
- 225.7006 (air circuit breakers for naval vessels).
- 225.7010 (certain naval vessel components).

II. Discussion and Analysis

DoD reviewed the domestic source restrictions in 10 U.S.C. chapter 148 as implemented in DFARS subpart 225.70. DoD proposes to amend DFARS 225.7002–2, which implements 10 U.S.C. 2533a (Berry Amendment), to include an exception in a new paragraph (o) to implement section 897.

DoD does not propose to amend DFARS 225.7003, which implements 10 U.S.C. 2533b (specialty metals), because these restrictions apply to direct purchase of specialty metals by DoD or acquisition of items (*e.g.,* aircraft or missiles containing specialty metals or components for naval vessels) that are of a military nature that GSA does not contract for and that another Federal agency or a State or local government would not be purchasing. Note that ''automotive item'' is defined at DFARS 225.7003 to cover military transport tactical vehicles and does not include commercially available off-the-shelf vehicles, construction equipment, or other self-propelled equipment such as cranes or aircraft ground support.

DoD also does not propose to amend DFARS 225.7004 (buses), 225.7005 (certain chemical weapons antidotes), 225.7006 (air circuit breakers for naval vessels), or 225.7010 (certain naval vessel components), which implement 10 U.S.C. 2534. With the exception of buses, these are items for which GSA does not contract. Furthermore, 10 U.S.C. 2534(f) sets forth a principle of statutory construction, which requires a subsequent law to specifically reference 10 U.S.C. 2534 in order to modify it. Section 897 does not specifically reference 10 U.S.C. 2534, so there is not the required indication that section 897 is authorizing a modification to 10 U.S.C. 2534. Applying section 897 to 10 U.S.C. 2534, while not directly changing the language of 10 U.S.C. 2534, would change the way DoD currently applies 10 U.S.C. 2534.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This case does not add any new provisions or clauses or impact any existing provisions or clauses.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Nevertheless, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This rule implements section 897 of the National Defense Authorization Act for Fiscal Year 2016. The objective of this rule is to eliminate the domestic source restrictions of 10 U.S.C. chapter 148 when contracts executed by DoD as a result of the transfer of contracts from the General Services Administration (GSA) or for which DoD serves as an item manager for products on behalf of GSA, to the extent that such contracts are for the purchase of products by other Federal agencies or State or local governments.

DoD does not anticipate frequent application of this rule. The rule removes a limitation on potential sources for the specified items. In the rare instance in which the circumstances of the statute apply, it is possible that an item could be acquired from a foreign source, rather than a domestic source, which could potentially be a small business. It is not possible to estimate the number of small entities that may be affected, because it is unknown the extent to which the given circumstances may occur.

There are no projected reporting, recordkeeping, or other compliance requirements.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD has not identified any alternatives which would minimize any economic impact on small entities and still meet the requirements of the statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2016–D009), in correspondence.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 225

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 225 is proposed to be amended as follows:

PART 225—FOREIGN ACQUISITION

■ 1. The authority citation for 48 CFR part 225 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 225.7002–2 by adding paragraph (o) to read as follows:

225.7002–2 Exceptions.

* * * * *

(o) Acquisitions that are interagency, State, or local purchases that are

executed by DoD as a result of the transfer of contracts from the General Services Administration or for which DoD serves as an item manager for products on behalf of the General Services Administration. According to section 897 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92), such contracts shall not be subject to requirements under chapter 148 of title 10, United States Code (including 10 U.S.C. 2533a), to the extent such contracts are for purchases of products by other Federal agencies or State or local governments.

[FR Doc. 2016–06727 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 231

[Docket DARS–2016–0002]

RIN 0750–AI86

Defense Federal Acquisition Regulation Supplement: Costs Related to Counterfeit Electronic Parts (DFARS Case 2016–D010)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 that amends the allowability of costs of counterfeit electronic parts or suspect counterfeit electronic parts and the cost of rework or corrective action that may be required to remedy the use or inclusion of such parts.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before May 24, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2016–D010, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2016–D010'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2016–D010.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2016–D010'' on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2016–D010 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to amend the DFARS to implement section 885(a) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92). Section 885(a) provides that the costs of counterfeit parts or suspect counterfeit parts and the cost of rework or corrective action that may be required to remedy the use or inclusion of such parts may be allowable if—

- The counterfeit electronic parts or suspect counterfeit electronic parts were obtained by the contractor in accordance with the regulations described in paragraph (c)(3) of section 818 of the NDAA for FY 2012, as amended;
- The contractor discovers the counterfeit electronic parts or suspect counterfeit electronic parts; and
- The contractor provides timely (*i.e.,* within 60 days after the contractor becomes aware) notice to the Government.

A final rule is in process under DFARS Case 2014–D005, Detection and Avoidance of Counterfeit Parts—Further Implementation, to implement section 818(c)(3) of the NDAA for FY 2012, as amended. A proposed rule was published under DFARS Case 2014–D005 in the **Federal Register** on September 21, 2015 (80 FR 56939). The final rule under this case 2016–D010 will not be published until after publication of the final rule under DFARS Case 2014–D005.

II. Discussion and Analysis

This rule proposes to amend the cost principle at DFARS 231.205–71 to incorporate the new provisions of section 885(a) of the NDAA for FY 2016.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Nevertheless, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule implements section 885(a) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92).

The objective of this rule is to amend the allowability of costs for counterfeit parts or suspect counterfeit parts and the cost of rework or corrective action that may be required to remedy the use or inclusion of such parts. Such costs may be allowable if—

- The parts were obtained by the contractor/subcontractor in accordance with the regulations described at section 818(c)(3) of the NDAA for FY 2012, as amended (such regulations will be published as a final rule under DFARS Case 2014–D005);
- The contractor discovers the counterfeit electronic parts or suspect counterfeit electronic parts; and
- The contractor provides timely notice to the Government.

DoD is unable to estimate the number of small entities that will be impacted by this rule. This rule will apply to all DoD prime and subcontractors with cost contracts. This rule will only impact cost allowability if the contractor or subcontractor has complied with DFARS 246.870, but nevertheless acquired, used, or included counterfeit electronic parts or suspect counterfeit electronic parts in performance of a DoD contract or subcontract, and has

discovered such parts and provided timely notification to DoD.

There is no change to the projected reporting, recordkeeping, or other compliance requirements associated with the rule.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD has not identified any alternatives that are consistent with the stated objectives of the applicable statute. However, DoD notes that the impacts of this rule are expected to be beneficial, because it expands the allowability of costs for counterfeit parts or suspect counterfeit parts and the cost of rework or corrective action that may be required to remedy the use or inclusion of such parts.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2016–D010), in correspondence.

V. Paperwork Reduction Act

The rule does not contain information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 231

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 231 is proposed to be amended as follows:

PART 231—CONTRACT COST PRINCIPLES AND PROCEDURES

■ 1. The authority citation for 48 CFR part 231 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise section 231.205–71 to read as follows:

231.205–71 Costs related to counterfeit electronic parts and suspect counterfeit electronic parts.

(a) *Scope.* This subsection implements the requirements of section 818(c)(2), National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81), as modified by section 833, National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239) and section 885 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92).

(b) The costs of counterfeit electronic parts and suspect counterfeit electronic parts and the costs of rework or corrective action that may be required to remedy the use or inclusion of such parts are unallowable, unless—

(1) The contractor has an operational system to detect and avoid counterfeit parts and suspect counterfeit electronic parts that has been reviewed and approved by DoD pursuant to 244.303;

(2) The counterfeit electronic parts or suspect counterfeit electronic parts are Government-furnished property as defined in FAR 45.101 or were obtained by the contractor in accordance with the clause at DFARS 252.246–70XX, Sources of Electronic Parts [as proposed to be added at 80 FR 56939, September 21, 2015]; and

(3) The contractor—

(i) Discovers the counterfeit electronic parts or suspect counterfeit electronic parts; and

(ii) Provides timely (*i.e.,* within 60 days after the contractor becomes aware) notice to the cognizant contracting officer(s).

[FR Doc. 2016–06728 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket No. DARS–2016–0011]

Acquisition of Items for Which Federal Prison Industries Has a Significant Market Share

AGENCY: Department of Defense (DoD).

ACTION: Notice.

SUMMARY: DoD is publishing the updated annual list of product categories for which the Federal Prison Industries' share of the DoD market is greater than five percent.

DATES: Effective April 7, 2016.

FOR FURTHER INFORMATION CONTACT: Sheila Harris, telephone 703–614–1333.

SUPPLEMENTARY INFORMATION: On November 19, 2009, a final rule was published in the **Federal Register** at 74 FR 59914, which amended the Defense Federal Acquisition Regulation Supplement (DFARS) subpart 208.6 to implement Section 827 of the National Defense Authorization Act for Fiscal Year 2008, Public Law 110–181. Section 827 changed DoD competition requirements for purchases from Federal Prison Industries, Inc. (FPI) by requiring DoD to publish an annual list of product categories for which FPI's share of the DoD market was greater than five percent, based on the most recent fiscal year data available. Product categories on the current list, and the products within each identified product category, must be procured using competitive or fair opportunity procedures in accordance with DFARS 208.602–70.

The Director, Defense Procurement and Acquisition Policy (DPAP), issued a memorandum dated March 8, 2016, that provided the current list of product categories for which FPI's share of the DoD market is greater than five percent based on fiscal year 2015 data from the Federal Procurement Data System. The product categories to be competed effective April 7, 2016, are the following:

- H946 (Other QC/Test/Inspect–Water Purification and Sewage Treatment Equipment)
- L071 (Technical Representative—Furniture)
- 3990 (Miscellaneous Materials Handling Equipment)
- 7210 (Household Furnishings)
- 7230 (Draperies, Awnings, and Shades)
- 8405 (Outerwear, Men's)
- 8410 (Outerwear, Women's)
- 8415 (Clothing, Special Purpose)
- 8470 (Armor, Personal)
- 9905 (Signs, Advertising Displays, and Identification Plates)

The DPAP memorandum with the current list of product categories for which FPI has a significant market share is posted at: *http://www.acq.osd.mil/dpap/cpic/cp/specific_policy_areas.html#federal_prison.*

The statute, as implemented, also requires DoD to—

(1) Include FPI in the solicitation process for these items. A timely offer from FPI must be considered and award procedures must be followed in accordance with existing policy at Federal Acquisition Regulation (FAR) 8.602(a)(4)(ii) through (v);

(2) Continue to conduct acquisitions, in accordance with FAR subpart 8.6, for items from product categories for which FPI does not have a significant market share. FAR 8.602 requires agencies to conduct market research and make a written comparability determination, at the discretion of the contracting officer. Competitive (or fair opportunity) procedures are appropriate if the FPI product is not comparable in terms of price, quality, or time of delivery; and

(3) Modify the published list if DoD subsequently determines that new data requires adding or omitting a product category from the list.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

[FR Doc. 2016–06729 Filed 3–24–16; 8:45 am]

BILLING CODE 5001–06–P

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Federal Register

Vol. 81, No. 58

Friday, March 25, 2016

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FEDERAL REGISTER PAGES AND DATE, MARCH

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